EasyChair Preprint

№ 13726

Proposing Heuristic Guidelines for Auditory Interfaces in Medical Device Usability Evaluation

Junghoon Shin, Kyungwoo Kwon and Kiechan Namkung

July 1, 2024

Proposing Heuristic Guidelines for Auditory Interfaces in Medical Device Usability Evaluation

Junghoon Shin[1][0009-0007-9633-7888], Kyungwoo Kwon[1]

and Kiechan Namkung[2][0000-0003-4009-4892]

[1] Interaction Design Lab. TED, Kookmin University, Seoul 02707, Republic of Korea
[2] Department of AI Design, Kookmin University, Seoul 02707, Republic of Korea;
soundux@kookmin.ac.kr

Abstract. This research introduces heuristic guidelines for evaluating auditory interfaces in medical devices, focusing on integrating often-neglected auditory evaluations in usability assessments. Utilizing the IEC 60601-1-8 standard, pivotal auditory components impacting device safety and efficiency were identified and structured into a heuristic framework. The process involved expert user experience professionals using closed card sorting to draft and refine these guidelines, supported by further expert reviews. The study underscores the capability of these guidelines to uncover previously undetected usability and safety issues in medical devices, marking significant progress in incorporating comprehensive auditory interface assessments into usability evaluations. This advancement is vital for enhancing the effectiveness of user-centered medical device designs, providing a structured approach to integrating auditory interface evaluations that have been historically overlooked in the field.

Keywords: Usability, UEQ-MD, Medical device, Auditory Interface, Formative Evaluation, Heuristic Guidelines

1. Background

For many years, the field of medical device design has emphasized systematic safety design to ensure patient safety [1]. The consideration of usability and user experience (UX) in medical device design can enhance efficiency and safety. However, research in this area has not been vigorously pursued [2]. Recently, the importance of user-centered design in medical devices has been increasingly emphasized, supported by the rise in international standards related to usability [3][4][5][6]. Most countries now require usability evaluations as a mandatory component to validate these international standards. Currently, usability evaluations predominantly focus on the interaction with visual user interfaces of devices equipped with displays, whereas evaluations related to auditory interfaces are relatively underdeveloped.

The evaluation of auditory interfaces in medical devices involves assessing a range of sound environments, not merely identifying sources of high noise levels [7]. The standard IEC 60601-1-8 [8] addresses auditory and voice alarm signals in medical

electrical equipment, detailing aspects related to safety and effectiveness. However, these guidelines are challenging to apply in real-world usability evaluation settings.

The aim of this research is to assess auditory interfaces in medical devices to facilitate designs that are both efficient and safe. This involves applying heuristic evaluation principles and the Medical Device User Experience Questionnaire (UEQ-MD) derived from previous studies to propose heuristic principles for evaluating auditory interface during formative usability testing of medical devices.

2. Literature Review

2.1 Usability Evaluation Process and Standards for Auditory Assessment

Medical device usability evaluation is classified into formative and summative assessments. It is recommended to conduct at least one formative evaluation before the summative assessment, and it is effective to perform small-scale formative evaluations 2-3 times [9]. Evaluating user interfaces requires significant resources, hence simpler methods like expert review are beneficial during formative evaluations [10].

The IEC 60601-1-8 standard, which mentions specific frequencies, rise and fall times, waveforms, sound levels (dB), pulse widths, repetition rates, and harmonics, addresses the auditory specifications related to medical devices [8]. However, these details mostly cover the acoustic aspects of auditory alarm signals, and methods evaluating emotional responses from users are not provided. Additionally, the specifications allow manufacturers to adjust settings, which complicates the effective evaluation of auditory interfaces in practice.

2.2 Heuristic Evaluation and UEQ

Heuristic evaluation is a widely used expert evaluation method in the field of user experience, where experts use established principles to inspect interfaces and identify usability issues, evaluating aspects such as severity, frequency, and importance [11]. This method is cost-effective and intuitive, suitable for early development stages. The Food and Drug Administration (FDA) has proposed heuristic analysis as an analytical approach to review and evaluate user interactions with devices [12]. While heuristic evaluation is an effective method for preliminary identification of usability issues in medical device interfaces, it is not yet a standard method in medical device usability evaluations [13].

The User Experience Questionnaire (UEQ) serves as a tool for directly and rapidly assessing product user experience, offering modular scales that can be customized for specific research questions [14]. This reliability and validity make it a complement to other evaluation methods [15]. Specifically, the Medical Device User Experience Questionnaire (UEQ-MD) has been developed to reflect the particular characteristics of medical devices[17], comprising scales for dependability, efficiency, Perspicuity, Trust, Result quality, and usefulness. Each scale evaluates aspects of user experience essential for assessing the usability of medical devices.

3. Method

This study aimed to define heuristic evaluation principles for auditory interface in medical device design. To achieve this, eight user experience experts were engaged to identify auditory evaluation factors and conduct closed card sorting. The resulting heuristic guideline were subsequently verified and refined with three experts. The development of heuristic guideline can be validated and improved based on feedback from 3-5 experts [11][16].

3.1 Extraction of Auditory Interface Evaluation Factors Based on Standards

Evaluation key factors were derived based on the IEC 60601-1-8 standard, which covers auditory and alarm signals for heuristic evaluation. This included considerations of safety and effectiveness as specified in the standard, encompassing auditory elements that significantly impact the safety and performance of medical devices.

