

Methodische Ansätze zur Ermittlung gefährdungsbezogener Interaktionen bei  
Medizinprodukten in der Intensiv- und Notfallmedizin

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# Publikationen

## Publikationen, die die Dissertation darstellen

### **Publikation 1:**

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### **Publikation 3:**

Coldewey B, Klausen A, Otto-Sobotka F, Röhrig R, Lipprandt M. Usability of Automated External Defibrillators: A Randomized, Comparative Simulator Study. *International Journal of Human–Computer Interaction*. 2023;40(22),6972–6983.

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## Weitere Publikationen

### **Fullpaper**

Puladi B, Coldewey B, Volmerg JS, Grunert K, Berens J, Rashad A, Hölzle F, Röhrig R, Lipprandt M. Improving detection of oral lesions: Eye tracking insights from a randomized controlled trial comparing standardized to conventional approach. *Head & neck*.

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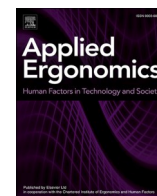
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# Causes of use errors in ventilation devices - Systematic review

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## ABSTRACT

A systematic review according to the PRISMA reporting standard was performed to identify causes of use errors in mechanical ventilators described in the literature. The PubMed search resulted in the inclusion of 16 papers. The errors described were systematically analyzed with regard to their causes and categorized in an adapted cause-and-effect diagram. The causes of use errors were related to specific usability issues and to the general condition that medical staff often work with different ventilators. When many devices are used, the different user interfaces are a source of use errors, since, for example, the same ventilation modes have different names. In order to avoid the identified causes for use errors in the future, this work offers manufacturers of ventilation devices design recommendations and the possibility to include the results in their risk management. In addition, standardizing user interface content across all ventilators, as in ISO 19223, can help reduce use errors.

## 1. Introduction

Mechanical ventilation provides life-saving support to patients in various environments such as anaesthesia, emergency medicine, intensive care units and intensive home care. The interventions are safety-critical for patients dependent on ventilation. Ventilation parameters and modes must be adapted to the patient's status in order not to further endanger his or her health. In case of health deterioration, a rapid intervention by the health care provider is necessary. (Pham et al., 2017; Windisch et al., 2017)

Several studies have investigated incidents related to mechanical ventilation (Cassidy et al., 2011; Cooper et al., 1978; Kamio and Masamune, 2018; Pham et al., 2016). Causes for avoidable incidents were e.g. assigned to human error or equipment malfunction. Mechanical ventilators are part of a complex socio-technical system together with the working environment, the users and the patients (Backhaus, 2010). According to the Swiss Cheese Model, hazardous situations occur due to an unfavorable sequence of several errors and contributing factors caused by holes in different securing layers (Reason, 2000). Human performance is not constant and errors are to be expected (St.Pierre and Hofinger, 2014; Kohn et al., 2000). Therefore, when hazardous situations occur, it should not be searched for a culprit, but rather analyzed why and how the system or the existing security layers have failed (Reason, 2000; St.Pierre and Hofinger, 2014).

Depending on the intended use context, there is a wide range of modern ventilators available on the market, which differ in the scope and implementation of their functionality (Kacmarek, 2011; L'Her et al., 2014). Despite the use of approved equipment, (serious) incidents<sup>1</sup> may occur. Use errors can lead to hazardous situations with adverse outcome for the patient (Mattox, 2012; Harrington, 2019; ISO 62366-1). The design of the user interface and its adaptation to the intended context of use can contribute to the avoidance of use errors and enables an effective, efficient and satisfying use (Fairbanks and Caplan, 2004; ISO 62366-1, 2015; Wiklund et al., 2016). Due to technological progress in the medical field, more and more functionalities of mechanical ventilators lead to an increase in complexity, which is reflected in the user interface (Chatburn et al., 2014; Kacmarek, 2011). In numerous studies, usability problems have been described as determining factors for the performance and avoidance of use errors (Gonzalez-Bermejo et al., 2006; Marjanovic et al., 2017; Spaeth et al., 2017). Especially in emergency situations under stress, fatigue or lack of experience, usability becomes a critical factor in the process of care (ISO 62366-1).

Known use errors and their causes should be taken into account for the improvement of existing techniques and the development of new user interfaces. Individual problems are addressed in various publications, but there is no comprehensive overview of problem areas to be considered. The aim of this work is to identify and provide an overview of published causes of use errors in mechanical ventilation devices.

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<sup>1</sup> For detailed information on the terminology used, see Glossary in Appendix A.

## 2. Methods

A systematic review was conducted to identify usability issues and contributing factors that can lead to use errors. The literature search was performed via PubMed using a combination of the keywords “mechanical ventilation”, “usability” and “risk”. Since the terms are used rather diversified, corresponding Medical Subject Heading terms (MeSH terms) and text words (e.g. human-computer interaction and user friendliness) were included for each to get a comprehensive search string. The search includes all entries published in English or German language and was not restricted with regard to the publication period. The exact search string and filters are provided in [Appendix B](#).

The selection of eligible publications was carried out according to the preferred reporting items for systematic reviews and meta-analyses (PRISMA) ([Page et al., 2021](#)). Articles were first screened based on titles and abstracts. Articles were excluded if they contained research where the keywords, especially mechanical ventilation, were not used according to the focus of our study or as a subsidiary factor. These are, for example, studies on respiratory protective equipment, air conditioning or descriptions of medical procedures (see [Fig. 1](#)). In addition, technological progress in this field has led to the exclusion of papers that are no longer relevant. In a further step, the full-text of the remaining articles were assessed. Articles were eligible for inclusion if detailed information on usability issues and contributing factors as cause for reported incidents or use errors in mechanical ventilation devices was given.

The selected articles were qualitatively analyzed with regards to the causes that can lead to use errors. The findings were systematically listed in a cause-and-effect diagram by the occurring main categories. Two reviewers (computer scientists) independently assessed the articles. The analysis of the relevant content was supported by another computer scientist and a medical doctor. All conflicts were resolved by consensus.

We explicitly looked for the causes of use errors. These issues are of a qualitative nature. Even a single occurrence of a use error provides information about possible causes to be avoided. To ensure the validity of the usability issues, we defined the following quality metrics for the included articles:

- peer-reviewed journal
- suitable study design for usability evaluation and/or identification of use errors
- use of the device within its intended purpose
- the description of the use error has to give an indication of the cause of the issue.

In addition to the quality of the studies themselves, the limitations on the outcome of the review due to limitations in the studies are considered.

## 3. Results

### 3.1. Study selection

The search strategy in PubMed resulted in 692 papers listed until the end of February 2021. The titles and abstracts were assessed based on the inclusion and exclusion criteria leaving 44 studies for the full-text screening. After reading the remaining articles, 28 papers were excluded due to refined criteria. 16 studies remained for inclusion in our review (precision 2,3%). The process of systematic search is depicted in [Fig. 1](#).

### 3.2. Characteristics of included studies

The sixteen studies included contain detailed information on

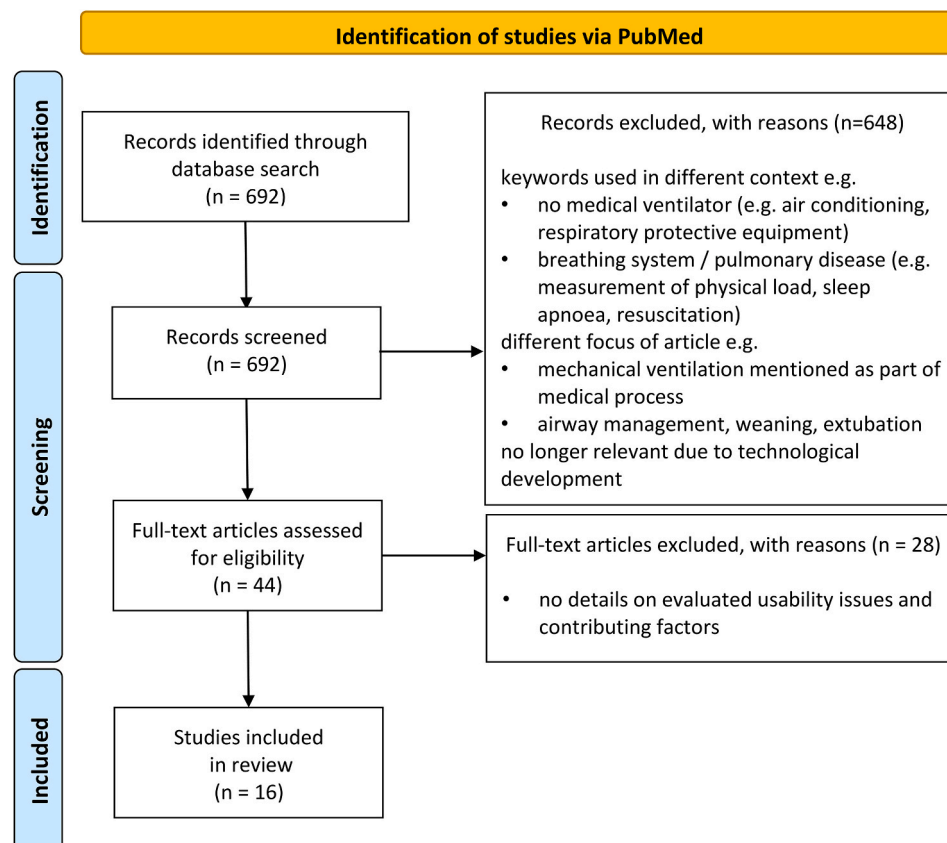


Fig. 1. PRISMA Flow Diagram with inclusion and exclusion criteria of study selection.

usability issues and contributing factors that can lead to use errors in mechanical ventilation devices. The studies were published between 2004 and 2020 in Canada, China, France, Germany, Japan, Sweden, Switzerland, United Kingdom or the USA. Table 1 in the Supplementary Data (Appendix C) gives an overview of the content of the included studies.

In terms of study design, fifteen of the sixteen studies are usability evaluation studies with task-based scenarios that were conducted in clinical simulation environments (Jiang et al., 2020, 2018b,a; L'Her and Roy, 2011; Vignaux et al., 2009; Uzawa et al., 2008; Gonzalez-Bermejo et al., 2006; Liu and Osvalder, 2004; Marjanovic et al., 2017; Marjanovic and L'Her, 2016; Maruyama et al., 2014; Morita et al., 2016; Spaeth et al., 2017; Templier et al., 2007; Wachter et al., 2006). Twelve of the fifteen compared mechanical ventilation devices (emergency and transport ventilators (Marjanovic and L'Her, 2016; Templier et al., 2007; L'Her and Roy, 2011), anaesthesia ventilators (Spaeth et al., 2017), critical care/intensive care unit ventilators (Jiang et al., 2020, 2018b,a; Vignaux et al., 2009; Uzawa et al., 2008; Marjanovic et al., 2017; Morita et al., 2016) and home care ventilators (Gonzalez-Bermejo et al., 2006)). Three of the fifteen evaluated the usability of prototypes with innovative graphical displays (Liu and Osvalder, 2004; Maruyama et al., 2014; Wachter et al., 2006). Several different quantitative methods were used to assess the ventilators and interface designs. All of the studies have investigated efficiency and effectiveness (e.g. task failure rate, processing time, the occurrence of errors or unnecessary treatments). For the investigation of subjective usability attributes like "ease of use" and "satisfaction", the twelve studies comparing the mechanical ventilation devices used several different questionnaires (USE (Jiang et al., 2018b), SUS (Marjanovic et al., 2017; Spaeth et al., 2017), PSSUQ (Morita et al., 2016), individual (Jiang et al., 2020, 2018a; Marjanovic and L'Her, 2016; Templier et al., 2007; L'Her and Roy, 2011; Vignaux et al., 2009; Uzawa et al., 2008; Gonzalez-Bermejo et al., 2006)). Additionally to the NASA-Task Load Index (NASA-TLX) method for measuring the subjective estimation of mental workload used in six of the fifteen studies (Jiang et al., 2020, 2018b; Marjanovic et al., 2017; Marjanovic and L'Her, 2016; Morita et al., 2016; Wachter et al., 2006), user's workload was investigated with the measurement and analysis of objective indicators like physical or psycho-physical parameters, e.g. heart and respiratory rate (Marjanovic et al., 2017) or changes of eye motion (Jiang et al., 2020, 2018b,a; Marjanovic et al., 2017).

Besides the evaluation studies, one study dealing with the analysis of reported incidents was eligible for inclusion (Cassidy et al., 2011). Here, the reported incidents recorded in the database used were systematically analyzed with regard to potential risks and opportunities to improve patient safety.

Use errors and their causes were described in all studies but were not the primary outcome. All included usability problems fulfill the established quality criteria. There are some limitations regarding the generalizability and scope of the results of this review.

The included usability studies deal with the use of the mechanical ventilation devices and design prototypes in a simulated environment and quantitative measurement of their usability. Potential causes of use errors are given as examples as explanations for the quantitative results in the discussion. In the usability studies only certain tasks, certain devices and certain user groups were tested. These studies do not cover all devices, user groups and scenarios.

The limited results of the included incident analysis study are due to the lack of identification and description of usability errors in the data.

### 3.3. Usability issues and contributing factors

In total, 51 text passages with descriptions of use errors and underlying causes identified in the context of usability studies and the analysis of critical events with different ventilators were analyzed. The identified issues were grouped into 15 subcategories based on similarity. The subcategories describe the issues in abstract terms. The issues were

systematically listed in a cause-and-effect diagram by the occurring main categories (Fig. 2). Deviating from widespread categorizations, e.g. the 6 M method (man, machine, method, milieu, materials, management) (Canham et al., 2018; Wilken et al., 2017), the main influencing factors were adopted to best match the aspects found. The main categories (root cause areas) cover different aspects of the design of the user interface and the context of use. Table 2 in the Supplementary Data (Appendix C) gives an overview of the relevant text passages from the included articles containing information about possible usability problems as well as the categorization of the findings.

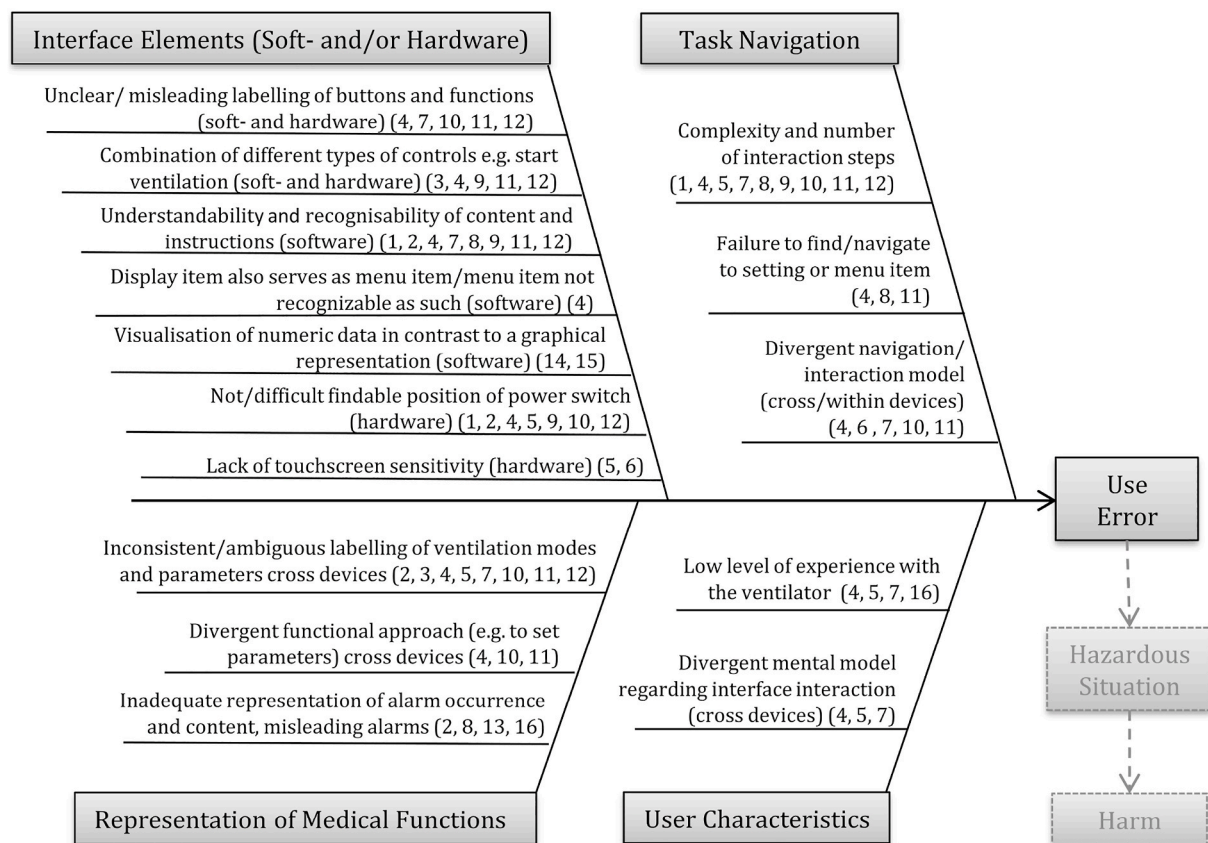
#### 3.3.1. Interface Elements (Soft- and/or hardware)

The category "Interface Elements" lists all problems found that are related to the design of the user interface elements, e.g. how the functions were made available and how the individual elements are designed and located. Depending on the design of the device, there are software elements for control and information elements available via a (touch) display, e.g. status bars and buttons, as well as hardware elements such as control knobs and switches:

Some aspects apply across soft- and hardware elements. Use errors and long processing times due to unclear or misleading labeling of buttons and functions were mentioned in several studies (Gonzalez-Bermejo et al., 2006; Marjanovic and L'Her, 2016; Spaeth et al., 2017; Templier et al., 2007; Uzawa et al., 2008). For example, the soft key provided for quitting alarms was not pressed, but the "Alarms" touchscreen-button which intended use is the opening of the menu for setting alarm limits (Spaeth et al., 2017). Regarding the choice of interaction elements, the use of a combination of hard- and software elements was not detrimental (Spaeth et al., 2017). However, the use of a touchpad enables the clear distribution of functions and parameters on individual screens, while the use of only hardware elements often requires several different types of controls for adjusting settings (Marjanovic and L'Her, 2016; Templier et al., 2007). Additionally, the use of a combination of mechanical and software controls, e.g. to start ventilation or set a parameter, was stated as the cause for inefficient interaction or even task failure as the operators did not expect an additional activation step (Spaeth et al., 2017).

Considering the issues regarding the software elements, a good recognizability and readability of the presented content, e.g. alarm messages and additional instructions, was named as a factor relevant to good performance (Jiang et al., 2018b; Marjanovic and L'Her, 2016; Spaeth et al., 2017; Templier et al., 2007). For example, a notification pointing to special interaction steps to start ventilation was overlooked during operation which considerably affected the execution of the task (Spaeth et al., 2017). The use of touchscreen offers new possibilities for information and interaction elements if they are used properly. Here, the design of a button that did not meet the user's expectations was described as an obstacle to setting the ventilation mode for one device. On the one hand, it served as the display of the current mode, on the other hand, it also served as a button for opening underlying functions, whereby the button was not recognizable as such and was placed differently than the other buttons (Spaeth et al., 2017). In addition, several studies dealt with an alternative graphical representation of data in comparison to traditional representations to enable clinicians better decision support and recognition of adverse respiratory events (Liu and Osvalder, 2004; Maruyama et al., 2014; Wachter et al., 2006).

Regarding especially the hardware elements, for powering on the ventilators, the position of the power switch, e.g. on the back of the device or hidden behind a flap, was described as problematic (Jiang et al., 2018b; Marjanovic et al., 2017). While this was done for safety reasons, it inversely makes fast operation more difficult in time-critical situations if it cannot be found (Jiang et al., 2018b; Marjanovic et al., 2017; Vignaux et al., 2009). Furthermore, the lack of the sensitivity of the touchscreen of some devices was mentioned as a source of confusion and barrier for the completion of some tasks (Marjanovic et al., 2017; Morita et al., 2016).



**Fig. 2.** Usability issues and contributing factors that can lead to use errors in mechanical ventilation devices and potential patient harm (1: Jiang et al. (2020), 2: Jiang et al. (2018b), 3: Jiang et al. (2018a), 4: Spaeth et al. (2017), 5: Marjanovic et al. (2017), 6: Morita et al. (2016), 7: Marjanovic and L'Her (2016), 8: L'Her and Roy (2011), 9: Vignaux et al. (2009), 10: Uzawa et al. (2008), 11: Templier et al. (2007), 12: Gonzalez-Bermejo et al. (2006), 13: Maruyama et al. (2014), 14: Wachter et al. (2006), 15: Liu and Osvalder (2004), 16: Cassidy et al. (2011)).

### 3.3.2. Task Navigation

The category “Task Navigation” contains problems regarding the concepts behind the surface in terms of how to interact with the system:

The large number of functionalities offered due to the technical progress leads to a multitude of interaction steps with possibilities for use errors compared to simpler devices with only limited functionalities (Marjanovic and L'Her, 2016). While task performance was sometimes limited due to number of steps needed to perform the tasks, some tasks could not be executed because the user was not able to find the menu item or navigate to the setting, e.g. if they were placed in a submenu (Spaeth et al., 2017; Templier et al., 2007). It was also found that the efficient execution of some tasks was impaired by intra-machine or inter-machine inconsistencies in navigation (Morita et al., 2016; Spaeth et al., 2017). Especially the comparison of the task performance between the devices indicates that the choice of the interaction model interferes with task completion (Morita et al., 2016; Spaeth et al., 2017).

### 3.3.3. Representation of Medical Functions

The category “Representation of Medical Functions” names the problems that have arisen due to the underlying assumptions about the medical domain. These domain-specific issues are independent of the actual implementation of the design of the interface elements. The key issue here is the conceptual implementation of the domain-specific requirements that medical professionals demand of ventilators:

In performing tasks such as selecting and identifying ventilation modes, parameter settings and monitoring values several studies describe as a major problem the heterogeneous terminology used (Jiang et al., 2018b; Marjanovic et al., 2017; Marjanovic and L'Her, 2016; Spaeth et al., 2017; Templier et al., 2007). The various ventilator

manufacturers use different labels for the same functions (e.g. “Tplat”, “TIP:TINSP” and “Tpause”), which leads to unnecessary confusion, additional workload and operational failures (Jiang et al., 2018b; Spaeth et al., 2017). Likewise, the language-specific use of the french acronyms led to confusion and inadequate ventilation due to their similarity (Marjanovic and L'Her, 2016; Templier et al., 2007). On the contrary, elements that were labeled in an internationally conform manner (e.g. PEEP, ventilation frequency, tidal volume) enabled the shortest processing times and the fewest assistance (Spaeth et al., 2017). Use errors could also be observed in relation to a divergent functional approach to set parameters and their calculation (e.g. the ratio of inspiratory-to-expiratory time set as “I:E-ratio” or via the selection of the absolute inspiration time on the ventilators labeled “TINSP” or “Ti”) (Spaeth et al., 2017; Templier et al., 2007). While e.g. the setting of the inspiratory pressure as pressure amplitude above PEEP, is physiological reasonable, it is still cause of confusion despite the corresponding labeling of the respective button (PC above PEEP) (Spaeth et al., 2017). Furthermore, some studies mention the need for a more suitable presentation of alarms as essential for the handling of these (Cassidy et al., 2011; Jiang et al., 2018b; Maruyama et al., 2014). The user must be able to quickly recognize the occurrence of the alarm and understand the alarm content (Jiang et al., 2018b; Maruyama et al., 2014) and not be misled by the information given (Cassidy et al., 2011). In addition to an easy to perceive presentation, e.g. auditory and visual, more detailed information on the alarm should enable fast response with less workload (Maruyama et al., 2014).

### 3.3.4. User Characteristics

The category “User Characteristics” summarizes problems that refer

to the properties of the user. “User” refers to the users who use the devices for the treatment of patients in a clinical environment. We distance ourselves from a user-centered shame and blame culture. As part of the socio-technical system, the known user characteristics are to be taken into account as a basis within the development process in order to avoid potential use errors:

For medical devices, there are regulations that request manufacturer training (Morita et al., 2016; Spaeth et al., 2017). However, Templier et al. (2007) pointed out that “some physicians have few opportunities to use ventilators and may therefore forget some of their initial training” (Templier et al., 2007) and “in theory, physicians should receive training before using a new ventilator. In practice, however, training may be cursory” (Templier et al., 2007). Spaeth et al. (2017) additionally mention that in time-critical situations and at a high level of stress the cognitive processing and performance of trained operators can be impaired to a comparable degree of naive operators. The influence of experience with certain ventilators, corresponding mental models and individual preferences becomes particularly clear when different devices are used (Marjanovic et al., 2017; Marjanovic and L’Her, 2016; Spaeth et al., 2017). In addition, larger deviations in the performance indicate different user characteristics, so that probably not every concept is equally suitable for every user (Spaeth et al., 2017).

## 4. Discussion

### 4.1. Principal results

Possible causes of use errors were identified in this systematic review. The causes of use errors described in the 16 included papers could be grouped into 15 subcategories. These in turn could be categorized into four root cause areas in the cause-and-effect diagram (Fig. 2). On the one hand, the use errors refer to the direct interaction with the ventilator. On the other hand, there are also use errors due to the use of many different devices (annotated cross device in the diagram). The findings presented show only a selection of possible causes for use errors, but include the main problems mentioned in the literature. Due to the safety-critical area of application, even the single occurrence of an error must be taken seriously.

The cause or contributing factor for the use errors in the direct device interaction was either a violation of design guidelines or an insufficient or incorrect use requirement. The identified problems “Unclear or misleading labeling of buttons and functions” and “Inadequate representation of alarm occurrence and content”, for example, are indications of weaknesses in self-descriptiveness and suitability for the user’s tasks. “Combination of different types of controls” and “Display item also serves as menu item/menu item not recognizable as such” lack of conformity with user expectations. The aspect “understandability and recognizability of content and instructions” violates the principles of dialog design detectability and unambiguous interpretability. “Complexity and number of interaction steps” and “Failure to find/navigate to setting or menu item” can be reduced by faster accessibility of the most frequently used functions and by flatter hierarchies. In general, it can be said that adherence to design guidelines (e.g., ISO 9241-110; ISO 9241-112; ISO 9241-125) and heuristics (Nielsen, 1994; Nielsen and Mack, 1994) contribute to error prevention and good design. Furthermore, the underlying needs and user requirements must be correctly identified. An analysis of the medical context is therefore indispensable.

In contrast to problems that affect the human-machine interaction between a user and a concrete device, some problems only occur when a user has to work with several devices (cross-device interaction). This is caused by manufacturer-specific use concepts, which differ from each other in a relevant way but are not always directly recognizable to the user. Ventilation modes are one example. The number of ventilation modes has increased with technological progress (Mireles-Cabodevila et al., 2013; Chatburn et al., 2014). These ventilation modes have

different names for the same mode depending on the manufacturer and, conversely, different modes are hidden behind the same names. Furthermore, activated features with parameterization lead to new ventilation modes that are not assigned a name. This situation makes familiarization with new devices time-consuming and, above all, switching between different devices and their operation a risk to patient safety. For patient safety, it is essential that all available ventilation modes are understood to avoid adverse events (Barnes et al., 2010). To address this problem across devices, Chatburn et al. (2014) propose a standardized glossary with a taxonomy that leads to harmonization of ventilation modes regardless of manufacturer. The ISO 19223 standard adopts this approach and defines a standardized vocabulary adapted to the context of use, which use should limit the potential for incorrect use.

Risk management should anticipate use errors at an early stage in the development process and avoid them by means of suitable usability tests. An example of a risk minimization measure according to ISO 14971 is the design of the power switch. Here, there is a tension between accidentally turning off the ventilator which must be avoided at all costs and finding the power switch quickly and easily (Jiang et al., 2018b; Spaeth et al., 2017; Marjanovic et al., 2017; Vignaux et al., 2009). Design decisions based on risk minimization may therefore be perceived as usability errors by the user. In this case, medical staff must be instructed separately on the criticality of the controls. But is training sufficient when the challenge is to overcome confusion, for example, in selecting ventilation modes or setting parameters when use is infrequent and stress levels are high? User expectations and experiences, and associated mental models regarding interaction through previous experience, can compound problems. Due to lack of standardization and commercialization issues, the ventilator is a “black box” in many cases. Advanced training in technical issues beyond that of individual devices is required for the user (Dellaca et al., 2017). Organizational work-arounds such as providing training and lists/overviews for reference can support the user. However, such measures should not relieve manufacturers of their responsibility.

In summary, it can be said that the qualitatively listed usability issues could all be sorted into differentiated cause categories. This made it possible to identify solution options for the use errors. In the context of a systematic error analysis (Vincent et al., 2000) the causes are multi-causal. The manufacturer is responsible for designing the user interface in such a way that patient safety is not compromised. Here, risk management and requirements analysis as well as usability testing during manufacturing play a significant role. This work offers manufacturers and users the opportunity to take a multi-perceptual look at the causes of errors. The analysis offers the possibility to include frequent error causes in the checklists for avoidance.

### 4.2. Strengths and weaknesses of the study

In the review process, only a few studies could be found that dealt with concrete causes of use errors with ventilators. The methodology used and the results of the review are subject to some limitations. Despite these limitations, some descriptions of usability problems could be identified. For our qualitative analysis, a single mention of an error and a description of its cause was sufficient. A detailed analysis of the quality of the paper was therefore not significant. Additionally, the nature of the findings does not allow any statement to be made about their relevance and the associated risk. However, due to the generalized categorization, the results nevertheless provide a useable overview for the reduction of use-related risks.

The search for publications was complicated by the lack of established MeSH terms and the inconsistent use of the term “usability”. Instead of the term usability, other terms (e.g. ease of use (Spaeth et al., 2017; Templier et al., 2007), ergonomic evaluation or ergonomics (Jiang et al., 2018b; Marjanovic and L’Her, 2016; Marjanovic et al., 2017), human factors or human factors study (Morita et al., 2016; Spaeth et al., 2017), self-explanatory interface (Spaeth et al., 2017) and

user experience (Jiang et al., 2018b; Morita et al., 2016)) are often used synonymously. Likewise, instead of use error, a variety of alternative terms were used. In addition to the terminology used, there may also be a misinterpretation of the causes of incidents, so that potential usability problems are not described as such. Therefore, despite the extensive search string, it is possible that studies containing usability problems and contributing factors were not found by the search strategy implemented. At the same time, the chosen search string led to numerous findings that did not meet the inclusion criteria. For better discoverability, for example, the MeSH term “user-centered design” introduced in 2021 is the first step. In addition to establishing suitable methods at the manufacturer, however, the user’s awareness of usability and not the individual as the cause of errors must also be strengthened.

The focus of this review was on scientific publications on systematically analyzed usability problems. The search for these was done only via PubMed. An extension of the search in other publication databases could lead to further suitable publications. Moreover, incidents involving medical devices are primarily reported to the regulatory authorities, so there may be no separate publications on them. The analysis of entries in corresponding incident reporting systems such as the German Critical Incident Reporting System (CIRS) and reports to the Federal Institute for Drugs and Medical Devices (BfArM) could reveal further issues and enables an extension of the overview already created in this paper.

In fifteen of the studies, different ventilators and alternative displays were tested against each other. The studies measured and evaluated usability metrics such as effectiveness, efficiency and satisfaction. The measurement procedures used were limited to quantitative methods that offered information on performance. These provided a concrete result for the usability and comparability of the ventilators among themselves. The analysis of use errors and underlying usability problems was not the primary goal of the studies. The causes mentioned were only a secondary outcome and only given as examples to explain the quantitative results in the discussions. The amount of information and its level of detail was therefore sometimes very limited. For the detailed analysis of the underlying causes, the application of qualitative methods, such as video analysis and thinking aloud, is required to allow a more in-depth examination (Morita et al., 2016).

A large number of publications from the area of reported incidents and systematic reviews of these were excluded due to a lack of information about concrete usability problems. The structured analysis of reported incidents provided indications of existing problems in addition to quantitative results, e.g. on the severity of the incidents, but did not sufficiently analyze their causes. A lack of detail and understanding of what happened in reports often leads to poor data quality, so that the exact causes cannot be traced (Cassidy et al., 2011; Pham et al., 2016). In addition to a sufficient level of detail, suitable incident analysis methods are essential for the correct assignment of causes and the initiation of appropriate risk management methods (Lipprandt et al., 2020).

#### 4.3. Conclusions and practical applications

This paper gives a systematic overview of the causes of use errors in mechanical ventilators. The issues could be divided into categories that allow a cause analysis. In addition to non-compliance with design guidelines and underlying requirements, the causes of use errors mainly concern the use of several devices in alternation. Very different interaction designs and inconsistent naming of ventilation modes are challenging for users. Efforts to standardize the user interface components may lead to a reduction in use errors and thus increase patient safety. In order to avoid the identified causes for use problems in the future, this work offers manufacturers of ventilation devices design recommendations and the possibility to include the results in their risk management.

#### Contribution of the authors

R.R. and M.L. conceived the original idea. B.C., R.R. and M.L. were involved in the conception and design of the work. B.C., A.D., R.R. and M.L. performed the data acquisition, analysis and interpretation.

B.C. took the lead in drafting of the work. R.R., A.D. and M.L. revised it critically for important intellectual content.

#### Declaration of competing interest

The authors declare the following financial interests/personal relationships, which may be considered as potential competing interests:

The article was conceived as part of the simpliVENT project funded by the Federal Ministry of Education and Research. The respirator manufacturer Löwenstein Medical Technology GmbH + Co KG functions as a project partner. However, they were not involved in this subtask and the creation of this article. The findings presented were examined regardless of assignment to specific ventilators and manufacturers.

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#### Appendix A. Glossary

**Harm:** “injury or damage to the health of people, or damage to property or the environment” (ISO 14971).

**Hazard:** “potential source of harm” (ISO 14971).

**Hazardous situation:** “circumstance in which people, property or the environment is/are exposed to one or more hazards” (ISO 14971).

**Usability:** “characteristic of the user interface that facilitates use and thereby establishes effectiveness, efficiency and user satisfaction in the intended use environment” (ISO 62366-1).

**Use error:** “user action or lack of user action while using the medical device that leads to a different result than that intended by the manufacturer or expected by the user” (ISO 62366-1).

**Normal use:** “operation, including routine inspection and adjustments by any user, and stand-by, according to the instructions for use or in accordance with generally accepted practice for those medical devices provided without instructions for use” (ISO 62366-1).

**Incident:** “means any malfunction or deterioration in the characteristics or performance of a device made available on the market, including use-error due to ergonomic features, as well as any inadequacy in the information supplied by the manufacturer and any undesirable side-effect; ” (MDR, 2017/745).

**Serious incident:** “means any incident that directly or indirectly led, might have led or might lead to any of the following: the death of a patient, user or other person, the temporary or permanent serious deterioration of a patient’s, user’s or other person’s state of health, a serious public health threat; ” (MDR, 2017/745).

#### Appendix B. Search string and filters used via pubmed

((respiration OR breathing OR ventilation) OR (respirator OR ventilator) OR “Respiration, Artificial”[Mesh] OR “Ventilators, Mechanical”[Mesh] OR “Respiratory Therapy”[Mesh]) AND (usability OR “user friendliness” OR ergonomics OR ergonomic OR “user experience” OR “User-centered design” OR “human factors” OR “user interface” OR “interaction design” OR “interface design” OR “human-computer interaction” OR “human-machine interaction” OR HMI OR HCI OR “User-Computer Interface”[Mesh] OR “Ergonomics”[Mesh] OR “User-Centered Design”[MeSH]) AND ((risk OR risks OR “risk”[Mesh]) OR (error OR errors) OR hazard OR incident OR mishaps OR “patient harm” OR “patient safety” OR “adverse event” OR “adverse effects” OR “critical incident” OR “Use Safety” OR “usability

problems” OR failure OR “Patient Harm”[Mesh] OR “Patient Safety”[Mesh] OR “Medical Errors”[Mesh] OR “Harm Reduction”[Mesh] OR “Near Miss, Healthcare”[Mesh])) AND (German[Language] OR English [Language])

## Appendix C. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.apergo.2021.103544>.

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## Supplementary material

Table 1: Overview of the characteristics of the included studies with regard to objectives and methods, completed measurements and the main results

| Publication                        | Objective / Methods                                                                                                                                                                                                | Measurements                                                                                                                                                                                                                           | Main Results                                                                                                                                                                                                                                                 |
|------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Jiang et al. (2020)<br>China       | Comparative Usability Study<br>3 ICU ventilators<br>16 respiratory therapists (training was provided)<br>5 maintenance tasks                                                                                       | Task error rate and completion time<br>Physiological workload (eye-fixation duration)<br>Perceived workload (NASA-TLX)<br>User experience (3 questions)                                                                                | Maintenance user interface differ in performance and have a high task error rate<br>Maintenance-related usability problems were identified                                                                                                                   |
| Jiang et al. (2018b)<br>China      | Comparative Usability Study<br>3 ICU ventilators<br>16 respiratory therapists (training was provided)<br>7 tasks                                                                                                   | Task error rate<br>Physiological workload (eye motions: blink rate and duration)<br>Subjective workload (NASA-TLX)<br>Usability-Questionnaire (USE Questionnaire)                                                                      | Ventilators differ significantly<br>Usability shortcomings increased the mental workload and can lead to failures<br>Optimizing the design of the user interface is needed                                                                                   |
| Jiang et al. (2018a)<br>China      | Comparative Usability Study<br>3 ICU ventilators<br>16 respiratory therapists (training was provided)<br>6 tasks                                                                                                   | Task error rate and completion time<br>Task difficulty and cognitive demands (pupil diameter change, average slope of pupil diameter change)<br>3 questions regarding user-friendliness and safety of user-interface                   | Ventilators used have poor ergonomics with high task error rates<br>Optimization of the design of user-interfaces of ventilators is needed to avoid these ergonomic problems leading to use errors                                                           |
| Spaeth et al. (2017)<br>Germany    | Comparative Usability Study<br>4 anaesthesia ventilators<br>20 naive operators (medical students with no relevant experience with any anaesthesia ventilator) + 6 experienced operators for comparison<br>20 tasks | Success of task execution, requests for assistance, processing times<br>Eye motion (gaze points and time to first fixation (TFF))<br>Usability-Questionnaire (SUS)                                                                     | Evident differences in usability<br>Device-specific barriers impaired efficient task performance<br>Associated interface issues could be revealed<br>Eliminating the specific usability issues might improve the operator's performance and patient's safety |
| Marjanovic et al. (2017)<br>France | Bench test (technical performance) + Comparative Usability Study<br>6 ICU ventilators (+ 1 reference device)<br>20 senior ICU physicians (unfamiliar with the tested devices)<br>11 tasks                          | Technical bench tests<br>Task failure rate<br>Physiological response / stress (Pupil diameter modifications, heart and respiratory rate and thoracic volume variations)<br>Usability-Questionnaire (SUS)<br>Mental workload (NASA-TLX) | Similar technical performance<br>Inadequate ergonomics with high risk of misuse<br>Significant differences in terms of devices' usability<br>Lack of adaptation of device's development to end users' requests                                               |
| Morita et al. (2016)<br>Canada     | Comparative Usability Study<br>4 critical care ventilators (CCVs)<br>48 critical care respiratory therapists (experience balanced among the four families of ventilators)<br>7 scenarios composed of 16 tasks      | Percentage of tasks with use errors or close calls<br>Usability- Questionnaire (PSSUQ)<br>Mental workload (NASA-TLX)                                                                                                                   | Usability of ventilators differ<br>Different user interfaces, interaction designs and quality of the Hardware used may have had impact on users performance and perception                                                                                   |

|                                          |                                                                                                                                                                                                                                                               |                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                    |
|------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Marjanovic and L'Her (2016)<br>France    | Comparative Usability Study<br>13 emergency and transport ventilators (simple, sophisticated, and ICU-like)<br>12 emergency physicians (mainly unfamiliar with the tested machines)<br>9 tasks                                                                | Success of task execution<br>3 questions regarding ease of use, willingness to use and user-friendliness<br>Mental workload (NASA-TLX)                | Interface design relevant to the occurrence failures<br>Choice of a device not only depends on technical characteristics but also clinical workflow and the ergonomics of the device                                                                                                                                                                                               |
| L'Her and Roy (2011)<br>Canada/France    | Bench test + Comparative Usability Study<br>4 volume-cycled ventilators and 2 pressure-cycled ventilators (emergency ventilators)<br>6 senior respiratory therapists and 6 senior emergency physicians (no experience with these ventilators)<br>7 or 8 tasks | Physical characteristics, technical performance, gas consumption<br>Task error rate and completion time<br>Ease of / willingness to use (2 questions) | Huge heterogeneity of performance, gas consumption, and ergonomics<br>The ventilator-taskfailure rate may be substantially improved by very simple design modifications<br>A closer relationship between end-users and manufacturers should be promoted during ventilator development<br>Recommendations regarding the value of the ventilators for mass-casualty events are given |
| Vignaux et al. (2009)<br>Switzerland     | Comparative Usability Study<br>7 ICU ventilators<br>10 physicians (unfamiliar with tested machines)<br>8 tasks                                                                                                                                                | Task error rate and time needed compared to a reference time<br>Subjective impression of overall difficulty of interaction (Score 0-10)               | Substantial heterogeneity between machines<br>Many new generation ventilators present poor ergonomics, leading to delayed or impossible user-machine interactions<br>Closer ties between end-users and manufacturers should be promoted                                                                                                                                            |
| Uzawa et al. (2008)<br>Japan             | Comparative Usability Study<br>4 ICU ventilators<br>21 medical resident physicians (no experience with selected ventilators)<br>8 tasks                                                                                                                       | Task error rate and processing time<br>Overall subjective rating of the ease of use (Score 0-100)                                                     | Design of the user interface is relevant to the occurrence of operational failures<br>Understanding mechanical ventilation does not guarantee the capability of operating mechanical ventilators without operational failures<br>Basic user interface should be standardized among the clinically used mechanical ventilators.                                                     |
| Templier et al. (2007)<br>France         | Comparative Usability Study<br>2 transport ventilators<br>20 senior emergency physicians (unfamiliar with the study ventilator)<br>15 tasks                                                                                                                   | Success of task execution<br>Errors (number, type and potential risk)<br>Satisfaction / perceived ease of use (individual Score)                      | Ventilators differ in ease of use<br>More studies to evaluate occurrence of errors to improve the ergonomics of interfaces recommended                                                                                                                                                                                                                                             |
| Gonzalez-Bermejo et al. (2006)<br>France | Comparative Usability Study<br>11 home ventilators<br>13 ICU physicians (without practical experience in home mechanical ventilation and mainly unfamiliar with devices)<br>6 tasks                                                                           | Task error rate and time needed compared to a reference time<br>Global assessment of ease of use (Score 0-10)                                         | Trained intensive care unit physicians perform poorly when confronted with home mechanical ventilators without specific prior training<br>User friendliness of home ventilators for other categories of users might be questionable<br>Results should encourage corrective actions by both the manufacturers and the medical community                                             |

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| Maruyama et al. (2014)<br>Japan   | Comparative Usability Study<br>conventional system vs. additional prototype<br>15 Nurses<br>6 leakage scenarios                                                                                               | Time to identify the site of the leak in a respiratory circuit                                                                              | Rapid and successful recognition improved due to novel alarm system<br>Further development and more studies needed before generalized conclusions can be made                                                                                              |
| Wachter et al. (2006)<br>USA      | Comparative Usability Study<br>Pulmonary graphical display prototype vs. control display<br>9 clinical volunteers<br>5 simulated respiratory events                                                           | Time to diagnosis<br>Time to treatment for each adverse respiratory event<br>Number of unnecessary treatments<br>Mental workload (NASA-TLX) | Graphic displays can be advantageous over the display of numerical values<br>May serve as a useful adjunct to traditional displays                                                                                                                         |
| Liu and Osvalder (2004)<br>Sweden | Comparative Usability Study<br>Graphical circular display prototype vs. control display<br>20 nursing students<br>6 tasks                                                                                     | Detection time<br>Error rates<br>Subjective judgment and comments of participants                                                           | Helps to interpret the meanings of parameter deviations<br>No improvement in detection time and getting the overall picture of the situation<br>Graphical circular display was subjectively preferred by more test subjects<br>Further improvements needed |
| Cassidy et al. (2011)<br>UK       | Review of patient safety incident reports related to anaesthetic equipment<br>Database search (National Reporting and Learning System for England and Wales)<br>1029 relevant incidents between 2006 and 2008 | Equipment category<br>Type and cause of incident<br>Level of patient harm                                                                   | Equipment was often faulty, user error or unfamiliarity also played a part<br>Aspects of equipment problems related to human error seem to be under-represented<br>Recommendations for improving practice were made                                        |

Table 2: Relevant text passages from the included articles containing information about possible usability problems as well as the categorization of the findings for the cause-and-effect diagram

| Publication          | Relevant text passages                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Categorization                                                                                                                                                                                                                                                  |
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| Jiang et al. (2020)  | <p>"Notably, the self-test user interface for the Evita 4 was poorly designed. The self-test user interface for this ventilator was below the center of the screen, making it difficult for the participant to check the information. Further, the self-test feedback information was displayed in a small font at the bottom of the user interface, making it difficult to read. In addition, the translation of the self-test information was not accurate, which was confusing to the participants."</p> <p>"Furthermore, the design of the ventilator power switch showed a usability limitation. [...] In our study, nearly all participants used their right hand to search for the power switch on the ventilator. The Boaray 5000D and the Servo I had the power switches on the left-hand side. Moreover, the Servo I power switch was concealed behind a sliding cover, thus participants wasted time searching for the switch and starting the machine."</p> <p>"For the Boaray 5000D, the battery status was easily obtained from the user interface, while the battery status for the Servo I was via a menu, thus locating it was challenging, resulting in high task failure rates (Table 1). However, the only way to see the battery status for the Evita 4 was to turn off the power, which may harm patients."</p> | <p>Software Interface Elements - Understandability and recognisability of content and instructions</p> <p>Hardware Interface Elements - Not/difficult findable position of power switch</p> <p>Task Navigation - Complexity and number of interaction steps</p> |
| Jiang et al. (2018b) | <p>"[...] the power switch presents several problems. As to be expected given that 91% of Chinese people are right-handed [33], in the study, researchers noted that all the participants looking for the power switch ("on/off" button) start from the right-hand side of the machine, but only the Evita 4 put it on the right side. For the Boaray 5000D and Servo I, whose switches are on the back left of the machine, and particularly for the Servo I, where the power switch is hidden behind a sliding cover, it was difficult for participants to find the switch and turn it on, thereby making it hard to use in urgent environments."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | <p>Hardware Interface Elements - Not/difficult findable position of power switch</p>                                                                                                                                                                            |

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|                      | <p>"The most significant usability problem noted by our study was the different terminology in use between ventilators. In the mode and setting parameters recognition and ventilator monitoring values recognition tasks, participants got confused with the different terminology that each ventilator used. Most ventilation terminology was presented in English acronyms and different ventilator manufacturers used different acronyms for the same terms. However, the use of different acronyms among ventilators resulted in unnecessary user confusion, added additional operational error, and increased the workload for task completion."</p> <p>"Furthermore, the ventilators' alarms also need additional attention. The visual and auditory stimulation and display interface for the alarms need improvement so that users can quickly recognize the occurrence of the alarm and easily read and understand the alarm content."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | <p>Representation of Medical Functions - Inconsistent/ambiguous labelling of ventilation modes and parameters cross devices</p> <p>Software Interface Elements - Understandability and recognisability of content and instructions</p> <p>Representation of Medical Functions - Inadequate representation of alarm occurrence and content, misleading alarms</p>                                                                                    |
| Jiang et al. (2018a) | <p>"First, the terms of ventilation parameters are not uniform among ventilators. For example, on the ventilation parameters settings page, the fraction of inspired oxygen was listed as "O2[%]" on the Evita 4, "O2" on the Servo I and "FiO2(%)" on the Boaray 5000D. This can cause confusion in emergency situations."</p> <p>"Second, the adjustment method of ventilation mode and parameters are different among ventilators. For the Evital 4, the adjustment of mode and parameters only requires to operation of a knob in the bottom right corner of the screen, with confirmation of the change by pressing the knob. However, in the Boaray 5000D and Servo I, in addition to the operation common to the Evital 4, one needs to click an "accept" button on the screen, a task most participants found easy to forget. The difference in design of the user-interface resulted in unnecessary operational failures and increased the task completion times;"</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            | <p>Representation of Medical Functions - Inconsistent/ambiguous labelling of ventilation modes and parameters cross devices</p> <p>Interface Elements - Combination of different types of controls (e.g. start ventilation)</p>                                                                                                                                                                                                                     |
| Spaeth et al. (2017) | <p>"The experienced operators rated usability even worse for the Flow-i and better for both Dräger devices. This is in accordance with the finding that operators are subject to habituation and tend to evaluate known systems disproportionately better and unknown systems disproportionately worse. Our experienced operators routinely work with the Primus and are therefore likely to be used to the interface of Dräger systems. Thus, they may have been unaware of the shortcomings of these systems in usability. Given that clinicians are bound to work with devices of specific types and manufacturers, we have anticipated this phenomenon and primarily focused our study on testing through naive operators."</p> <p>"Device-specific barriers impeded the participants' abilities to perform particular tasks more efficiently. Some tasks were conspicuously impeded by either intra-machine or inter-machine inconsistencies in navigation. Thereby, it has to be noticed that a large variation of processing times and TTF in certain tasks might suggest an interface design that works for some but not for all of our test persons." [...] "Nearly all identified shortcomings were device specific, given the fact that in the other devices the naive subjects were able to perform the same task well. In other words, for each task there were design solutions available that provided for an efficient operation by users who were not specifically trained."</p> <p>"The menu for setting ventilation mode in the Flow-i may serve as an example for a ventilator's display item not meeting a user's expectation. In this device, the field displaying the current ventilation mode also serves as a touchscreen button that opens a menu providing underlying functions. However, in contrast to other buttons displayed at the bottom of the screen, this field is placed at the right top and is not marked off as a button."</p> <p>"Likewise, when the operators were requested to quit the alarm for the Perseus, instead of pressing the respective soft key, they often pressed the 'Alarms . . .' button, which is for accessing the alarm limits. Long TTF and a diffuse distribution of gaze fixations indicated that the operators were not able to recognize the respective underlying function but rather searched for it within the vicinity of the buttons for the other functions."</p> | <p>User Characteristics - Low level of experience with the ventilator</p> <p>Task Navigation - Divergent navigation/interaction model cross/within devices</p> <p>User Characteristics - Divergent mental model regarding interface interaction</p> <p>Software Interface Elements - Display item also serves as menu item/menu item not recognizable as such</p> <p>Interface Elements - Unclear/misleading labelling of buttons and functions</p> |

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|                          | <p>"Nearly all operators claimed assistances to initiate mechanical ventilation using the Avance. This procedure required two consecutive operating steps. Users had to push the 'Start ventilation' button at the ventilator's interface and, subsequently, flick a lever situated on the ventilator's case. The second step, in particular, impeded the operators' performance. Long TTF resulted because the operators did not expect a mandatory additional mechanical activation step, even though respective instructions are given on the ventilator's screen. Similar to the Avance, the Flow-i provides a turn-switch for alternating between mechanical and manual ventilation. However, in the Flow-i the operation of this switch is not mandatory for starting or ending ventilation. Our naive operators handled this step even faster and with fewer assistance requests via the mechanical switch compared with touch-screen or soft-key, as realized for the devices from Dräger. Thus, a mechanical switch for this task does not appear to be disadvantageous unless combined with an additional touchscreen operation."</p> <p>"In a series of tasks, the naive operators' performances may have been particularly impeded by inconsistent labelling of buttons aiming at the same functionality in devices from different manufacturers. On the Avance and the Flow-i, the ratio of inspiratory-to-expiratory time is set as 'I:E-ratio', whereas the same variable is set via selection of the absolute inspiration time on the ventilators from Dräger, labelled 'TINSP' on the Primus and 'Ti' on the Perseus. On the Flow-i, the button for this function is placed in a sub-menu and was associated with frequent assistances. Also for both Dräger machines this task caused frequent assistances, although the respective button is positioned in the front menu. However, with respect to the short TFF, we rather assume that the operators had difficulties in translating the change in inspiratory time to a change in I:E ratio. Comparable ambiguity arose when setting the endinspiratory pause during VCV. Except for the Avance, this function is placed in a submenu, which partly explains the relatively long TFF and processing times for these devices. It has also to be noted that the labels, all aiming at the same functionality, vary between 'Tplat' on the Perseus, 'TIP:TINSP' on the Primus, and 'Tpause' on the Avance and the Flow-i. [...] Accordingly, the benefit of consistent labelling became apparent in tasks including functionalities that were labelled in an internationally conform manner (e.g. PEEP, ventilation frequency, tidal volume). In these tasks, we found the shortest processing times and fewest claimed assistances."</p> <p>"Setting inspiratory pressure follows a divergent functional approach in the Flow-i, causing a prolonged processing time but also a short TFF. In this device, the inspiratory pressure is set as the pressure amplitude above PEEP. Although this might be reasonable from a physiological point of view, our naive and our experienced operators struggled to execute this operating step even though the function is labelled at the respective button ('PC above PEEP'). Noticeably, the given examples of misinterpretation took place even though our naive operators had received a comprehensive introduction into mechanics of controlled ventilation, including definitions of I:E ratio, endinspiratory pause, PEEP, and inspiratory pressure in a preceding tutorial."</p> <p>"Ventilator functions such as immediate start of ventilation, switch to manual ventilation, or identifying emergency oxygen supply are crucial. Noticeably, searching for the emergency oxygen supply demanded the longest processing times and longest TFF for the Flow-i. The respective heat map reveals that operators missed this function placed right in the front of the ventilator's case, probably because it is covered by a panel with only discrete labelling."</p> | <p>Interface elements - Combination of different types of controls (e.g. start ventilation)</p> <p>Software Interface Elements - Understandability and recognisability of content and instructions</p> <p>Task Navigation - Complexity and number of interaction steps</p> <p>Task Navigation - Failure to find/navigate to setting or menu item</p> <p>Representation of Medical Functions - Inconsistent/ambiguous labelling of ventilation modes and parameters cross devices</p> <p>Representation of Medical Functions - Divergent functional approach (e.g. to set parameters) cross devices</p> <p>User Characteristics - Divergent mental model regarding interface interaction</p> <p>Hardware Interface Elements - Not/difficult findable position of power switch</p> <p>Interface Elements - Unclear/misleading labelling of buttons and functions</p> |
| Marjanovic et al. (2017) | <p>"[...] it is still surprising that some ventilators could not be powered on by a majority of physicians or that the NIV mode could not be easily activated. Excluding powering on/off tests from analysis, considering that these may be very different tasks that have been voluntarily been made difficult by the manufacturers for safety reasons, did not modify the overall results."</p> <p>"The lack of sensitivity of the S1 touch screen proved to be a barrier for some task completion and a significant source of confusion. [...] the lack of sensitivity of the S1 touch screen was specifically considered by the participants as responsible for an increased mental workload and higher rates of task failures."</p> <p>"While it may be one of the main tasks routinely performed, ventilator setting readings had the worst results of all tasks, probably because of the absence of a homogenized terminology among manufacturers."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             | <p>Hardware Interface Elements - Not/difficult findable position of power switch</p> <p>Hardware Interface Elements - Lack of touchscreen sensitivity</p> <p>Representation of Medical Functions - Inconsistent/ambiguous labelling of ventilation modes and parameters cross devices</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |

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|                             | <p>"[...] the better results of the Avea can clearly be related to the users' knowledge of and experience with this device and not specifically to a better interface. Given the overall expertise of all the physicians from the five ICUs with this device, it was used in the comparison as a reference value."</p> <p>"Considering our results and the impact of tasks on dimensions like performance and effort for some devices, manufacturers may primarily focus on interface simplification and rationalization, immediately providing the most important settings and alarms on a first screen, leaving expert settings to a second one. However, given individual physicians' heterogeneity, the perfect ventilator may be a difficult goal to achieve, and even with experience, some element of frustration and/or temporal workload may still occur, as with our reference device."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | <p>User Characteristics - Low level of experience with the ventilator</p> <p>Task Navigation - Complexity and number of interaction steps</p> <p>User Characteristics - Divergent metal model regarding interface interaction</p>                                                                                                                                                                                                                                                                                                                                                                                                               |
| Morita et al. (2016)        | <p>"For instance, the lack of sensitivity of the G5's touchscreen proved to be a barrier for task completion and a significant source of frustration, while the SERVO-U's user interface was praised by the participants."</p> <p>"The qualitative data also collected in this study indicate that the choices of interaction model of each ventilator (e.g., how to select information on the screen, adjusting settings, and confirming) seem to interfere with task completion and affect users' overall perception of the devices."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>Hardware Interface Elements - Lack of touchscreen sensitivity</p> <p>Task Navigation - Divergent navigation/interaction model cross/within devices</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| Marjanovic and L'Her (2016) | <p>"Most test failures with the sophisticated emergency and transport ventilators were observed during the ventilatory mode changes, compared with other categories. This difference could be explained by the fact that only a few settings and modes are available on simple devices, whereas many more possibilities and confirmation steps are necessary for the other 2 categories. Sophisticated and ICU-like emergency and transport ventilators also need 2 or 3 steps to power off, whereas simple devices only need a single button switch."</p> <p>"Emergency and transport ventilator human/machine interfaces have only marginally evolved over time, and most current devices are somewhat similar from one brand to the other, which may explain such results among a population of well-trained emergency physicians."</p> <p>"Concerning sophisticated emergency and transport ventilators, there was also frequent confusion between spontaneous noninvasive ventilation and invasive ventilation modes, when such an option had to be selected. Another frequent cause of failure was confusion between volumecontrol continuous mandatory ventilation (VC-CMV) and volume-control intermittent mandatory ventilation (VCIMV) modes. Indeed, VAC (for "volume assiste' contro'le"), the French acronym that is routinely used (corresponding to VC-CMV) is quite similar to VACI (for "volume assiste' contro'le' intermittent," corresponding to VC-IMV). Another example, the HT70 ventilatory modes, only display English acronyms, and as a result, VC-IMV was frequently mistaken for noninvasive ventilation modes. Thus, it clearly seems necessary to standardize the terminology and to simplify mode recognition in order to avoid such failures but also to ensure that the device's human/machine interface is fully adapted to the users' experience and country."</p> <p>"With regard to simple emergency and transport ventilators, the failures mainly concerned setting and alarm readings and were considered to be linked to poor monitoring precision."</p> <p>"As observed in our study, a combination of buttons is frequently required to start or stop a function, the labeling of the buttons may not always be clear, and screens are often absent or somewhat difficult to read. [...] several devices may induce significant mental overload and/or failures due to an increase in the number of steps required to complete a single task."</p> <p>"Confusing human/machine interface aspects, designed without sufficient input from the end users, may lead to inadequate solutions in the clinical setting. Although our results may not be totally conclusive, the screen interface and the availability of curve monitoring were associated with a better perceived user-friendliness and willingness to use, which may thus indirectly affect the task failure rate despite the fact that simple devices also led to fewer task failures. Similar results have already been observed by Uzawa et al who took into account 4 modern ICU ventilators and observed that different human/ machine interface designs resulted in different rates of operational failures."</p> | <p>Task Navigation - Complexity and number of interaction steps</p> <p>User Characteristics- Low level of experience with the ventilator</p> <p>Representation of Medical Functions - Inconsistent/ambiguous labelling of ventilation modes and parameters cross devices</p> <p>User Characteristics - Divergent metal model regarding interface interaction</p> <p>Software Interface Elements - Understandability and recognisability of content and instructions</p> <p>Interface Elements - Unclear/misleading labelling of buttons and functions</p> <p>Task Navigation - Divergent navigation/interaction model cross/within devices;</p> |

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| L'Her and Roy (2011)   | <p>"Alarm reading time was longest with the Carevent ALS, whereas it is only represented by the maximum pressure value for the relief valve, which is written in a very small font."</p> <p>"Ventilation-setting modifications were significantly shorter with the Oxylator EMX (P .006), mainly because only a modification of the pressure is possible, and the respiratory rate depends only on the flow; there are no other adjustable settings."</p> <p>"The EPV100 seemed less ergonomic than the other volumecycled ventilators to both the respiratory therapists and the emergency physicians. This difference, which is much more important to the overall task-failure rate, was due mainly to difficulties in trying to shut down the alarms, which is a function that is unavailable with the other ventilators."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | <p>Software Interface Elements - Understandability and recognisability of content and instructions</p> <p>Representation of medical Functions - Inadequate representation of alarm occurrence and content, misleading alarms</p> <p>Task Navigation - Complexity and number of interaction steps</p> <p>Task Navigation - Failure to find/navigate to setting or menu item</p>                                                                                                                                                                                                    |
| Vignaux et al. (2009)  | <p>"First, turning on the ventilator. The Elysee can be turned on very quickly: as soon as it is powered, an on-screen message appears, reading "to switch on press the button", and an arrow showing its location. At the other end of the spectrum, tortuous paths must be followed, such as performing several actions in different panels (Avea, Engstro"mCarestation), double validation (on-screen and on the side of the ventilator, PB840) or finding the switch concealed behind a small sliding cover (Servo i). There is, of course, a logical safety goal here which is avoiding the accidental switching off of the machine. However, in the interest of safety, one might devise an asymmetric procedure, i.e. difficult to switch off and easy and quick to switch on."</p> <p>"Second, the high error rate (30–40%) and long delay (60–150 s) to correctly identify the ventilatory mode and set/measured parameters constitute another ergonomic shortcoming. [...] Clear display and ease of ventilator mode recognition should be a priority in ventilator design and selection, given the safety issues involved [15], and there is obviously room for improvement."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | <p>Task Navigation - Complexity and number of interaction steps</p> <p>Interface Elements - Combination of different types of controls (e.g. start ventilation)</p> <p>Hardware Interface Elements - Not/difficult findable position of power switch</p> <p>Software Interface Elements - Understandability and recognisability of content and instructions</p>                                                                                                                                                                                                                   |
| Uzawa et al. (2008)    | <p>"The graphic user interface of the Evita XL seemed to be less intuitive for the selected subjects and affected the rate of operational failures. Setting-changes are frequently done through a colorful graphic interface. However, a graphic user interface often comes with multiple layers in the menus, and it sometimes takes a long time to browse or search for a specific control button through the multiple layers. In order to ease the operation, some ventilators have developed a hybrid of graphic interface with analog interface."</p> <p>"In the setting-change tasks there were significant differences among ventilators in the operational failures, in part due to the result of the confusion in terminologies that each ventilator uses. For instance, the mode of spontaneous breathing with continuous positive airway pressure is expressed as CPAP on some ventilators, but as SPONT on others. Pressure-control ventilation is labeled as BIPAP in one ventilator but as PCV in others."</p> <p>"When pressure-control ventilation is used and a level of pressure control is set, some ventilators target the peak pressure as the set level of pressure control, whereas others target the peak pressure as the set level of pressure control plus the positive end-expiratory pressure."</p> <p>"The locations of the inspiratory outlet port and the expiratory port are different among the ventilators. In some ventilators the inspiratory port is located on the left side of the ventilator and the expiratory port on the right side. On other ventilators the locations are opposite. This caused confusion and errors; some subjects connected the inspiratory limb to the expiratory port. Similarly, the power button was located on the front of the machine on some ventilators, but on others it was on the back. Although there is no rationale to have any specific location from the end-user perspective, it would make sense to have the relative locations standardized internationally across the ventilator industry. The standardization could also include the relative locations of the frequently used functions, such as the manual breathing button, the fraction of inspired oxygen, alarm silence, et cetera."</p> | <p>Task Navigation - Complexity and number of interaction steps</p> <p>Representation of Medical Functions - Inconsistent/ambiguous labelling of ventilation modes and parameters cross devices</p> <p>Representation of Medical Functions - Divergent functional approach (e.g. to set parameters) cross devices</p> <p>Task Navigation - Divergent navigation/interaction model cross/within devices</p> <p>Interface Elements - Unclear/misleading labelling of buttons and functions</p> <p>Hardware Interface Elements - Not/difficult findable position of power switch</p> |
| Templier et al. (2007) | <p>"Failure to Find a Setting Site or a Display Site. These represented about half of the errors with each ventilator."</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         | <p>Task Navigation - Failure to find/navigate to setting or menu item</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |

"Confusion With Another Setting Site or Display Site. Confusion between assist-control ventilation (these ventilators display the acronym VAC for the French term ventilation assistée contrôlée) and synchronized intermittent mandatory ventilation (SIMV, but the ventilator displays the acronym VACI for the French term ventilation assistée contrôlée intermittente). [...] The most common error was choosing SIMV (French acronym VACI) mode rather than assist-control ventilation (French acronym VAC) on the Oxylog 3000, which resulted in ventilation with an inappropriately increased inspiratory-expiratory ratio (inspiratory time lengthened by default in VACI). The absence of the acronym ACV (for assist-control ventilation) next to the label for assist-control ventilation on the access button for this mode might explain this, especially since the French acronyms VAC and VACI are so similar."

"The indirect adjustment of a requested setting appears to be one source of difficulty. One example is the high error rate in adjusting the inspiratory flow on the Oxylog 3000. One must adjust the inspiratory-expiratory ratio and, often, also the end-inspiratory pause."

"In the conditions of our study, the Elise 250 was significantly easier to use than the Oxylog 3000. This is probably due to the difference in concept between the 2 interfaces (a touch-pad vs a combination of various types of controls). The small size of these ventilators may complicate the search for ideal ergonomics as well. The touchpad of the Elise 250 allows for placement of different categories of parameters on different distinct screens. The letters can be larger, which facilitates recognition. Adjusting a setting is simpler because the user does not have to manipulate multiple controls of different types. The Oxylog 3000 allows direct access to basic adjustments, similar to those on simple pneumatic ventilators (tidal volume, respiratory rate, maximum inspiratory pressure, and FIO<sub>2</sub>), which could be advantageous in emergencies. Yet the physician errors in making these basic settings (frequency, tidal volume) were more frequent than with the Elise 250. For advanced parameters, manipulating different types of controls is often necessary to visualize or confirm a given parameter. This undoubtedly represents a potential source of confusion and error for the new or occasional user. [...] The reasons for these errors are probably the same as those previously noted, including the advantage of directly adjusting the essential parameters, advantage of grouping the same functions on one screen, and the advantage of not having many different types of control buttons."

"Inappropriate setting of inspiratory trigger sensitivity was fairly common. On the Elise 250, the technology of the trigger does not depend on detection of the flow or pressure, but on the gradient of the pressure drop. Therefore, no units are marked, which might contribute to errors. Clear indication on the controls of the trigger sensitivity (eg, from "very sensitive" to "least sensitive") might reduce this type of error."

Gonzalez-Bermejo et al. (2006)

"The only two ventilators that proved to be more difficult to start were unlike the others. In one case, it was the position of the "on/off" button (Knightstar1: on the side of the machine instead of the front panel); in the other case, it was the type of operation required to activate the button (Neftis1: brief instead of prolonged pressure). Even though it can appear to be a trivial point, this suggests that the ventilator on/off button should be systematically placed on the front panel of the machine, and should be operated by pressure sufficiently long enough to meet the ISO standard safety requirements (i.e. "means shall be provided to prevent accidental operation of the on/off switch" [6, 7]), but without imposing a time limit."

"In this context, the results of test 2 provide a good indication of a real problem: the mean unlocking times greatly exceeded the reference times, and a certain number of failures were recorded (systematically for one of the machines). Two physicians achieved unlocking times that were not statistically different from the reference time, yet the difference (average 49 and 59 s, versus 12 s for the technician) might be clinically significant in a crisis situation. The ISO 10654-6:2004 standard [6] states that "mechanical control techniques such as locks, shielding, friction-loading and detents are considered suitable". The present authors consider these solutions to be preferable to the current ones, especially when the present solutions impose multiple button combinations that are particularly "anti-intuitive"."

Representation of Medical Functions - Inconsistent/ambiguous labelling of ventilation modes and parameters cross devices

Representation of Medical Functions - Divergent functional approach (e.g. to set parameters) cross devices

Task Navigation - Divergent navigation/interaction model cross/within devices

Task Navigation - Complexity and number of interaction steps

Software Interface Elements - Understandability and recognisability of content and instructions

Interface elements - Combination of different types of controls (e.g. start ventilation)

Interface Elements - Unclear/misleading labelling of buttons and functions

Hardware Interface Elements - Not/difficult findable position of e.g. power switch

Interface Elements - Unclear/misleading labelling of buttons and functions

Task Navigation - Complexity and number of interaction steps

Interface Elements - Combination of different types of controls (e.g. start ventilation)

|                         |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |                                                                                                                                                                                                                                 |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                         | "Though the setting recognition charts were completed quite rapidly by the physicians, 49% of the charts were incorrect. The two main sources of error were, on the one hand, the sequential display of the measured values and the set values on the same screen and, on the other hand, the heterogeneous terminology (table 2)."                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     | Software Interface Elements - Understandability and recognisability of content and instructions<br><br>Representation of Medical Functions - Inconsistent/ambiguous labelling of ventilation modes and parameters cross devices |
| Maruyama et al. (2014)  | "In our study, the SCMVP accelerated and facilitated identification of leaks, presumably due to the automatically diagnosed graphical information indicating the site of the leak displayed on the monitor [...] We found that the SCMVP decreased the troubleshooting time and improved the success rate of troubleshooting of simulated leaks in a respiratory circuit through an increase in prompt identification of leaks. More studies must be conducted using a refined SCMVP and a broader range of scenarios before generalized conclusions can be made."                                                                                                                                                                                                                                                                                                                                                                                                                                                      | Representation of medical Functions - Inadequate representation of alarm occurrence and content, misleading alarms                                                                                                              |
| Wachter et al. (2006)   | "The present study found that clinician volunteers using the intervention graphical pulmonary display diagnosed and treated selected pulmonary events more quickly and more accurately. Intervention subjects also reported a perceived decrease in workload. [...] We conclude that the graphical pulmonary display may be a useful adjunct to conventional monitors when used to manage selected adverse respiratory events in intubated, mechanically ventilated patients."                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          | Software Interface Elements - Visualisation of numeric data in contrast to a graphical representation                                                                                                                           |
| Liu and Osvalder (2004) | "The following conclusions can be drawn from the present study, based on the usability test results: 1. The graphical circular display is better than the numerical display in helping users to interpret the meanings of parameter deviations accurately. 2. The graphical circular display does not contribute to improving the users' detection time. 3. Concerning the errors in detecting the number of deviations and the error rates in getting the overall picture of the situation, the graphical circular display does not contribute any improvement. 4. The graphical circular display does not facilitate 'ease of detecting deviations' better than the normal numerical display, although the graphical circular display was subjectively preferred by more of the test subjects. 5. Further improvements and modifications are necessary for the graphical circular display design, and an integrated graphical display which combines both graphical and numerical representation has been suggested." | Software Interface Elements - Visualisation of numeric data in contrast to a graphical representation                                                                                                                           |
| Cassidy et al. (2011)   | "[...] and misleading alarms such as low airway pressure or high drive gas pressure."<br><br>"Staff unfamiliar with machines (particularly when spare machine differed from those usually used or in case of locum staff"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               | Representation of medical Functions - Inadequate representation of alarm occurrence and content, misleading alarms<br><br>User Characteristics- Low level of experience with the ventilator                                     |

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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.

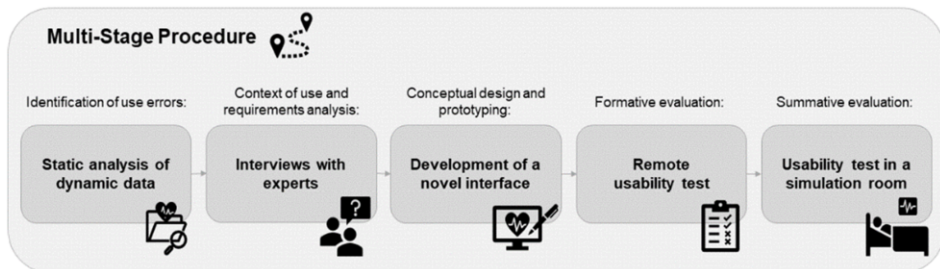


Figure 1. Model of the multi-stage procedure in line with the usability engineering process

### 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.sosicisurvey.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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## Usability of Automated External Defibrillators: A Randomized, Comparative Simulator Study

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# Usability of Automated External Defibrillators: A Randomized, Comparative Simulator Study

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## ABSTRACT

The aim of this study was to investigate whether one particular automated external defibrillator (AED) is superior to another in use by a layperson such that there is a clinically relevant difference from first contact with the device to the time of shock delivery (TimeToShock (TTS)). Causes for interaction problems and delays were analyzed. The study was conducted as a randomized, two-arm manikin study using the AED training devices “Lifepak CR-T AED Trainer” (Medtronic Physio-Control) and “AED Trainer 3” (Philips Medical Systems). In each study arm, the participants used one of the AEDs in a simulated resuscitation. The interaction was recorded by a mobile eye tracker. The TTS was compared with the Wilcoxon rank-sum test. The study was conducted with 28 participants inexperienced in AED use. A significant difference ( $p < 0.05$ ) in TTS was measured at 32.5 s median between the two devices (61 s (IQR: 58 s–76 s, range: 51 s–115 s) for the AED Trainer 3 and 93.5 s (IQR: 91 s–103 s, Range: 80 s–129 s) for the Lifepak CR-T AED Trainer). Causes of delays and interaction problems included differences in the use of voice instruction (length, pauses, and terminology), iconography on the device and electrodes, and device opening mechanisms. The measured clinically relevant difference can be attributed to the usability of the interaction elements, which differ significantly between the devices. Besides specific design elements, the extent of user guidance provided by the AEDs is crucial for efficient and error-free interaction.

## KEYWORDS

Resuscitation; automated external defibrillators; ergonomics; usability testing; patient safety; user error

## 1. Introduction

Out-of-hospital cardiac arrest (OHCA) is a life-threatening condition (Gräsner et al., 2021; Gräsner et al., 2020; Kiguchi et al., 2020). In Europe, OHCA occurs with an incidence of 67–170 per 100,000 inhabitants per year (Gräsner et al., 2021). The later the resuscitation is started, the less likely people are to survive or survive without neurological damage (Gold et al., 2010; Larsen et al., 1993). The survival rate after an OHCA at the time of hospital discharge in Europe is 8% on average, varying from 0–18% (Gräsner et al., 2021).

In the case of ventricular fibrillation (VF) or pulseless ventricular tachycardia (pVT), early defibrillation can improve the survival rate in an OHCA (Bækgaard et al., 2017; Brooks et al., 2022; Hawkes et al., 2017; Olasveengen et al., 2021; Weaver et al., 1986). For delayed defibrillation, there was a decrease in survival of 1.1% per minute for witnessed cardiac arrest due to VF, calculated using linear regression (Larsen et al., 1993). A linear model shows that shortening the time to defibrillation by an average of 3 min

30 s appeared to improve overall yearly survival by 10–13% (Weaver et al., 1986). If continuous CPR is started immediately, there is an absolute risk reduction of about 2% per 30 s (Valenzuela et al., 1997). This is equivalent to a number needed to treat of 50 for 30 s time reduction.

Up to 20 min can elapse from the time of the emergency call to the arrival of the emergency services (Schehadat et al., 2017). This interval must be bridged by laypersons (Dainty et al., 2022; Olasveengen et al., 2021). The European Guidelines for Resuscitation recommended the use of automated external defibrillators (AEDs) in lay resuscitation since 1998 (Handley et al., 1998; Olasveengen et al., 2021). For non-trained persons, resuscitation is challenging, especially when it involves the use of an AED. This results in high demands on the human-machine interaction to quickly deliver a shock: it can be assumed that the users, often laypersons without emergency medical training, are operating this type of device for the first time. Safe and efficient use requires an ad hoc understanding of the interface and

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unambiguous instructions (Fairbanks & Caplan, 2004; Food and Drug Administration, 2016; IEC 62366-1, 2015). Various AEDs with different use concepts are available on the market (Ho et al., 2016; Torney et al., 2018). Studies have demonstrated that effectiveness and efficiency differ between AEDs (Andre et al., 2004; Callejas et al., 2004; Dong et al., 2020; Eames et al., 2003; Fleischhackl et al., 2004; Lei et al., 2022; Polikaitis, 2005) and ergonomic features affect the speed of delivering a shock (Mosesso et al., 2009). An analysis of user interface features in terms of effectiveness, efficiency and possible use errors, especially with eye trackers, has not yet been carried out or published. We set 30 s as a clinically relevant value for the different duration of use of AEDs.

The objective of this study was to investigate whether one of the two AEDs is superior in terms of efficiency of use, such that there is a clinically relevant time difference from first contact with the device to the time of first shock delivery (TimeToShock (TTS)). The secondary objective was to identify the causes of problems in human-machine interaction and delays during the use of the devices.

## 2. Methods

### 2.1. Study design

A randomized, comparative manikin study was conducted. The participants used an AED in a simulated resuscitation. The two study arms differed in the type of AED used. The participants were randomly assigned and equally divided between the study arms. The study was positively evaluated by the ethics committee (ethics vote 2018-082, Medical Ethics Committee of the Carl von Ossietzky University of Oldenburg, Chairman Prof. Dr Frank Griesinger).

### 2.2. Setting and equipment used

AED trainers used for the study were AED Trainer 3 (Philips Medical Systems, model 861467) with a soft case and LIFEPAK CR-T AED Trainer (Medtronic Physio-Control, model 3201804-012). In this paper, AED Trainer 3 is referred to as AED1 and LIFEPAK CR-T AED Trainer as AED2. The device features are described in Table 1. The CPR training model “Resusci Anne” (Laerdal Medical AS) served as a manikin. The participants wore eye-tracker glasses (Tobii Pro Glasses 2).

The simulated resuscitation was performed in a quiet meeting room on the manikin lying on a solid base. The participant was asked to use the AED while a supervisor from the study team performed the CPR (Figure 1). The AED was positioned 3 m away in a location known to the participant.

### 2.3. Participants

Medical laypersons were recruited for the study. The inclusion criteria were age 18–65 years and written informed consent. The exclusion criteria were medical or nursing training or professional experience with emergencies (e.g. members

of fire brigades) as well as an individual training in defibrillators (but not participation in a demonstration of an AED, e.g., as part of a first aid course) so that the tests would not be influenced by people’s previous experience and skills to deal with emergency situations. Additionally, people with health limitations that restrict or prevent resuscitation of a person (manikin) were excluded (see Figure 3).

### 2.4. Procedures

After giving informed consent, the participant completed a questionnaire on demographic data. After the start signal to begin the simulation, the participant had the task of fetching the AED and attaching it to the manikin to deliver a shock while a supervisor of the study team performed the CPR continuously. The simulation follows the ERC BLS guide (Olasveengen et al., 2021): 1. Check response and breathing (no response or breathing; both actors); 2. Call for help (both actors); 3. Start CPR (supervisor) and get AED (participant); 4. Once AED arrives – switch on and follow instructions (participant, AED instructions see Table 1) while continuing CPR (supervisor). The use of the AED includes: 1. Switching on the AED; 2. Calling for help (AED2 only); 3. Applying the electrodes (clothing was removed from the patient’s chest by the supervisor before CPR is started); 4. Rhythm analysis (initiated by AED); 5. Delivering a shock. The simulation was terminated after the shock was delivered. Subsequently, the participant evaluated the usability of the AED and their comments on the usage were discussed.

The AED model was randomly assigned (drawn without return by the participant). The aim of the study was kept from the participant to avoid an exam-like situation. The participant was told that personal interaction during resuscitation was the main objective. After the study, the participant was debriefed and explained the study’s objectives.

### 2.5. Outcomes

Figure 2 shows an overview of the collected times. The primary outcome is the difference between study arms in time from first contact with the AED (T1) to delivery of the first shock (T5)–TimeToShock (TTS).

The secondary outcomes regarding the individual subtasks are the task completion and difference between time from first contact to the start of the AED (TimeToStart), time from the start of the AED to the start of the analysis (TimeStartToAnalysis) and time from the end of the analysis to the delivery of the first shock (TimeEndAnalysisToShock). Further secondary outcomes for comparing the usability of the devices are the subjective evaluation of usability by the participants and use errors during interaction with the AEDs and underlying causes.

### 2.6. Data acquisition and analysis

The simulation was recorded by video camera and eye-tracker glasses worn by the participant in order to examine

**Table 1.** Features of AED1 and AED2 (voice instructions translated into English, original German version see [supplemental material](#)).

| Features                                            | AED1                                                                                                                                                                                                  | AED2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|-----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                                     |                                                                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| Power-on mechanism                                  | On/off button on inside of a box with velcro                                                                                                                                                          | On/off button for opening the lid on inside of a box with velcro                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| Start of Analysis of the heart rhythm               | The test supervisor triggered the start of the analysis via the training AED remote control.                                                                                                          | The test supervisor triggered the start of the analysis via the training AED remote control.                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| Visual instructions                                 | Power LED; shock button LED; illustration of the manikin with the position of both electrodes on AED                                                                                                  | Shock button LED; handling instructions and illustration of the manikin with the position of both electrodes on electrode package; illustration of the manikin with the position of both electrodes and electrode pad indicator LEDs on AED                                                                                                                                                                                                                                                                                                                      |
| Pad design                                          | Two electrodes on a foil inside the box next to the AED, preconnected plug; frontal view on a manikin with the position of both electrodes, indication of the respective electrode position by arrows | Two electrodes on a foil in a tear-open package under the opening lid, pre-connected plug; frontal/lateral view on a manikin with the position of the respective electrode                                                                                                                                                                                                                                                                                                                                                                                       |
| Voice instructions                                  |                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Power up                                            | Beep sound + 3.5 s break                                                                                                                                                                              | Beep sound + "Attention, follow the instructions of the device"                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Call for help                                       | /                                                                                                                                                                                                     | "Call for emergency help" + 2 s break                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Pad placement                                       | "Apply pads to the exposed chest of the patient" (repetition after 12 s (varying instructions) until electrodes are connected)                                                                        | "Remove all clothing from patient's chest" + 10s break + "pull red handle to open bag and pull out pads" + 4s break + "look at the pictures on the pads" + 1s break + "peel one pad off blue plastic" + 1s break + "apply pad to bare skin exactly as shown in the picture" + 1s break + "press pad firmly to chest" + 1.5s break + "peel other pad off blue plastic" + 1s break + "apply pad to bare skin exactly as shown in the picture" + 1s break + "press pad firmly to chest" (repetition after 3s (varying instructions) until electrodes are connected) |
| Rhythm analysis                                     | "Do not touch the patient. Analysis running" + 6.5s break                                                                                                                                             | "Attention, do not touch the patient. Evaluating heart rhythm" + 3.5s break                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| Analysis result                                     | "Shock recommended. Do not touch patient" + 1.5s break                                                                                                                                                | "Stand by, preparing to shock" + 3.5s break + "Attention, now no one is allowed to touch the patient"                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| Shock delivery                                      | "Deliver shock now" + beep sound (repetition after 3s: "Press flashing orange button now")                                                                                                            | "Press flashing button" + beep sound                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Resuming CPR                                        | "Shock delivered" + 1.5s break "provide chest compressions and rescue breaths"                                                                                                                        | "Shock delivered" + 1s break + "provide 30 chest compressions and 2 rescue breaths alternately"                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| Overall operation time (power up to shock delivery) | 27 s                                                                                                                                                                                                  | 83 s                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |

the simulation in detail following the study with regard to primary and secondary endpoints. The eye tracker was calibrated with every participant before the start of the simulation. The demographic data and the subjective evaluation of usability were collected in questionnaires.

The digital transfer of questionnaires was performed by two researchers. In the case of deviations, the results were checked against the original data. The analysis of the quantitative data was carried out by two independent researchers and double programming with the statistical software



**Figure 1.** Picture of the setup of the simulated resuscitation scenario (two study managers as actors).

packages SPSS 26 and R 3.6.3. Additionally, the use errors were consolidated by discussion in order to reduce or control for individual confounding and avoid errors in data analysis.

#### **2.6.1. Analysis of task performance and time intervals**

The tasks were considered completed when the respective goal (start AED/position electrodes/deliver shock) had been achieved. The calculation of the time intervals was carried out by determining the time points T1–T5 to an accuracy of one second from the recordings. The determined periods were averaged and the variability between the results was calculated. Delays in AED operation caused by the test supervisor, e.g., due to the remote control of the AEDs to start the analysis, were taken into account and subtracted from the overall time. For AED1, some participants placed the electrodes before the AED was switched on contrary to the regular procedure. After that, the voice prompt for attaching the electrodes was given and lasted for 3.5 s. In the main analysis, difference of TTS was assessed using the Wilcoxon rank-sum test.

#### **2.6.2. Analysis of the usability questionnaire**

Usability was evaluated using 11 closed questions on a four-point Likert scale: eight questions from the standardized questionnaire System Usability Scale (SUS) (J. Brooke, 1996) and three individual questions. The procedure described by Brooke (J. B. Brooke, 2013; J. Brooke, 1996) for calculating a global usability score was adapted accordingly. The analysis was descriptive with the calculation of mean values, standard

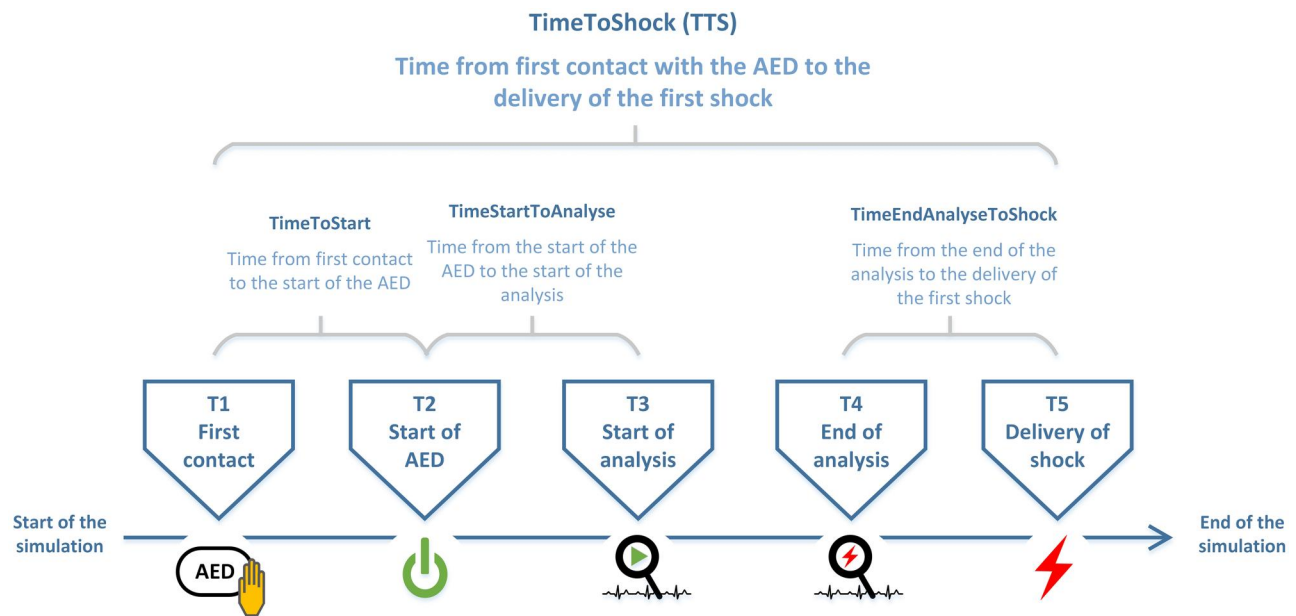
deviations and 95% confidence intervals (bootstrapping, sample size 1000) for both groups.

#### **2.6.3. Analysis of use errors and underlying causes**

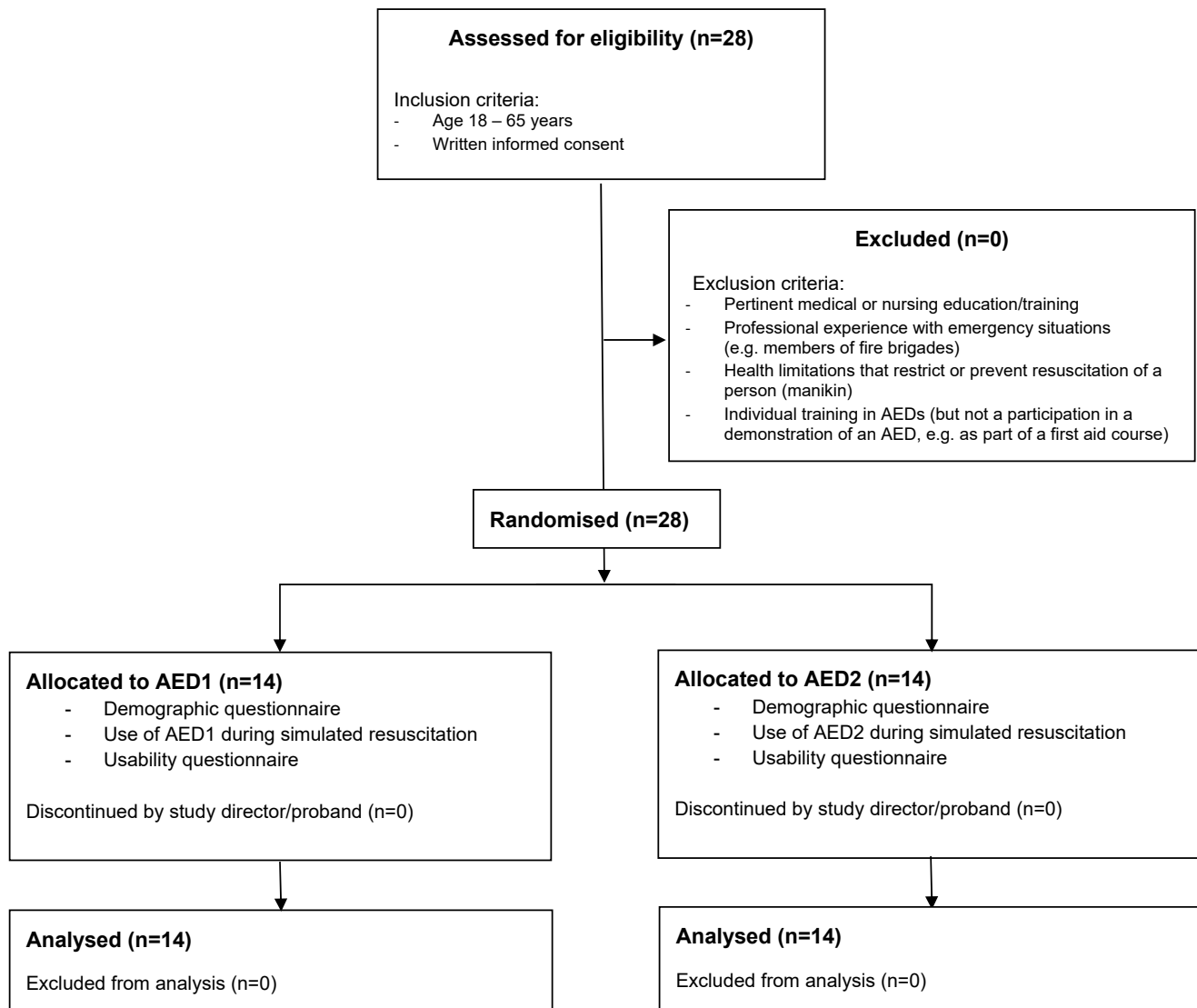
The participants' statements as well as the recordings of the simulation were examined for interaction problems with the AED and usability issues as possible cause for unsuccessful or delayed shock delivery. Analysis of the use errors is based on risk management concepts according to ISO 14971, 2019. Use errors during the use of a medical device lead to a different result than intended by the manufacturer or expected by the user (IEC 62366-1, 2015). The consequences of use errors are interaction errors (e.g. wrong button pressed), a loss of time, which is a clinically relevant parameter, or user uncertainty. The interpretation of the underlying causes is based on assumptions about the context of use and users' mental models, as well as interaction principles (ground rules) for designing usable products (Geis & Johner, 2020; IEC 62366-1, 2015; ISO 9241-110; Wiklund et al., 2016). We have determined the occurrence (frequency) for each use error per study arm (AED1 vs. AED2) and specified the 95% confidence interval.

#### **2.7. Sample size calculations**

To test the primary hypothesis, a group sequential design with two stages was planned. There was no information about the expected distribution of possible differences and standard deviations of the data. For the first stage, the assumption was made that the mean difference between the two groups was one standard deviation (significance level:  $\alpha = 0.05$ , power = 0.8). This resulted in a required sample



**Figure 2.** Relevant time points during the interaction with the AED and corresponding time intervals. The time points are defined as follows: T1: First contact: first haptic contact when fetching the AED; T2: Start of AED: pressing the power button; T3: Start of analysis: start of the acoustic audio output at the start of the analysis; T4: End of analysis: start of the acoustic audio output for the analysis result; T5: Delivery of shock: pressing the shock button after being instructed by the AED.



**Figure 3.** Flow diagram of the study procedure.

**Table 2.** Demographic data of the participants.

|                                   | Total |      | AED1 |      | AED2 |      |
|-----------------------------------|-------|------|------|------|------|------|
|                                   | N     | %    | n    | %    | n    | %    |
| Gender                            |       |      |      |      |      |      |
| Female                            | 20    | 71.4 | 11   | 78.6 | 9    | 64.3 |
| Male                              | 8     | 28.6 | 3    | 21.4 | 5    | 35.7 |
| Diverse                           | 0     | 0.0  | 0    | 0.0  | 0    | 0.0  |
| Total                             | 28    | 100  | 14   | 100  | 14   | 100  |
| Age                               |       |      |      |      |      |      |
| 18–25 years                       | 4     | 14.3 | 1    | 7.1  | 3    | 21.4 |
| 26–35 years                       | 17    | 60.7 | 9    | 64.3 | 8    | 57.1 |
| 36–45 years                       | 2     | 7.1  | 0    | 0.0  | 2    | 14.3 |
| 46–55 years                       | 1     | 3.6  | 1    | 7.1  | 0    | 0.0  |
| 56–65 years                       | 4     | 14.3 | 3    | 21.4 | 1    | 7.1  |
| Total                             | 28    | 100  | 14   | 100  | 14   | 100  |
| Highest level of school education |       |      |      |      |      |      |
| Hauptschulabschluss               | 0     | 0.0  | 0    | 0.0  | 0    | 0.0  |
| Realschulabschluss                | 4     | 14.3 | 4    | 28.6 | 0    | 0.0  |
| Abitur                            | 8     | 28.6 | 4    | 28.6 | 4    | 28.6 |
| Hochschulabschluss                | 16    | 57.1 | 6    | 42.9 | 10   | 71.4 |
| Total                             | 28    | 100  | 14   | 100  | 14   | 100  |

of 28 participants (equal distribution) for a Wilcoxon rank-sum test. For the early successful termination of the study after the interim analysis (futility level:  $\alpha_0 = 0.5$ ), the significance level of  $\alpha_1 = 0.0044$  was calculated according to the method of inverse combination of the normal distribution. In the case that  $\alpha_1 < p < \alpha_0$  applied to the p-value of the interim analysis, the case number planning for the entire study would be carried out using the available data. In the final analysis, the original significance level  $\alpha = 0.05$  could then be used. Due to the compact nature of the study, no dropouts were expected.

### 3. Results

#### 3.1. Characteristics of study subjects

The study was conducted in three sessions between April 2019 and July 2019. A total of 28 participants were included (Figure 3). The demographic characteristics of the participants and their distribution between the study arms are shown in Table 2. All participants were able to communicate fluently in German. None of the participants had practical experience in the use of AEDs.

#### 3.2. Main results

##### 3.2.1. Task performance and execution times

**3.2.1.1. Primary outcome.** All participants successfully delivered a shock using an AED. For the primary outcome (TTS), a median of 61 s (IQR: 58.5 s–75.8 s, range: 51.5 s–114.5 s) was measured for AED1 and 93.5 s (IQR: 91.3 s–102.1 s, range: 80 s–128.5 s) for AED2 (Figure 4). The median difference in operating time was 32.5 s. The p-value of the interim analysis was  $p_1 = 0.0005$  and thus below the significance level defined for the interim analysis. The study was terminated accordingly after the interim analysis.

**3.2.1.2. Secondary outcomes.** The subtask of starting the AED was successfully performed by all participants. Only

one participant pressed the shock button on AED1 directly without first switching on the device (AED1:  $n = 1$ , 7%, 95% CI: 0%–22%). AED1 is designed in such a way that this action switches on the device.

The positioning of the electrodes was incorrect in three cases: (1) One participant (AED1:  $n = 1$ , 7%, 95% CI: 0%–22%) swapped the electrodes. (2) One participant (AED2:  $n = 1$ , 7%, 95% CI: 0%–22%) positioned the electrodes on the other side of the body (left instead of right and vice versa). (3) One participant (AED2:  $n = 1$ , 7%, 95% CI: 0%–22%) positioned both electrodes on the same side of the body. He realized the mistake after delivering the shock.

For the subtasks, the median differences in execution times were: TimeToStart: –10.5 s (AED1: 18.8 s, AED2: 8.3 s), TimeStartToAnalyse: 39.3 s (AED1: 26 s, AED2: 65.3 s) and TimeEndAnalyseToShock: 4.2 s (AED1: 7.8 s, AED2: 12 s). Figure 4 shows a graphical representation of the data. The discrepancy between observer 1 and observer 2 for the calculation of TTS is a median of –1.0 s (IQR: –1.0 s – –1.0 s, range: –2.0 s – 1.0 s) for AED1 and a median of 0.0 s (IQR: 0.0 s – 1.0 s, range: –1.0 s – 1.0 s) for AED2. Detailed data for the execution times and discrepancies are given in the supplemental material.

##### 3.2.2. Usability questionnaire

For the SUS, the mean score for AED1 was 86.6 (SD: 5.2; 95% CI: 83.9 – 89.3) and for AED2 79.3 (SD: 10.5; 95% CI: 73.9 – 84.8). Only one question was not answered by a participant (Missing data: AED1  $n = 0$ , AED2  $n = 1$ ). Figure 5 shows the detailed results of the usability questionnaire. The original German questionnaire is attached in the supplemental material.

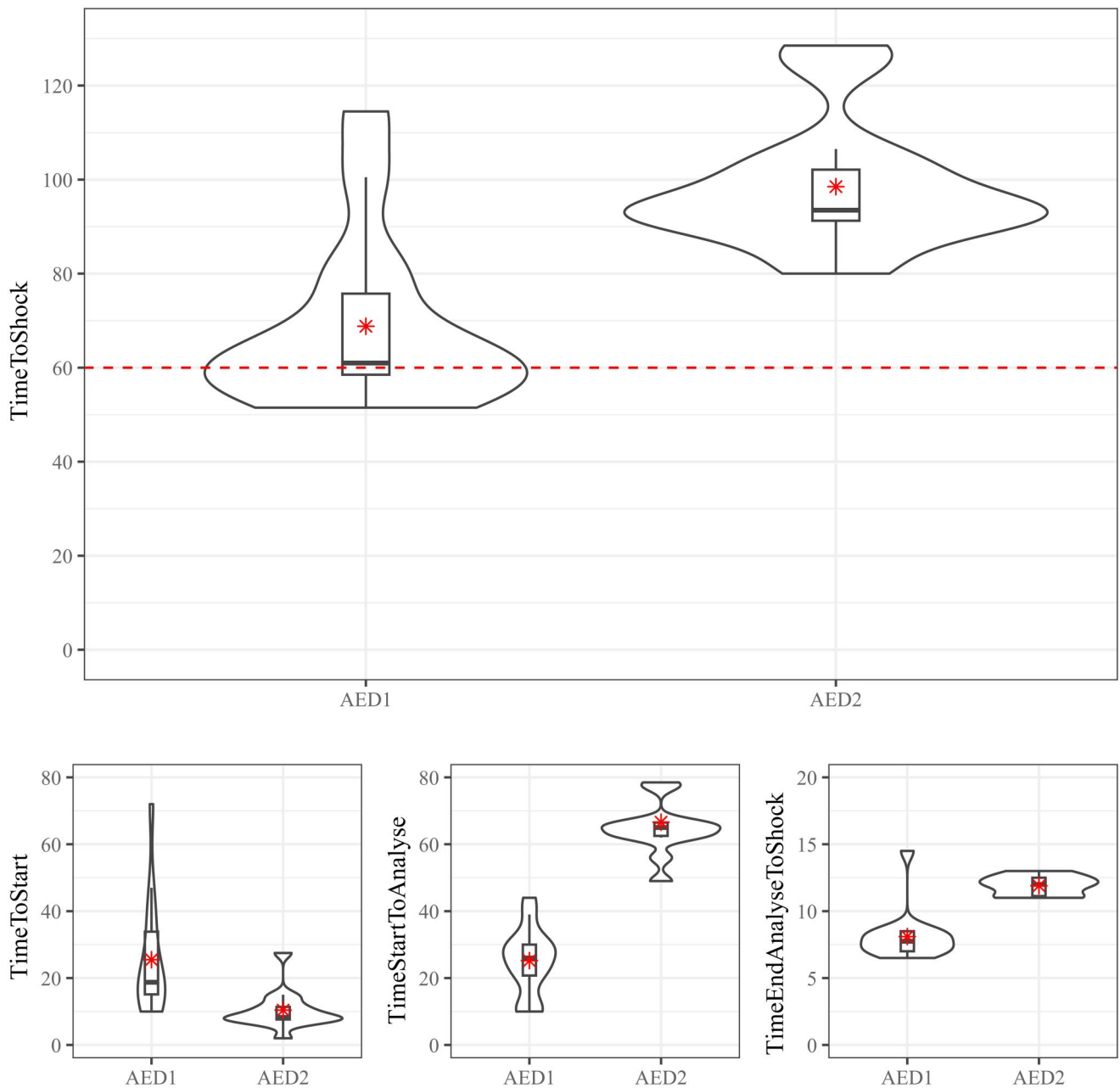
##### 3.2.3. Analysis of use errors and potential underlying causes

Table 3 shows a list of use errors for AED1 and AED2 as a possible cause for unsuccessful or delayed shock delivery. In total, there were 20 use errors for AED1 and 19 errors for AED2. On average, each participant made 1.39 errors (AED1:  $n = 1.43$ , AED2:  $n = 1.36$ ). Selected screenshots of the eye-tracker recording of the use errors that occurred are given in the supplemental material.

### 4. Discussion

This randomized confirmatory study showed a significant, clinically relevant difference in time to shock delivery between two AEDs (AED1: 61 s, AED2: 93.5 s,  $p < 0.05$ ). In the study of Eames et al. (2003), three AEDs were tested with a mean TTS of 74.8 s (range 60–90 s), 83.0 s (range 54–111 s) and 153.4 s (range 92–240 s). In the study of Fleischhackl et al. (2004), six AEDs were tested with a mean TTS from 78 s (95% CI: 68–89 s) to 128 s (95% CI: 110–146 s) and eight AEDs were tested with a mean TTS from 48 s (SD:  $\pm 2$  s) to 101 s (SD:  $\pm 1$  s) by Müller et al. (2015).

In addition to the time to first shock delivery, the correct placement of the electrodes is important. There was one



**Figure 4.** Box-whisker plots with the execution times for AED1 and AED2. The median, quartiles and the largest and smallest values within the 1.5 times the inter-quartile range above and below the quartiles are plotted. The dots represent measured values outside this range. The violin plot function shows the smoothed distribution within the range (minimum–maximum values). The red stars mark the mean value.

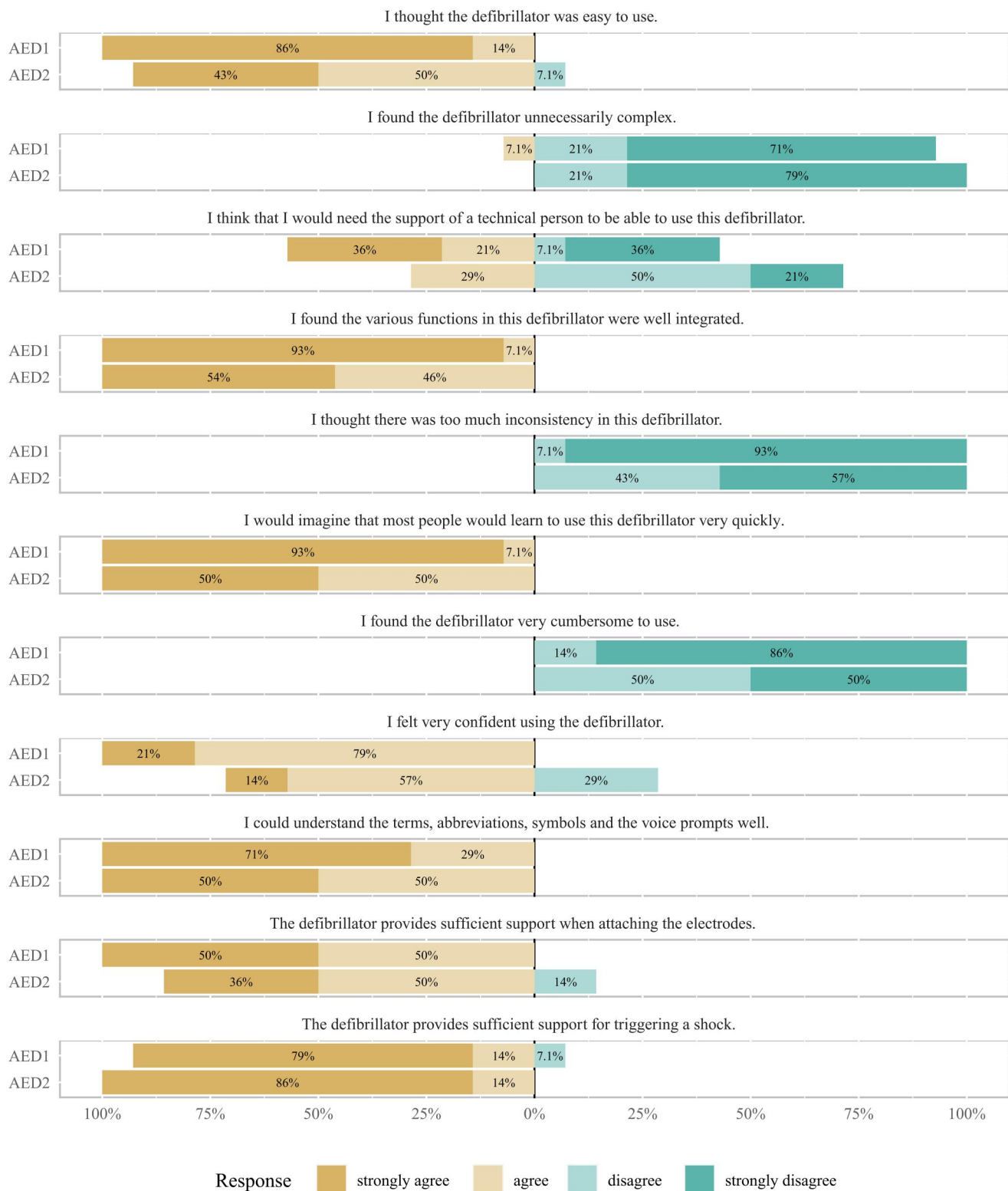
misplacement with AED1 and two with AED2. Of these, two were critical for AED2 and none for AED1. We identified several categories of use errors and usability issues as possible causes of unsuccessful or delayed shock delivery. This demonstrates that usability has a relevant impact on the use and therefore safety- and time-critical performance of an AED.

The AEDs have a minimum operating time set by the manufacturer because of the voice instructions and pauses (see Table 1). AED1 had less instructions and therefore an operation time of 27 s from pressing the power button to delivering a shock. In our study, the shortest time needed was 51.5 s. Seven participants needed less than 60 s. AED2 had an intended duration of 83 s with detailed voice instructions. The only way to reduce the TTS was to apply the

electrodes independently of the voice instructions. Two participants “skipped” the voice instructions and required minimum 80 s. Most participants followed the voice instructions completely.

An additional delay occurred for a large number of participants due to the occurrence of use errors. The identified use errors could be divided into five topics (unpacking, attaching electrodes, delivering shocks, a different sequence of actions and asynchronous sequence of actions; see Table 3).

When unpacking the AED1, participants had problems identifying the opening mechanism of the packaging (a large velcro fastener). They also unnecessarily tried to remove the AEDs from their packaging. Longer operating times due to packaging have been observed by Mosesso et al. (2009) and offer an opportunity for improvement.



**Figure 5.** Results of the usability questionnaire for AED1 and AED2 (%-values rounded).

The errors in attaching the electrodes suggest problems regarding the design of the pictograms on the electrodes, which are crucial for correct positioning (Andre et al., 2004; Bødtker & Rosendahl, 2018; Foster & Deakin, 2019; Nurmi & Castrén, 2005; Polikaitis, 2005). While Nurmi and Castrén (2005) have observed that a lateral view results in a better placement of the apical electrode, in this study, electrode misplacement was observed for AED2 in two cases due to

the perspective view. According to Foster and Deakin (2019), an optimal representation of images on adhesive electrodes is a rotated anterolateral view.

During shock delivery, the wording of the verbal instructions of AED1 was such that they did not provide an unambiguous instruction to act (“Deliver shock now” for AED1 vs “Press flashing button” for AED2). The instruction should be sufficiently informative or formulated as a precise request for

**Table 3.** Use errors that occurred in the simulated scenario, their frequency, consequences, and possible causes.

| Category                         | Use error                                                                                                                                                                                                                                                                                                                                           | Frequency                  |                              | Consequences of use errors                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                | Causes for use errors + violated interaction principles (ISO 9241-110)                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                                  |                                                                                                                                                                                                                                                                                                                                                     | AED1                       | AED2                         | AED1                                                                                                                                                                                                                                                                                  | AED2                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Unpacking                        | Search for a mechanism to open the AED package (AED1 only) and/or (attempt to) remove the device from its package                                                                                                                                                                                                                                   | 9 (64%)<br>95%-CI: 35%–86% | 6 (43%)<br>95%-CI: 14%–72%   | Time loss of up to 20 s                                                                                                                                                                                                                                                               | Time loss of up to 5 s                                                                                                                                                                                                                                                                                                                         | Unclear recognition of the mechanism for opening the device (black border of the cover was mistaken for a zip) (self-descriptiveness)<br>The envelope is perceived as packaging to be removed (conformity with user expectations)<br>The arrow pictograms representing the electrode position are not perceived correctly (AED1) (self-descriptiveness)<br>Pictograms on electrodes shows a perspective view of the patient, view of the AED user on the right side of the patient is assumed (AED2) (Suitability for the user's tasks) |
| Attaching electrodes             | Electrodes incorrectly positioned:<br>- swapping the electrodes (AED1 only)<br>- Correction of positioning (AED1 only)<br>- Deviation from specified positioning (side reversed) (AED2 only)<br>- Deviation from specified positioning (both on one side of the body) (AED2 only)                                                                   | 2 (14%)<br>95%-CI: 0%–36%  | 2 (14%)<br>95%-CI: 0%–36%    | Time loss due to correction of up to 8 s<br>Ineffective shock delivery due to incorrect pad position                                                                                                                                                                                  | Ineffective shock delivery due to incorrect pad position                                                                                                                                                                                                                                                                                       | No request for action was recognised in the voice instruction "Deliver shock now" (Suitability for the user's tasks)<br>Lack of user control and information on system status, need for action and sequence of action not clear:<br>- Initial activation via button necessary to start user support<br>- Shock is only delivered after analysis and explicit request by the unit (Self-descriptiveness)<br>Display of nontask-relevant information (AED1) (Suitability for the user's tasks)                                            |
| Delivering shock                 | Shock delivery delayed after request                                                                                                                                                                                                                                                                                                                | 1 (7%)<br>95% CI: 0%–22%   | 0 (0%)                       | Time loss of up to 6 seconds, shock button pressed only after the second, differently worded prompt                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| A different sequence of actions  | Performing actions deviating from the intended sequence of actions:<br>- Attaching the electrodes before switching on (AED1 only)<br>- Pressing the shock button instead of the start button (AED1 only)<br>- (thinking about) pressing the shock button before being prompted by the device<br>- Searching for information about the functionality | 3 (21%)<br>95% CI: 0%–43%  | 2 (14%)<br>95%-CI: 0%–36%    | Reading safety instructions on the back of the packaging of the electrodes, loss of time of up to 21 s before switching on<br>Fault tolerance of system: switch-on also possible via shock button, no shock delivery if not intended according to analysis<br>Uncertainty of the user | Uncertainty of the user                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| Asynchronous sequence of actions | Actions asynchronous to voice instructions:<br>- Performing activities before being prompted by the device e.g. unpacking and attaching electrodes<br>- Performing activities slower than the sequence provided by voice prompts in the device                                                                                                      | 5 (36%)<br>95%-CI: 14%–65% | 11 (79%)<br>95%-CI: 57%–100% | Uncertainty of the user due to unnecessary or inappropriate instructions for action<br>Time-saving through abbreviation                                                                                                                                                               | Time loss of up to 30 seconds due to a faulty attempt to open the electrode packaging<br>Uncertainty of the user due to unnecessary/inappropriate instructions for action<br>Time-saving through abbreviation<br>Loss of time due to missing/waiting for appropriate action instruction, in some cases compensation through independent action | Opening mechanism and voice prompt "Pull the red handle" after an action has already been performed is misunderstood (AED2) (Use error robustness)<br>Timed actions, insufficient support of the user (Controllability)                                                                                                                                                                                                                                                                                                                 |

Literaturverzeichnis.

ISO 9241-110: ISO 9241-110:2020-05, Ergonomics of human-system interaction - Part 110: Interaction principles.

action (Andre et al., 2004; Eames et al., 2003; Mosesso et al., 2009).

Some participants performed actions deviating from the intended process. With AED1, three participants attached the electrodes first and started the AED afterwards. On the AED2, the first required step was to open the lid; the AED does not allow for alternative actions. The alternative sequence is not considered incorrect, but it is not the intended use of the AED. This can and led to errors in perception, cognition and action. It is likely that the subjects are unaware that the voice instruction after starting the AED, explicitly refers to individual steps to assist the user in performing them. The same applies to the awareness of the need to analyze the heart rhythm and the timing of the shock delivery. Similar to our observations, Mosesso et al. (2009) found that the time to power on was shorter for devices with open lids and pull handle mechanisms than for those with a push button.

The AED2 in particular experienced interaction errors and asynchronous action sequences due to the length of and pauses between the voice prompts. The time slot for delegating the emergency call was too short and, as the patient was already undressed, there was a waiting time that made the participants feel insecure or led them to initiate the next steps before the appropriate announcement. In total, 11 people (79%) deviated from the procedure intended by the voice instructions due to the small-step instructions for positioning the electrodes. Nevertheless, it has been shown that voice instructions can improve electrode positioning (Andre et al., 2004; Mosesso et al., 2009). In our study, the voice instructions were a potential source of error: participants did not follow the prescribed sequence. If there are too many voice interactions, some of may be missed, especially in a noisy environment or under stress. In addition, a study of AEDs in hospitals has shown that TTS took in median only about half of the time of 30 s (IQR: 28–32 s) (Wurmb et al., 2015). This may be due to the trained users (nurses). However, there were differences, suggesting that interrupting the voice instructions results in a huge gain in shock delivery efficiency. It is debatable whether voice instructions help inexperienced users adhere to correct use and slow down experienced users in the process. However, voice instructions may not be audible in noisy environments. Even for non-native speakers, voice instructions can be a barrier and therefore a hazard.

In the evaluation of the SUS, the usability was rated as acceptable (J. B. Brooke, 2013), with AED1 being rated better than AED2. In the study by Polikaitis (2005), the five AEDs evaluated also scored well in the satisfaction assessment using individual questions (mean: 4.33 of 5, SD: 0.33). A significantly lower level of satisfaction was found for the AED whose median time to shock was also significantly longer (Polikaitis, 2005).

#### 4.1. Strengths and weaknesses of the study

The strength of the comparative study is the randomized confirmatory study design in a simulator study. The study design followed the guidelines for clinical trials. As a result, a

clinically relevant effect was significantly demonstrated. This shows the importance of usability concepts for patient safety. By testing the AEDs in a simulated scenario their usability could be compared and evaluated in a controlled environment. In particular, the use of eye-tracker recordings to analyse use errors provided detailed insights into the causes of the differences found. This not only allowed device-specific interaction problems to be identified but also revealed which design aspects were better or worse in comparison.

The selected scenario (shockable rhythm and end of simulation after first shock delivery) enables evaluation of the essential functionalities of the AEDs. Other scenarios, e.g., a non-shockable rhythm, were not tested.

A detailed evaluation of the correct electrode position (Andre et al., 2004; Eames et al., 2003; Polikaitis, 2005) was not performed. Firstly, the manikin was already undressed by the second actor at the beginning. Secondly, the positioning of the pads was distorted by the ECG connections on the manikin's torso.

For this study, the two AEDs with the largest market share (in Germany) were examined exemplarily. The training devices are not identical to devices intended for real-life use, e.g., with regard to labelling and electrode packaging. The problems identified are therefore only partially transferable to other devices.

ILCOR recommends a short period of CPR until the defibrillator is ready for analysis or defibrillation in unmonitored cardiac arrest (weak recommendation, low-certainty evidence) (Nolan et al., 2020; Wyckoff et al., 2022). This was accounted for in this study by a two-helper resuscitation operation. Despite standardized procedures, the influence of human–human communication on the results cannot be completely excluded.

In a real emergency, stress, characteristics of the first responder such as language skills or hearing impairment, as well as contextual factors such as ambient noise, communication with other actors, the patient's clothing or bad weather also influence efficiency and use errors. We have omitted these external factors from the simulation to analyze solely the use of the AED. Since the participants primarily come from the age group 26–35 with a higher level of education, the population may not be representative of all potential AED users.

#### 4.2. Conclusion

Testing the two AEDs in a simulated scenario shows a clinically relevant difference in TTS. The duration of use was different due to the interaction design of the AEDs. This includes differences in the use of voice instruction (length, pauses, and terminology), iconography on the device and electrodes, and device opening mechanisms. This resulted in lost time, use errors, and participant uncertainty during the interaction.

No general conclusions can yet be drawn from this study regarding an interface design that works best for AEDs, but it provides a basis for further research. An investigation of further devices currently available on the market in this study design to identify differences in the performance of the devices and further user interface issues is a logical

consequence of these study results. The next step is to (re-)start research to improve the interfaces and develop a catalog of criteria and best practices for AED interfaces. Manufacturers can draw on and factor the revealed problems into their risk management. The use concept for an AED should ensure certain freedom of control and abbreviation of processes for faster operation. If voice instructions are used, short instructions are preferable to long ones. Training should not be the sole solution for effective, efficient, and safe use. Instead, it should serve the purpose of communicating the relevance of AEDs and removing any fears about using them. For future development, there should be benchmark tests for the minimum time of use, which should serve as a limit value for development. The time of use must no longer be a game of luck depending on the AED that is used.

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## Disclosure statement

No potential conflict of interest was reported by the author(s).

## Author contributions

ML, AK, and RR conceived the original idea. BC, AK, ML, and RR have developed the study design and performed the data acquisition, analysis and interpretation. FO supported the study design, sample size estimation and data analysis as a biometrician. BC wrote the draft of the manuscript. AK, FO, RR, and ML contributed substantially to its revision.

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## Data availability statement

The data that support the findings of this study and the R-script are available via zenodo. The video recordings will not be provided due to privacy protection.

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# Usability of Automated External Defibrillators (AEDs): A Randomized, Comparative Simulator Study

## Supplementary data

### 1. AED Features with German voice instructions

Table 1: Features of AED1 and AED2 (original German version of voice instructions)

| Features                                     | AED1                                                                                                                                                                                                   | AED2                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|----------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Power-on mechanism</b>                    | On/off button on inside of a box with velcro                                                                                                                                                           | On/off button for opening the lid on inside of a box with velcro                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Start of Analysis of the heart rhythm</b> | The test supervisor triggered the start of the analysis via the training AED remote control.                                                                                                           | The test supervisor triggered the start of the analysis via the training AED remote control.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| <b>Visual instructions</b>                   | Power LED; shock button LED; illustration of the manikin with the position of both electrodes on AED                                                                                                   | Shock button LED; handling instructions and illustration of the manikin with the position of both electrodes on electrode package; illustration of the manikin with the position of both electrodes and electrode pad indicator LEDs on AED                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>Pad design</b>                            | Two electrodes on a foil inside the box next to the AED, pre-connected plug; frontal view on a manikin with the position of both electrodes, indication of the respective electrode position by arrows | Two electrodes on a foil in a tear-open package under the opening lid, pre-connected plug; frontal/lateral view on a manikin with the position of the respective electrode                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>Voice instructions</b>                    |                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>power up</b>                              | Beep sound + 3.5s break                                                                                                                                                                                | Beep sound + „Achtung, folgen Sie den Anweisungen des Gerätes“                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| <b>Call for help</b>                         | /                                                                                                                                                                                                      | „Notruf veranlassen“ + 2s break                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>Pad placement</b>                         | „Pads auf den entblößten Brustkorb des Patienten kleben“ (repetition after 12s (varying wording) until electrodes are connected)                                                                       | „Gesamte Kleidung vom Brustkorb des Patienten entfernen“ + 10s break + „Roten Handgriff ziehen um Verpackung zu öffnen und Klebeelektroden entnehmen“ + 4s break + „Beachten Sie die Abbildungen auf den Klebeelektroden“ + 1s break + „Eine Elektrode von blauer Folie abziehen“ + 1s break + „Klebeelektrode wie abgebildet fest auf den nackten Brustkorb kleben“ + 1s break + „Elektrode fest am Brustkorb andrücken“ + 1.5s break + „Andere Elektrode von blauer Folie abziehen“ + 1s break + „Klebeelektrode wie abgebildet fest auf den nackten Brustkorb kleben“ + 1s break + „Elektrode fest am Brustkorb andrücken“ (repetition after 3s (varying wording) until electrodes are connected) |
| <b>Rhythm analysis</b>                       | „Patient nicht berühren. Analyse läuft“ + 6.5s break                                                                                                                                                   | „Achtung! Patient nicht berühren. Herzrhythmus wird ausgewertet“ + 3.5s break                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Analysis result</b>                       | „Schock empfohlen. Patient nicht berühren“ + 1.5s break                                                                                                                                                | „Bereit. Schock wird vorbereitet“ + 3.5s break + „Achtung, jetzt darf niemand den Patienten Berühren“                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>Shock delivery</b>                        | „Schock jetzt abgeben“ + beep sound (repetition after 3s: „Blinkend, orangefarbene Taste jetzt drücken“)                                                                                               | „Blinkende Taste drücken“ + beep sound                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Resuming CPR</b>                          | „Schock abgegeben“ + 1.5s break<br>„Herzdruckmassage und Beatmung beginnen“                                                                                                                            | „Schock wurde abgegeben“ + 1s break + „30 Herzmassagen und 2 Beatmungen abwechselnd durchführen“                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
| <b>Overall operation time</b>                | 27 s                                                                                                                                                                                                   | 83 s                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |

## 2. *Determined execution times for AED1 and AED2*

Table 2: Execution times in sec for AED1 and AED2

| Parameter             | n         | mean        | Sd          | median      | Q1          | Q3            | min         | max          |
|-----------------------|-----------|-------------|-------------|-------------|-------------|---------------|-------------|--------------|
| <b>AED1</b>           |           |             |             |             |             |               |             |              |
| <b>TimeToShock</b>    | <b>14</b> | <b>68.8</b> | <b>18.7</b> | <b>61.0</b> | <b>58.5</b> | <b>75.8</b>   | <b>51.5</b> | <b>114.5</b> |
| TimeToStart           | 14        | 25.5        | 17.4        | 18.8        | 15.1        | 33.9          | 10.0        | 72.0         |
| TimeStartToAnalyse    | 14        | 25.2        | 10.1        | 26.0        | 20.8        | 30.0          | 10.0        | 44.0         |
| TimeEndAnalyseToShock | 14        | 8.1         | 2.0         | 7.8         | 7.0         | 8.5           | 6.5         | 14.5         |
| <b>AED2</b>           |           |             |             |             |             |               |             |              |
| <b>TimeToShock</b>    | <b>14</b> | <b>98.5</b> | <b>13.7</b> | <b>93.5</b> | <b>91.3</b> | <b>102.13</b> | <b>80.0</b> | <b>128.5</b> |
| TimeToStart           | 14        | 10.4        | 5.9         | 8.3         | 7.6         | 11.4          | 2.0         | 27.5         |
| TimeStartToAnalyse    | 14        | 66.6        | 10.3        | 65.3        | 62.5        | 66.9          | 49.0        | 92.0         |
| TimeEndAnalyseToShock | 14        | 11.9        | 0.7         | 12.0        | 11.1        | 12.5          | 11.0        | 13.0         |

### 3. Discrepancy between observer 1 and observer 2 for the determined execution times

Table 3: Discrepancy between observer 1 and observer 2 for the determined execution times for AED1 and AED2 (deviation of the determined values from the calculated mean in seconds)

| Parameter             | n  | mean | Sd  | median | Q1   | Q3   | min  | max |
|-----------------------|----|------|-----|--------|------|------|------|-----|
| <b>AED1</b>           |    |      |     |        |      |      |      |     |
| TimeToShock           | 14 | -0.9 | 0.8 | -1.0   | -1.0 | -1.0 | -2.0 | 1.0 |
| TimeToStart           | 14 | -0.4 | 0.7 | 0.0    | -1.0 | 0.0  | -2.0 | 1.0 |
| TimeStartToAnalyse    | 14 | 0.1  | 0.8 | 0.0    | 0.0  | 0.0  | -1.0 | 2.0 |
| TimeEndAnalyseToShock | 14 | -0.6 | 0.5 | -1.0   | -1.0 | 0.0  | -1.0 | 0.0 |
| <b>AED2</b>           |    |      |     |        |      |      |      |     |
| TimeToShock           | 14 | 0.2  | 0.8 | 0.0    | 0.0  | 1.0  | -1.0 | 1.0 |
| TimeToStart           | 14 | 0.0  | 0.6 | 0.0    | 0.0  | 0.0  | -1.0 | 1.0 |
| TimeStartToAnalyse    | 14 | 0.1  | 0.7 | 0.0    | 0.0  | 0.8  | -1.0 | 1.0 |
| TimeEndAnalyseToShock | 14 | -0.1 | 0.5 | 0.0    | 0.0  | 0.0  | -1.0 | 1.0 |

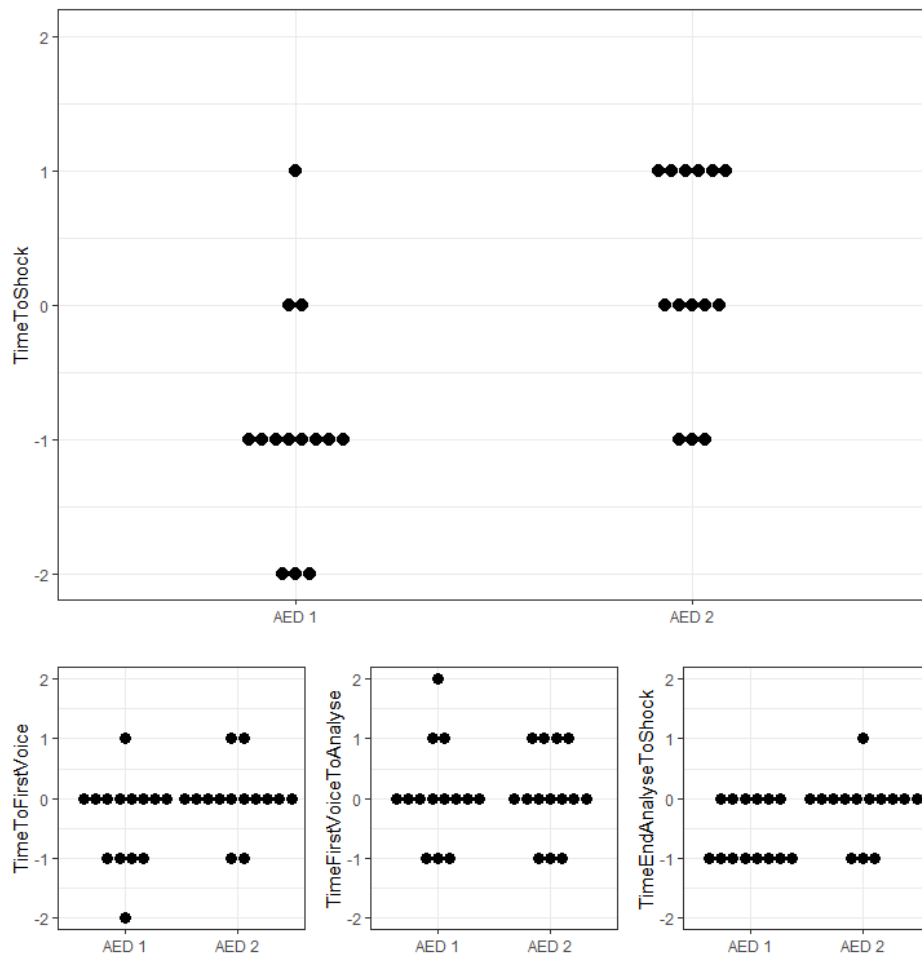


Figure 1: Discrepancy between observer 1 and observer 2 for the determined execution times for AED1 and AED2 (deviation of the determined values from the calculated mean in seconds)

#### 4. *German usability questionnaire*

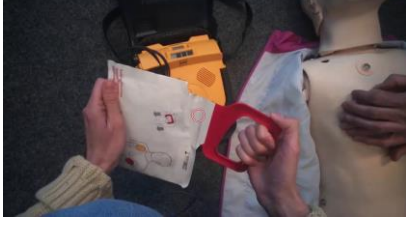
11 Questions, 4-Point Likert (trifft zu, trifft eher zu, trifft eher nicht zu, trifft nicht zu)

- Ich empfinde den Defibrillator als einfach zu benutzen.
- Ich empfinde den Defibrillator unnötig komplex.
- Ich dachte, dass ich Unterstützung brauche, um den Defibrillator zu benutzen.
- Ich finde, dass die verschiedenen Funktionen des Defibrillators gut integriert sind.
- Ich finde, dass es beim Defibrillator zu viele Inkonsistenzen gibt.
- Ich kann mir vorstellen, dass die meisten Leute sehr schnell lernen würden, mit diesem
- Ich empfinde die Bedienung des Defibrillators als sehr umständlich
- Ich habe mich bei der Benutzung des Defibrillators sehr sicher gefühlt.
- Ich konnte die Begriffe, Bezeichnungen, Abkürzungen, Symbole und die Sprachansagen.
- Der Defibrillator unterstützt hinreichend beim Anbringen der Elektroden.
- Der Defibrillator unterstützt hinreichend beim Auslösen eines Schocks.

### 5. *Selected screenshots of the eye-tracker recording of the use errors that occurred*

Table 4: Screenshots of the use errors that occurred in the simulated scenario

| Category             | Use error                                                                                                                                                                                                                                                                         | AED1                                                                                                                                                                   | AED2                                                                                                                                                                        |
|----------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Unpacking            | Search for a mechanism to open the AED package (AED1 only) and/or (attempt to) remove the device from its package                                                                                                                                                                 | <br> |                                                                                           |
| Attaching electrodes | Electrodes incorrectly positioned:<br>- swapping the electrodes (AED1 only)<br>- Correction of positioning (AED1 only)<br>- Deviation from specified positioning (side reversed) (AED2 only)<br>- Deviation from specified positioning (both on one side of the body) (AED2 only) |                                                                                      | <br> |
| Delivering shock     | Shock delivery delayed after request                                                                                                                                                                                                                                              |                                                                                                                                                                        |                                                                                                                                                                             |

|                                                |                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                   |                                                                                     |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------|-------------------------------------------------------------------------------------|
| <p><b>A different sequence of actions</b></p>  | <p>Performing actions deviating from the intended sequence of actions:</p> <ul style="list-style-type: none"> <li>- Attaching the electrodes before switching on (AED1 only)</li> <li>- Pressing the shock button instead of the start button (AED1 only)</li> <li>- Searching for information about the functionality</li> <li>- Thinking about pressing the shock button before being prompted by the device</li> </ul> |  |                                                                                     |
| <p><b>Asynchronous sequence of actions</b></p> | <p>Actions asynchronous to voice instructions:</p> <ul style="list-style-type: none"> <li>- Performing activities before being prompted by the device e.g. unpacking and attaching electrodes</li> <li>- Performing activities slower than the sequence provided by voice prompts in the device</li> </ul>                                                                                                                |                                                                                   |  |

# Reporting checklist - Usability of Automated External Defibrillators (AEDs): A Randomized, Comparative Simulator Study

Based on the CONSORT guidelines.

|                           |                                                  |                      | Reporting Item                                                                                                                                                                              | Page |
|---------------------------|--------------------------------------------------|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------|
| <b>Title and Abstract</b> |                                                  |                      |                                                                                                                                                                                             |      |
| ✓                         | Title                                            | <a href="#">#1a</a>  | Identification as a randomized trial in the title.                                                                                                                                          | 1    |
| ✓                         | Abstract                                         | <a href="#">#1b</a>  | Structured summary of trial design, methods, results, and conclusions                                                                                                                       | 1    |
| <b>Introduction</b>       |                                                  |                      |                                                                                                                                                                                             |      |
| ✓                         | Background and objectives                        | <a href="#">#2a</a>  | Scientific background and explanation of rationale                                                                                                                                          | 1    |
| ✓                         | Background and objectives                        | <a href="#">#2b</a>  | Specific objectives or hypothesis                                                                                                                                                           | 2    |
| <b>Methods</b>            |                                                  |                      |                                                                                                                                                                                             |      |
| ✓                         | Trial design                                     | <a href="#">#3a</a>  | Description of trial design (such as parallel, factorial) including allocation ratio.                                                                                                       | 2    |
| /                         | Trial design                                     | <a href="#">#3b</a>  | Important changes to methods after trial commencement (such as eligibility criteria), with reasons                                                                                          | /    |
| ✓                         | Participants                                     | <a href="#">#4a</a>  | Eligibility criteria for participants                                                                                                                                                       | 2    |
| ✓                         | Participants                                     | <a href="#">#4b</a>  | Settings and locations where the data were collected                                                                                                                                        | 2    |
| ✓                         | Interventions                                    | <a href="#">#5</a>   | The experimental and control interventions for each group with sufficient details to allow replication, including how and when they were actually administered                              | 2    |
| ✓                         | Outcomes                                         | <a href="#">#6a</a>  | Completely defined prespecified primary and secondary outcome measures, including how and when they were assessed                                                                           | 2    |
| /                         | Outcomes                                         | <a href="#">#6b</a>  | Any changes to trial outcomes after the trial commenced, with reasons                                                                                                                       | /    |
| ✓                         | Sample size                                      | <a href="#">#7a</a>  | How sample size was determined.                                                                                                                                                             | 4    |
| ✓                         | Sample size                                      | <a href="#">#7b</a>  | When applicable, explanation of any interim analyses and stopping guidelines                                                                                                                | 4    |
| ✓                         | Randomization - Sequence generation              | <a href="#">#8a</a>  | Method used to generate the random allocation sequence.                                                                                                                                     | 2    |
| ✓                         | Randomization - Sequence generation              | <a href="#">#8b</a>  | Type of randomization; details of any restriction (such as blocking and block size)                                                                                                         | 2    |
| ✓                         | Randomization - Allocation concealment mechanism | <a href="#">#9</a>   | Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned | 2    |
| ✓                         | Randomization - Allocation concealment mechanism | <a href="#">#10</a>  | Who generated the allocation sequence, who enrolled participants, and who assigned participants to interventions                                                                            | 2    |
| /                         | Blinding                                         | <a href="#">#11a</a> | If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how.                                                   | /    |

|                          |                                                 |                      |                                                                                                                                                   |      |
|--------------------------|-------------------------------------------------|----------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|------|
| /                        | Blinding                                        | <a href="#">#11b</a> | If relevant, description of the similarity of interventions                                                                                       | /    |
| ✓                        | Statistical methods                             | <a href="#">#12a</a> | Statistical methods used to compare groups for primary and secondary outcomes                                                                     | 2-4  |
| ✓                        | Statistical methods                             | <a href="#">#12b</a> | Methods for additional analyses, such as subgroup analyses and adjusted analyses                                                                  | 2-4  |
| <b>Results</b>           |                                                 |                      |                                                                                                                                                   |      |
| ✓                        | Participant flow diagram (strongly recommended) | <a href="#">#13a</a> | For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome    | 5    |
| ✓                        | Participant flow                                | <a href="#">#13b</a> | For each group, losses and exclusions after randomization, together with reason                                                                   | 5    |
| ✓                        | Recruitment                                     | <a href="#">#14a</a> | Dates defining the periods of recruitment and follow-up                                                                                           | 6    |
| ✓                        | Recruitment                                     | <a href="#">#14b</a> | Why the trial ended or was stopped                                                                                                                | 6    |
| ✓                        | Baseline data                                   | <a href="#">#15</a>  | A table showing baseline demographic and clinical characteristics for each group                                                                  | 6    |
| ✓                        | Numbers analysed                                | <a href="#">#16</a>  | For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups           | 5    |
| ✓                        | Outcomes and estimation                         | <a href="#">#17a</a> | For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval) | 6    |
| ✓                        | Outcomes and estimation                         | <a href="#">#17b</a> | For binary outcomes, presentation of both absolute and relative effect sizes is recommended                                                       | 6    |
| ✓                        | Ancillary analyses                              | <a href="#">#18</a>  | Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory         | 6-9  |
| /                        | Harms                                           | <a href="#">#19</a>  | All important harms or unintended effects in each group (For specific guidance see CONSORT for harms)                                             | n.a. |
|                          |                                                 |                      | Use Errors as an equivalent for potential harms                                                                                                   | 9    |
| <b>Discussion</b>        |                                                 |                      |                                                                                                                                                   |      |
| ✓                        | Limitations                                     | <a href="#">#20</a>  | Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses                                  | 10   |
| ✓                        | Generalisability                                | <a href="#">#21</a>  | Generalisability (external validity, applicability) of the trial findings                                                                         | 6-10 |
| ✓                        | Interpretation                                  | <a href="#">#22</a>  | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence                                     | 6-10 |
| /                        | Registration                                    | <a href="#">#23</a>  | Registration number and name of trial registry                                                                                                    | /    |
| <b>Other information</b> |                                                 |                      |                                                                                                                                                   |      |
| ✓                        | Interpretation                                  | <a href="#">#22</a>  | Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence                                     | 6-10 |
| /                        | Registration                                    | <a href="#">#23</a>  | Registration number and name of trial registry                                                                                                    | /    |
| /                        | Protocol                                        | <a href="#">#24</a>  | Where the full trial protocol can be accessed, if available                                                                                       | /    |
| /                        | Funding                                         | <a href="#">#25</a>  | Sources of funding and other support (such as supply of drugs), role of funders                                                                   | /    |

# Zusammenfassung der Dissertation

In diesem Abschnitt werden die der Dissertation zugrundeliegenden Publikationen in einem übergeordneten Gesamtkontext zusammengefasst. Dabei werden die Problemstellung und der wissenschaftliche Hintergrund dargestellt, aus denen die zentralen Forschungsfragen abgeleitet wurden. Anschließend erfolgt eine kurze Beschreibung der angewandten Methodik und der wesentlichen Ergebnisse. Abschließend werden die Ergebnisse der Arbeit diskutiert, bestehende Limitationen aufgezeigt und ein Ausblick auf zukünftige Forschungsbedarfe gegeben.

## Hintergrund und Problemstellung

Durch den digitalen Wandel und neue Erkenntnisse aus der Forschung stehen in der Intensiv- und Notfallmedizin immer mehr und komplexere Technologien zur Verfügung. Diese sollen das medizinische Personal bei der optimalen Versorgung der Patient\*innen unterstützen (1,2). Ihre Nutzung kann sich positiv auf die Patient\*innensicherheit auswirken. Gleichzeitig entstehen durch die Einführung oder Veränderung eines technischen Artefakts innerhalb eines sozio-technischen Systems neue Risiken für Patient\*innen oder die Anwender\*innen (3). Die Komplexität der sozio-technischen Systeme in der Medizin machen diese anfällig für Fehler und Gefährdungen. Die Ursachen für Behandlungsfehler sind häufig multikausal bedingt und lassen sich nicht auf eine einzelne Person zurückführen, sondern resultieren aus einer Vielzahl von Schwachstellen im sozio-technischen System (4,5).

In der Intensiv- und Notfallmedizin ist die Mensch-Maschine-Interaktion häufig Bestandteil sicherheits- und zeitkritischer Prozesse. Daher werden hohe Anforderungen an die Gebrauchstauglichkeit (engl. Usability) der dort eingesetzten Systeme gestellt. Die Gebrauchstauglichkeit eines Produktes beeinflusst, inwieweit Nutzer\*innen ein Produkt in einem definierten Nutzungskontext durch Wahrnehmung, Verständnis von Informationen und Interaktion zweckmäßig zur Erreichung bestimmter Ziele nutzen können (6,7). Irreführende Informationen, nicht wahrnehmbare Alarmmeldungen oder eine schlechte Erlernbarkeit von Bedienelementen aufgrund einer unzureichenden Gestaltung sowie eine nicht korrekte Umsetzung der Nutzungsanforderungen sind Beispiele für Faktoren, die die Gebrauchstauglichkeit negativ beeinflussen können.

Bei der Gebrauchstauglichkeit unterscheidet man die Effektivität, die Effizienz und die Zufriedenheit. Die Effektivität ist das Maß für die Richtigkeit und Vollständigkeit der Aufgabenerfüllung, die Effizienz ist das Maß für den Aufwand, z. B. Ressourcen oder Zeit, der für die Erreichung des Ziels erforderlich ist und die Zufriedenheit misst die Abwesenheit störender Faktoren (6). Da in der Intensiv- und Notfallmedizin häufig kritische medizinische Situationen auftreten, die eine zeitkritische Interaktion erfordern, kommt neben der Effektivität auch die Effizienz eine besondere sicherheitsrelevante Bedeutung zu (7).

Trotz der bestimmungsgemäßen Anwendung von Medizinprodukten kann eine unzureichende Gebrauchstauglichkeit der Geräte zu Nutzungsfehlern (engl. Use Error) führen. Nutzungsfehler sind Handlungen oder Unterlassungen bei der Interaktion mit einem Medizinprodukt, die zu einem anderen Ergebnis führen als vom Hersteller vorgesehen oder vom Anwender erwartet. Je nach Produkt und seiner Zweckbestimmung hat dies einen Einfluss auf die Sicherheit von Anwender\*innen, Patient\*innen und anderen Personen. Nutzungsfehler können daher zu Gefährdungssituationen führen, wenn beispielsweise eine fehlerhafte Eingabe eine falsche Ausgabe zur Folge hat oder eine angezeigte Information zu einer falschen Handlung am Patienten oder an anderen Geräten führt. (7)

Regulatorisch ist daher die Anwendung geeigneter Usability-Engineering Prozesse und Methoden zur Identifizierung und Behandlung von gefährdungsbezogenen Interaktionen und Nutzungsfehlern von Medizinprodukten gefordert (7–10). Dieser mit dem Risikomanagement (11) und der Produktentwicklung (12) verbundene Prozess umfasst u. a. die Charakterisierung der Nutzergruppen und ihrer Anforderungen sowie eine systematische Analyse der Nutzerschnittstelle im Hinblick auf gefährdungsbezogene Nutzungs-Szenarien. Die Bewertung der Gebrauchstauglichkeit erfolgt im Rahmen formativer (entwicklungsbegleitende) und summativer (entwicklungsabschließende) Evaluationen. (7,10,13,14)

Mit Veröffentlichungen wie „To Err is Human: Building a Safer Health System“ (15) hat das Thema in den letzten Jahrzehnten an Bedeutung gewonnen. Trotz regulatorischer Vorgaben (8,9) bei der Entwicklung von Medizinprodukten kommt es zu Nutzungsfehlern und Gefährdungssituationen. Diese treten insbesondere bei unerfahrenen, aber auch erfahrenen Anwender\*innen oder in Notfall- und Stresssituationen auf (3,5,7).

## Zielsetzung und Forschungsfragen

Ziel dieser Arbeit ist die Entwicklung und Erprobung von Methoden zur Ermittlung gefährdungsbezogener Interaktionen und zur Vermeidung von Nutzungsfehlern in Bezug auf die Gebrauchstauglichkeit von Medizinprodukten. Dabei werden die verschiedenen Stufen des gebrauchstauglichkeitsorientierten Entwicklungs- und Risikomanagementprozesses unter Berücksichtigung der regulatorischen Anforderungen aus dem Medizinproduktegesetz und den harmonisierten Normen betrachtet. Dadurch sollen neue Erkenntnisse über den Einfluss der Gebrauchstauglichkeit auf die Patientensicherheit gewonnen und die folgenden Forschungsfragen beantwortet werden:

**F1: Wie können bekannte Nutzungsprobleme, die bei der Anwendung sicherheitskritischer Medizinprodukte auftreten, am Beispiel von Beatmungsgeräten systematisch ermittelt werden?**

**F2: Wie können dynamische Vitalwerte wie z. B. Beatmungsparameter visualisiert werden, um pathologische Veränderungen, die nur über die Zeitreihe erkennbar sind, besser wahrnehmbar zu machen?**

**F3: Welchen Einfluss hat die Gebrauchstauglichkeit technischer Artefakte wie z. B. automatischer externer Defibrillatoren (AEDs) in kritischen Versorgungssituationen auf die klinisch relevanten Endpunkte Effektivität und Effizienz?**

## Ansatz und Ergebnisse

Die Bearbeitung der Forschungsfragen erfolgte im Rahmen verschiedener Forschungsprojekte und Studien. Die Ergebnisse dieser Forschungsarbeit wurden in drei Publikationen veröffentlicht, die den Korpus dieser Dissertation bilden.

F1: Wie können bekannte Nutzungsprobleme, die bei der Anwendung sicherheitskritischer Medizinprodukte auftreten, am Beispiel von Beatmungsgeräten systematisch ermittelt werden?

Usability-Evaluationen im Rahmen der Produktentwicklung sind eine etablierte Methode zur prospektiven Identifikation von Nutzungsproblemen. Das Auftreten von Nutzungsfehlern kann dadurch jedoch nicht vollständig ausgeschlossen werden. Sowohl im Rahmen der Entwicklung als auch in der Herstellung nachgelagerten Phasen sind Informationen von Anwendern des Medizinprodukts oder ähnlicher Medizinprodukte heranzuziehen, um die Sicherheit der Produkte weiter zu verbessern. Im Rahmen dieser Forschungsfrage wurden daher verschiedene Methoden zur systematischen Ermittlung bekannter Nutzungsprobleme, die bei der Anwendung sicherheitskritischer Medizinprodukte auftreten, angewendet.

Um in der Literatur beschriebene Usability-Probleme und Faktoren, die zu Nutzungsfehlern beitragen, zu identifizieren, wurde am Beispiel von mechanischen Beatmungsgeräten ein systematisches Review nach dem PRISMA (Preferred Reporting Items for Systematic reviews and Meta-Analyses) Reporting Standard (16) durchgeführt. Die Suche in PubMed erfolgte mit einem Suchstring bestehend aus den MeSH-Terms „Ventilators, Mechanical“, „User Centered Design“ und „Patient Safety“ sowie geeigneten Synonymen und verwandten Begriffen. Artikel wurden in das Review aufgenommen und qualitativ analysiert, wenn sie detaillierte Informationen über Probleme der Gebrauchstauglichkeit und beitragende Faktoren als Ursache für gemeldete Zwischenfälle oder Nutzungsfehler bei Beatmungsgeräten enthielten. Die Recherche ergab 692 Einträge (Februar 2021), von denen 16 Artikel in das Review eingeschlossen wurden.

Bei den in der Literatur identifizierten Problemen handelt es sich überwiegend um Ergebnisse aus publizierten Usability-Tests. Die Ergebnisse wurden systematisch in einem Ursache-Wirkungs-Diagramm nach den auftretenden Hauptursachen „Interface Elements

(Soft- and/or Hardware)“, „Task Navigation“, „Representation of Medical Functions“ und „User Characteristics“ aufgelistet. Die Ursachen für Nutzungsfehler standen u. a. im Zusammenhang mit spezifischen Grundsätzen und Empfehlungen für die Informationsdarstellung und dem allgemeinen Umstand, dass das medizinische Personal häufig mit verschiedenen Beatmungsgeräten mit voneinander abweichenden Interaktionskonzepten und Interaktionselementen arbeitet.

Eine weitere Quelle für Beschreibungen von Nutzungsproblemen lieferte die Analyse von Vorkommismeldungen aus Berichtssystemen für kritische Ereignisse in der Medizin, z. B. CIRSmedical.de, oder Sicherheitsmeldungen des BfArM.

Die Arbeit wurde publiziert in:

Coldewey B, Diruf A, Röhrig R, Lipprandt M. Causes of use errors in ventilation devices - Systematic review. Applied ergonomics. 2022;98:103544. doi:10.1016/j.apergo.2021.103544

**F2: Wie können dynamische Vitalwerte wie z. B. Beatmungsparameter visualisiert werden, um pathologische Veränderungen, die nur über die Zeitreihe erkennbar sind, besser wahrnehmbar zu machen?**

Die Bereitstellung von gebrauchstauglichen Informationselementen kann nicht nur zur Vermeidung von Nutzungsfehlern beitragen, sondern auch die Wahrnehmung von für die Patientensicherheit relevanter Informationen durch die Anwender unterstützen. So kann z. B. das frühzeitige Erkennen von pathologischen Veränderungen über das dem medizinischen Personal zur Verfügung stehende Monitoring zu einer verbesserten Patientenversorgung führen. Im Rahmen der zweiten Forschungsfrage wurden daher verschiedene Usability-Methoden erprobt, um dynamische Vitalwerte wie z. B. Beatmungsparameter benutzerfreundlich zu visualisieren, um pathologische Veränderungen besser wahrnehmbar zu machen und das Auftreten von Gefährdungssituationen zu vermeiden.

Im Rahmen der Arbeit wurde in Anlehnung an den Usability-Engineering Prozess ein mehrstufiges Vorgehensmodell mit Fokus auf Biosignaldaten und der Wahrnehmung pathologischer Prozesse entwickelt und erprobt. Am Beispiel von Beatmungsgeräten und Aufzeichnungen von Beatmungsparametern wurden Nutzungsfehler identifiziert und Lösungsansätze evaluiert. Das Konzept gliedert sich in fünf Schritte:

1. statische Analyse der Daten zur Identifikation von Nutzungsproblemen
2. Durchführung von Interviews im Rahmen der Nutzungskontext- und Anforderungsanalyse zur genaueren Untersuchung der Probleme
3. Entwicklung neuer Interface-Konzepte zur Umsetzung der Anforderungen und eines Prototyps inklusive dynamischer Visualisierung der Daten
4. formative Evaluation z. B. mittels eines unmoderiertem Remote Usability-Test
5. Usability-Test mit realistischen Szenarien und Einflussfaktoren im Simulationsraum.

Die retrospektive Analyse von Beatmungsgeräteaufzeichnungen mittels statischer Visualisierung sowie die Annotation auffälliger Bereiche (Schritt 1) lieferten Erkenntnisse zur Qualität der medizinischen Behandlung und ermöglichten die Identifikation von Problemen bei der Früherkennung pathologischer Prozesse im Rahmen der Beatmung von Patienten. Die Interviewergebnisse (Schritt 2) wurden im Hinblick auf neue Anforderungen an die Schnittstelle des Medizinproduktes analysiert und in neue Konzepte für das Beatmungsgeräte-Interface umgesetzt (Schritt 3). Durch verschiedene Usability-Tests (Schritt 4 und 5) konnte die Wirkung des neu entwickelten Interfaces in Bezug auf eine optimale Patientenversorgung und gefährdungsbezogene Nutzungsszenarien evaluiert werden. Für die einzelnen Arbeitsschritte wurden verschiedene Software-Artefakte eingesetzt oder entwickelt.

Die Arbeit wurde publiziert in:

Coldewey B, Klöckener AM, Göbel C, Röhrig R, Lipprandt M. Usability Engineering of Dynamic Biosignal Displays Using Ventilation Data. *Studies in health technology and informatics*. 2023;302:626–30. doi:10.3233/SHTI230224

**F3: Welchen Einfluss hat die Gebrauchstauglichkeit technischer Artefakte wie z. B. automatischer externer Defibrillatoren (AEDs) in kritischen Versorgungssituationen auf die klinisch relevanten Endpunkte Effektivität und Effizienz?**

Eine gute Gebrauchstauglichkeit ist einerseits entscheidend für die sichere Nutzung eines Produktes. Andererseits beeinflusst auch bei einer fehlerfreien Interaktion die Effektivität das Ergebnis der Nutzung des Medizinproduktes. Im Rahmen zahlreicher publizierter Usability-Tests von AEDs wurde u. a. die Effektivität als Maß für die Gebrauchstauglichkeit erhoben. Die Studien und ihre Ergebnisse wurden jedoch nicht in direkten Bezug zu klinisch relevanten Endpunkten, wie die Überlebenswahrscheinlichkeit, gesetzt. Im Rahmen der

dritten Forschungsfrage wurde daher untersucht, wie der Einfluss der Gebrauchstauglichkeit technischer Artefakte am Beispiel von AEDs auf die Versorgungsqualität und Patientensicherheit in kritischen Versorgungssituationen evaluiert werden kann.

Um den Einfluss der Gebrauchstauglichkeit zu untersuchen, wurde mittels Simulation eine kritische Versorgungssituation nachgestellt. Dies ermöglichte die Evaluation in einem für alle Teilnehmer\*innen standardisierten Vorgehen. In der exemplarischen Simulationsstudie wurden zwei AEDs dahingehend untersucht, ob ein bestimmter AED in der Laienanwendung so überlegen ist, dass ein klinisch relevanter Unterschied zwischen dem ersten Kontakt mit dem Gerät und dem Zeitpunkt der Schockabgabe (TimeToShock (TTS)) besteht. Im Rahmen der Studie wurde den Teilnehmer\*innen randomisiert eines der AED-Schulungsgeräte „Lifepak CR-T AED Trainer“ (Medtronic Physio-Control) und „AED Trainer 3“ (Philips Medical Systems) zugeteilt und in einem simulierten Wiederbelebungszenario verwendet. Die Durchführung der kardiopulmonalen Reanimation wurde von einem eingewiesenen Studienmitarbeiter übernommen. Die Interaktion wurde mittels eines mobilen Eye-Trackers aufgezeichnet. Die Video-Aufzeichnungen wurden von einem interdisziplinären Team im Hinblick auf Ursachen für Interaktionsprobleme und Verzögerungen analysiert.

Es wurde ein Unterschied von 30 Sekunden als klinisch relevanter Effekt festgelegt und die Studie mit einem adaptiven Studiendesign durchgeführt, bei der eine Interimsanalyse nach 14 Proband\*innen pro Studienarm erfolgte. Das Studienziel wurde mit der Interimsanalyse erreicht.

Im Rahmen des Szenarios konnte von allen Teilnehmer\*innen ein Schock abgegeben werden. Es wurde ein klinisch relevanter Unterschied in der TTS mit einem Median von 32,5 s zwischen den beiden Geräten gemessen (61 s (IQR: 58 s-76 s, Bereich: 51 s-115 s) für den AED Trainer 3 und 93,5 s (IQR: 91 s-103 s, Bereich: 80 s-129 s) für den Lifepak CR-T AED Trainer) ( $p < 0,05$ ). Zu den Ursachen für Verzögerungen und Interaktionsprobleme gehörten Unterschiede in der Verwendung von Sprachanweisungen (Länge, Pausen und Terminologie), der Ikonographie auf dem Gerät und den Elektroden sowie den Öffnungsmechanismen der Geräte.

Die Arbeit wurde publiziert in:

Coldewey B, Klausen A, Otto-Sobotka F, Röhrig R, Lipprandt M. Usability of Automated External Defibrillators: A Randomized, Comparative Simulator Study. *International Journal of Human-Computer Interaction*. 2023;40(22),6972–6983. doi:10.1080/10447318.2023.2260973

## Diskussion

Die vorliegende Arbeit beschäftigt sich mit der Relevanz der Gebrauchstauglichkeit von Medizinprodukten und geeigneten Methoden zur Risikominimierung bei der Entwicklung und Evaluation der Benutzerschnittstelle (engl. User Interface). Durch die Anwendung verschiedener Ansätze und Methoden aus der Wissenschaft und dem Usability-Engineering konnten sowohl neue Erkenntnisse gewonnen als auch Defizite identifiziert werden, die zukünftig gezielt adressiert werden müssen, um die Gebrauchstauglichkeit weiter zu verbessern.

Die systematische Analyse publizierter Interaktionsprobleme mit Beatmungsgeräten (Publikation 1) sowie die Durchsicht von Vorkommismeldungen erwiesen sich als geeignete Methoden, um einen systematischen Überblick über bekannte Nutzungsprobleme zu erhalten. Zu deren Vermeidung trägt u. a. die Beachtung von Interaktionsprinzipien (6,17,18) und Heuristiken (19,20) bei. Darüber hinaus müssen die zugrundeliegenden Erfordernisse und Anforderungen der Nutzer und weiterer Stakeholder korrekt identifiziert werden. Eine Analyse des medizinischen Kontexts ist daher unerlässlich. Darüber hinaus wurden systematische Nutzungsfehler identifiziert, die erst durch die gleichzeitige Nutzung verschiedener Geräte entstehen. Dies ist auf herstellerspezifische Bedienkonzepte zurückzuführen, die sich voneinander unterscheiden. So hat z. B. die Anzahl der Beatmungsmodi mit dem technischen Fortschritt zugenommen (21,22). Dieselben Beatmungsmodi haben je nach Hersteller unterschiedliche Namen und umgekehrt verbergen sich hinter gleichen Namen unterschiedliche Modi. Darüber hinaus sind innerhalb der Beatmungsmodi umfangreiche Modifikationen möglich. Ein Wechsel zwischen verschiedenen Geräten ist nicht immer möglich, da die Modi nicht eins zu eins übertragbar sind. Dies erfordert eine zeitintensive Einarbeitung und macht die Bedienung der Geräte zu einem Risiko für die Patientensicherheit. Um diese Probleme geräteübergreifend zu lösen, sind regulatorische Vorgaben erforderlich (23). Für das Problem der Beatmungsmodi beschäftigen sich Chatburn et al. (21) sowie die ISO-Norm 19223 mit einem standardisierten Vokabular zur herstellerunabhängigen Harmonisierung der Beatmungsmodi. Die systematische Analyse hat weiterhin gezeigt, dass der Fokus der eingeschlossenen Publikationen nicht auf der Identifikation und Untersuchung von Nutzungsfehlern aufgrund unzureichender Usability liegt. Bei den Usability-Evaluationen wurden primär quantitative Endpunkte (u. a. Effektivität, Effizienz und Zufriedenheit) erhoben, um die Geräte miteinander zu vergleichen. Konkrete Hinweise auf Ursachen der

Fehlbedienungen und Verbesserungspotenziale liefern die Publikationen nur bedingt. Zudem decken die in den Studien gewählten Testszenarien nur einen begrenzten Ausschnitt der gefährdungsbezogenen Nutzungsszenarien bzw. Hauptbedienfunktionen ab, sodass kein umfassender Überblick über Nutzungsprobleme gegeben werden kann. Studien mit detaillierteren Analysen der Nutzerinteraktion sind notwendig, um nutzungsbedingte Risiken aufzudecken. Die publizierten Übersichtsarbeiten zu retrospektiven Analysen von Vorfällen lieferten ebenfalls nicht genügend Details, um Rückschlüsse auf konkrete Usability-Probleme und deren Ursachen zu ziehen. Dies erfordert eine erneute Sichtung der entsprechenden Datenbanken und ihrer Einträge. Um mögliche Lücken in der Übersicht zu schließen, sollte die systematische Recherche durch weitere Methoden, wie z. B. die Befragung von Nutzergruppen zur Anwendung der Geräte in der klinischen Versorgung, ergänzt werden.

Im Rahmen der weiteren Arbeiten wurde der Usability-Engineering Prozess mit dem Fokus auf die Identifikation von Nutzungsfehlern und Problemen bei der optimalen Einstellung der Beatmungsunterstützung für den Patienten sowie der Früherkennung von pathologischen Veränderungen und der Vermeidung von Patientenschäden durchlaufen. Das Konzept wurde exemplarisch an einem ausgewählten Problem erprobt. Die retrospektive Analyse realer Beatmungsdaten zeigte, dass aufgezeichnete Biosignaldaten das Potenzial haben, Erkenntnisse über die Gebrauchstauglichkeit für Forschung und Entwicklung zu liefern. Die Entwicklung und Implementierung eines neuen, gebrauchstauglichen Interface-Konzeptes auf Basis der gewonnenen Erkenntnisse könnte zu einer Entlastung des medizinischen Personals und zu einer verbesserten Patientenversorgung beitragen. Eine Optimierung der aktuellen Darstellungsform medizinischer Daten zur schnelleren und sichereren Erkennung und Beurteilung relevanter Informationen ist zukünftig zu evaluieren.

Im dritten Teil der Arbeit wurde eine detaillierte Analyse des Einflusses der Gebrauchstauglichkeit technischer Artefakte in kritischen Versorgungssituationen im Rahmen einer zweiarmigen Simulationsstudie mit zwei unterschiedlichen AEDs durchgeführt. Durch die realitätsnahe Simulation des zeitkritischen Szenarios konnte das Verhalten der Anwender kontrolliert und reproduzierbar beobachtet werden, ohne Patienten zu gefährden. Für den primären Endpunkt (Zeit bis zur Schockabgabe TimeToShock (TTS)) konnte ein klinisch relevanter Unterschied zwischen den Geräten ermittelt werden. Dies zeigt die klinische Relevanz der Effizienz als Maß für die Gebrauchstauglichkeit und Sicherheit (10). Derzeit gibt es noch keine regulatorischen Vorgaben für die maximale TTS. Die Studie zeigt, dass ein Grenzwert bei der TTS als Stand der Technik eingeführt werden

könnte. Publierte Usability-Evaluationen von z. B. AEDs oder Beatmungsgeräten beinhalten häufig Effizienzmessungen. Aufgrund der unterschiedlichen Aufgabengestaltungen und individueller Studienabläufe können diese jedoch nicht zusammengeführt und die mittleren Bedienzeiten im Rahmen von Metaanalysen verglichen werden. Darüber hinaus liefern die Untersuchungen dieser Studie einen detaillierten Einblick in die beobachteten Probleme und die zugrundeliegenden Ursachen, der in vorangegangenen Publikationen fehlte.

## Limitationen

Die Arbeit unterlag einigen Einschränkungen, die zum Teil bereits in den einzelnen Publikationen diskutiert wurden. Während der systematischen Recherche zeigte sich unter anderem, wie uneinheitlich die Fachterminologie verwendet wird. Dadurch sind Publikationen über Suchbegriffe wie „Usability“, „Human Factors“ oder den 2021 eingeführten MeSH-Term „User-Centered Design“ nur eingeschränkt auffindbar. Zusätzliche Suchbegriffe wie „user friendliness“ ermöglichen das Auffinden weiterer relevanter Publikationen, reduzieren jedoch die Sensitivität der Suchergebnisse. Gleiches gilt für Beschreibungen von Vorkommnissen. Die angegebenen Informationen lassen Rückschlüsse auf Nutzungsprobleme als Ursache zu, diese werden jedoch nicht als solche beschrieben. Sind die zugrundeliegenden Konzepte und Folgen mangelnder Gebrauchstauglichkeit nicht bekannt, wird der Nutzungsfehler (engl. Use Error) beispielsweise als Nutzerfehler (engl. User Error) beschrieben und der Nutzer als Verursacher angesehen.

Eine weitere Herausforderung, die sich bei der Planung und Vorbereitung von Evaluationsstudien in möglichst realistischen Simulationsszenarien gezeigt hat, ist die Implementierung geeigneter High-Fidelity-Mockups. Für die Evaluation neuer Interaktionselemente und -konzepte auf der Basis bestehender Interfaces stehen in der Regel keine Möglichkeiten zur Verfügung, die notwendigen Anpassungen am Medizinprodukt selbst vorzunehmen. Es muss eine Kopie des bestehenden Interfaces erstellt werden. Dynamische Anzeigen z. B. von Patientenmonitoren oder Beatmungsgeräten, bei denen die angezeigten Messwerte auf der Physiologie des zu behandelnden Patienten basieren, stellen hier eine Herausforderung dar. Um möglichst flexibel auf Nutzereingaben reagieren zu können, reicht die Hinterlegung einfacher vordefinierter Datensätze nicht aus. Neben der Verwendung physiologischer Modelle kann

eine Schnittstelle zum zugrundeliegenden Medizingerät in Verbindung mit Simulationsphantomen die Anzeige realistischer Werte ermöglichen. Speziell bidirektionale Schnittstellen sind jedoch nicht bei allen Geräten oder nur eingeschränkt verfügbar.

Die im Rahmen der Arbeit geplanten Studien waren durch die Einschränkungen und Herausforderungen der Corona-Pandemie geprägt. Studien im Rahmen des Requirement Engineerings (z. B. Interviews oder teilnehmende Beobachtungen) und Usability-Evaluationen mit Proband\*innen waren nicht oder nur unter hohen Auflagen möglich. Die ohnehin hohe Arbeitsbelastung und der Mangel an medizinischem Fachpersonal wirkten sich zusätzlich negativ auf die Rekrutierung von Studienteilnehmer\*innen aus.

## Zusammenfassung und Ausblick

Der Nutzen von Medizinprodukten hängt nicht allein von ihrer technischen Umsetzung ab; vielmehr trägt die Gebrauchstauglichkeit maßgeblich zur Sicherheit und Verbesserung der Patient\*innenversorgung bei. Im Rahmen dieser Arbeit konnten verschiedene Methoden aus der Wissenschaft und dem Usability-Engineering angewendet und weiterentwickelt werden, um Schwachstellen in der Gebrauchstauglichkeit zu identifizieren sowie neue Konzepte und bestehende Systeme zu evaluieren. Die Ansätze zeigten am Beispiel der maschinellen Beatmung von Patienten, wie Informationen über bekannte Probleme mit Beatmungsgeräten systematisch identifiziert werden können, ebenso wie die Analyse von Aufzeichnungen und Simulation von Beatmungsdaten zur Verbesserung der Usability genutzt werden kann. Auch die realitätsnahe Simulation von Laien-Reanimationen mit AEDs wurden im Rahmen der Usability-Evaluation untersucht. Neben Erkenntnissen zu bestehenden Nutzungsfehlern bei Medizinprodukten und der klinischen Relevanz u. a. der Effektivität als Maß für die Gebrauchstauglichkeit konnten Defizite bei den regulatorischen Vorgaben sowie der methodischen Vorgehensweise in publizierten Studien identifiziert werden. Regulatorische Vorgaben sind unabdingbar, um z. B. Defiziten zwischen Geräten unterschiedlicher Hersteller zu begegnen. Neben der Sensibilisierung für die Relevanz der Gebrauchstauglichkeit als Einflussfaktor für Nutzungsfehler sowohl bei den Anwender\*innen als auch den Herstellern ist die Entwicklung geeigneter Methoden und Werkzeuge für die Forschung und Entwicklung voranzutreiben. Zur Verbesserung der Gebrauchstauglichkeit von Medizinprodukten sind zukünftig umfangreiche Evaluationsstudien mit realitätsnahen Szenarien und Fokus auf sicherheitsrelevante Merkmale sowie die Erprobung neuer Ansätze in den verschiedensten Bereichen erforderlich.

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# Danksagung

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Auch wenn diese Dissertation eine eigenständige Arbeit darstellt, würde sie in dieser Form nicht ohne die gemeinsame Leistung all meiner Koautor\*innen, der Projektpartner und meiner Kolleg\*innen vorliegen. Durch gemeinsame Diskussionen über die beste Methodik, die Durchführung und Auswertung von Studien und nicht zuletzt mit dem Korrekturlesen habt ihr diese Arbeit maßgeblich vorangetrieben. Neben dem fachlichen Austausch habe ich auch die gute Arbeitsatmosphäre geschätzt. Besonders durch die Zusammenarbeit mit meinen Kolleg\*innen aus der Uniklinik RWTH Aachen und der Universität Oldenburg sowohl aus der Wissenschaft ebenso wie der Technik und Verwaltung hat die Arbeit erst Spaß gemacht.

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Zuletzt möchte ich mich herzlich bei meiner Familie und meinen Freunden für den Rückhalt und die vielseitige Unterstützung bedanken. Meine Eltern haben mich auf meinem Weg begleitet, ermutigt und in all meinen Entscheidungen unterstützt. Insbesondere danke ich meinem Partner Simon für seine Geduld, seine Aufmunterungen in Momenten der Verzweiflung ebenso wie seinen fachlichen Rat.

Ohne euch alle wäre diese Arbeit so nicht möglich gewesen!

## Erklärung § 5 Abs. 1 zur Datenaufbewahrung

Hiermit erkläre ich, dass die dieser Dissertation zu Grunde liegenden Originaldaten im Institut für Medizinische Informatik des Universitätsklinikums Aachen hinterlegt sind.

## Erklärung gemäß § 5 Abs. (1) und (2), und § 11 Abs. (3) 12. der Promotionsordnung

Hiermit erkläre ich, **Beatrice Coldewey**, an Eides statt, dass ich den wesentlichen Anteil an der Publikation:

**Coldewey B**, Diruf A, Röhrig R, Lipprandt M. Causes of use errors in ventilation devices - Systematic review. Applied Ergonomics 2022; 98:103544. doi: 10.1016/j.apergo.2021.103544 geleistet habe.

Die Anteile an der Arbeit waren wie folgt:

|                                   | Beatrice Coldewey | Annette Diruf | Prof. Dr. Rainer Röhrig | Jun.-Prof. Dr.-Ing. Myriam Lipprandt | Summe (%) |
|-----------------------------------|-------------------|---------------|-------------------------|--------------------------------------|-----------|
| Idee                              | 0                 | 0             | 40                      | 60                                   | 100       |
| Studiendesign/ Konzeption         | 70                | 0             | 10                      | 20                                   | 100       |
| Datenerhebung                     | 70                | 10            | 10                      | 10                                   | 100       |
| Datenauswertung                   | 60                | 15            | 5                       | 20                                   | 100       |
| Interpretation der Daten          | 60                | 5             | 5                       | 30                                   | 100       |
| <b>Verfassung des Manuskripts</b> | <b>100</b>        | 0             | 0                       | 0                                    | 100       |
| Korrektur des Manuskripts         | 0                 | 5             | 25                      | 70                                   | 100       |

Aus diesem wesentlichen Anteil ergibt sich selbstverständlich die Stellung als Erstautor / in.

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Beatrice Coldewey (Doktorandin und korrespondierender Autor)

Als Doktormutter bestätige ich die Angaben von Beatrice Coldewey.

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Jun.-Prof. Dr.-Ing. Myriam Lipprandt (Doktormutter)

Ich schließe mich der Erklärung von Jun.-Prof. Dr.-Ing Myriam Lipprandt als Koautor an

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Annette Diruf

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Univ.-Prof. Dr. Rainer Röhrig

## Erklärung gemäß § 5 Abs. (1) und (2), und § 11 Abs. (3) 12. der Promotionsordnung

Hiermit erkläre ich, **Beatrice Coldewey**, an Eides statt, dass ich den wesentlichen Anteil an der Publikation:

**Coldewey B**, Klöckener AM, Göbel C, Röhrig R und Lipprandt M. Usability Engineering of Dynamic Biosignal Displays Using Ventilation Data. Studies in health technology and informatics 2023; 302:626–30. doi: 10.3233/SHTI230224

geleistet habe.

Die Anteile an der Arbeit waren wie folgt:

|                                   | Beatrice Coldewey | Anne Marie Klöckener | Dr. Christof Göbel | Prof. Dr. Rainer Röhrig | Jun.-Prof. Dr.-Ing. Myriam Lipprandt | Summe (%) |
|-----------------------------------|-------------------|----------------------|--------------------|-------------------------|--------------------------------------|-----------|
| Idee                              | 50                | 0                    | 10                 | 10                      | 30                                   | 100       |
| Studiendesign/ Konzeption         | 60                | 5                    | 5                  | 10                      | 20                                   | 100       |
| Datenerhebung                     | 50                | 30                   | 0                  | 10                      | 10                                   | 100       |
| Datenauswertung                   | 50                | 10                   | 0                  | 10                      | 30                                   | 100       |
| Interpretation der Daten          | 60                | 0                    | 10                 | 10                      | 20                                   | 100       |
| Bereitstellung von Materialien    |                   |                      | x                  | x                       | x                                    | x         |
| <b>Verfassung des Manuskripts</b> | <b>100</b>        | 0                    | 0                  | 0                       | 0                                    | 100       |
| Korrektur des Manuskripts         | 0                 | 5                    | 5                  | 10                      | 80                                   | 100       |

Aus diesem wesentlichen Anteil ergibt sich selbstverständlich die Stellung als Erstautorin.

---

Beatrice Coldewey (Doktorandin und korresp. Autor)

Als Doktormutter bestätige ich die Angaben von Beatrice Coldewey.

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Jun.-Prof. Dr.-Ing. Myriam Lipprandt (Doktormutter)

Ich schließe mich der Erklärung von Jun.-Prof. Dr.-Ing. Myriam Lipprandt als Koautor an.

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Anne Marie Klöckener

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Dr. Christof Göbel

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Prof. Dr. Rainer Röhrig

## Erklärung gemäß § 5 Abs. (1) und (2), und § 11 Abs. (3) 12. der Promotionsordnung

Hiermit erkläre ich, **Beatrice Coldewey**, an Eides statt, dass ich den wesentlichen Anteil an der Publikation:

**Coldewey B**, Klausen A, Otto-Sobottka F, Röhrig R, Lipprandt M: Usability of Automated External Defibrillators: A Randomized, Comparative Simulator Study. Int. J Hum-Comput Int. 2023.

40(22),6972–6983. doi: 10.1080/10447318.2023.2260973

geleistet habe.

Die Anteile an der Arbeit waren wie folgt:

|                                   | Beatrice Coldewey | Dr. Andreas Klausen | Dr. rer. nat. Fabian Otto-Sobotka | Prof. Dr. Rainer Röhrig | Jun.-Prof. Dr.-Ing. Myriam Lipprandt | Summe (%) |
|-----------------------------------|-------------------|---------------------|-----------------------------------|-------------------------|--------------------------------------|-----------|
| Idee                              | 0                 | 10                  | 0                                 | 40                      | 50                                   | 100       |
| Studiendesign/ Konzeption         | 70                | 5                   | 5                                 | 10                      | 10                                   | 100       |
| Datenerhebung                     | 50                | 40                  | 0                                 | 5                       | 5                                    | 100       |
| Datenauswertung                   | 70                | 10                  | 5                                 | 5                       | 10                                   | 100       |
| Interpretation der Daten          | 70                | 10                  | 0                                 | 5                       | 15                                   | 100       |
| <b>Verfassung des Manuskripts</b> | <b>100</b>        | 0                   | 0                                 | 0                       | 0                                    | 100       |
| Korrektur des Manuskripts         | 0                 | 5                   | 5                                 | 15                      | 75                                   | 100       |

Aus diesem wesentlichen Anteil ergibt sich selbstverständlich die Stellung als Erstautor / in.

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Beatrice Coldewey (Doktorandin)

Als Doktormutter und korrespondierende Autorin bestätige ich die Angaben von Beatrice Coldewey.

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Jun.-Prof. Dr.-Ing. Myriam Lipprandt (Doktormutter und korresp. Autor)

Ich schließe mich der Erklärung von Jun.-Prof. Dr.-Ing. Myriam Lipprandt als Koautor an

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Dr. Andreas Klausen

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# Beatrice Coldewey

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## Curriculum Vitae

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### Berufliche Tätigkeit

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- Okt. 2016 – Juli 2019 Studentische Hilfskraft  
*Abteilung Medizinische Informatik, Carl von Ossietzky Universität Oldenburg*
- Sep. 2015 – Dez. 2015 Betreutes Praxisprojekt im Rahmen der Bachelorarbeit  
*Fraunhofer-Institut (Projekt CoCoo)*
- Sep. 2013 – Apr. 2015 Studentische Hilfskraft  
*Fachbereich Bauwesen Geoinformation Gesundheitstechnologie, Jade Hochschule Wilhelmshaven/Oldenburg/Elsfleth*
- Aug. 2011 – Juli 2012 Freiwilliges Soziales Jahr  
*KfH Kuratorium für Dialyse und Nierentransplantation e. V.*

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### Ausbildung und Studium

- Apr. 2017 – Sep. 2019 Master Informatik · Master of Science  
*Carl von Ossietzky Universität Oldenburg*
- Apr. 2016 – März 2017 Bachelor Informatik · Angleichungssemester für Master  
*Carl von Ossietzky Universität Oldenburg*
- Sep. 2012 – Feb. 2016 Bachelor Assistive Technologien · Bachelor of Engineering  
*Jade Hochschule Wilhelmshaven/Oldenburg/Elsfleth*
- Aug. 2004 – Juli 2011 Abitur  
*Herbartgymnasium Oldenburg*

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### Fortbildungen

- 2024 GCP Refresher
- 2023 Zertifikatskurs Forschungsmanager\*in
- 2022 UXQB Certified Professional for Usability and User Experience – Foundation Level (CPUX-F)
- 2020/2021 GCP Basiskurs & Aufbaumodul AMG/MPG