3.2 Closed Card Sorting According to UEQ MD Classification

The identified key evaluation elements were classified into six categories as specified by the Medical Device User Experience Questionnaire (UEQ MD) using closed card sorting techniques.

3.3 Expert Evaluation and Validation

The auditory experience of dermatological medical devices was evaluated by three experts (eee Table 1). These experts used the derived auditory heuristic principles for evaluation, recording any issues identified during the process. Post-evaluation, feedback was collected to refine and amend the heuristic principles.

Table 1. Profile of Experts.

No.	Occupation	Experience	Education
1	Usability Engineer for MD	8 years	Master's degree
2	UX Designer	14 years	Doctoral candidate
3	Auditory UX Designer	20 years	Ph.D

4. Result

4.1 Derivation of Auditory Interface Evaluation Factors Based on Standards

The study reviewed the guidelines and annexes of the IEC 60601-1-8 standard[8], assessing the requirements for auditory and alarm signals in medical devices. This review led to the identification of 27 auditory interface evaluation factors (see Table 3).

Table 3. Auditory Interface Evaluation Factors based on Standards(IEC 60601-1-8).

Scale	Description
Subclause A. General Guidelines and Basis (14)	Clarity of alarms / Perception of urgency and severity / Signal distortion / Consistency of signal quality / Signals according to risk levels / User awareness time / Rapid recovery in case of errors / Consistent signal cycles / Distinct error guidance signals / Awareness of start and end of visual interface operations / Signals considering the operating environment / Simultaneous operation of alternative signals besides auditory signals / Location and device identification capability / Promptness of alarms and signals
Subclause B. Marks and Labels for ME Equipment and ME Systems (3)	Practicality of information / Accessibility of information access / Use of standard terminology
Subclause C. Indicator Symbols (3)	Consistency and integration of visual interface / Help for signals / Guidance for indicators other than signals
Subclause D. Guidelines for Auditory Alarm Signals (1)	Volume, frequency, and alarm frequency adjustment
Subclause E. Speech Alarm Signals (3)	Differentiation between multiple alarm systems / Validity of auditory alarm signals / Priority between signals
Subclause G. Auditory Alarm Signals (3)	Number of auditory and alarm signals / Validity of alarm signals / Operability of emergency signals

4.2 Derivation of Auditory Interface Evaluation Factors Based on Standards

The identified 27 auditory evaluation factors were classified according to the UEQ MD scale, and each factor was defined. After drafting a heuristic guideline for auditory interfaces, an expert evaluation was conducted on medical devices. This evaluation uncovered a total of 32 issues that were difficult to detect with previous methods, indicating that auditory heuristic principles could significantly enhance the usability and safety of user interfaces.

Further, expert reviews suggested the need to re-evaluate the appropriateness of the UEQ MD scale and the classification of evaluation factors. Ultimately, the heuristic evaluation factors and their detailed definitions for auditory interfaces were refined and presented in Table 4.

Table 4. Evaluation factors of auditory interface classified UEQ MD Scale

Scale	Evaluation Factors of auditory interface	Definition
Controllability	Guidance for indicators other than signals	Does the system provide signals other than alarms to allow users to quickly identify system-related errors?
	Rapid recovery in case of errors	Are appropriate instructions provided to users in case of errors?
	Volume, frequency, and alarm frequency adjustment	Does adjustment of alarms and signals enable flexible handling in the operating environment?
Efficiency	Number of auditory and alarm signals	Are appropriate alarm signals and the number of signals provided to prevent user confusion?

	User awareness time	Are sounds that are easy to perceive in a medical environment provided to allow users to quickly recognize the device?
Learnability	Distinct error guidance signals	Are error-related signals clearly distinguished from general event signals and delivered clearly?
	Signals according to risk levels Priority between signals Perception of urgency and severity	Is the priority between signals clear according to the risk level, allowing users to perceive urgency and severity?
	Use of standard terminology	Are standard words used to ensure that users can understand the intended messages
	Validity of alarm signals Clarity of alarms	Are alarm signals clear and effectively audible to users?
	Awareness of start and end of visual interface operations	Are signals for starting and ending operations clear?
	Validity of auditory alarm signals	Is the effectiveness of auditory alarm signals (intensity. voice format, pronunciation, emotional response, etc.) such that users can quickly understand the alarms?
	Differentiation between multiple alarm systems	Can important alarms be quickly identified in situations where multiple alarms are sounding?
Trust	Operability of emergency signals	Does the device operate quickly in emergency scenarios to respond promptly to urgent situations?
	Consistent signal cycles Consistency of signal quality Signal distortion	Are signals output consistently in terms of cycle and quality to avoid confusion in alarms?
	Promptness of alarms and signals	Do alarms and signals operate promptly without delay?
Result Quality	Simultaneous operation of alternative signals besides auditory signals	Do alternative feedback mechanisms outside of auditory and alarm signals operate accurately?
	Awareness of start and end of visual interface operations	Is the information provided consistent between auditory and visual interfaces?
Usefulness	Signals considering the operating environment	Are alarm sounds clear and audible without interference from ambient noise, allowing them to be distinguished quickly without confusion with alarms from other situations?
	Help for signals Practicality of information Accessibility of information access	Does the system enhance user understanding of alarms and enable them to take appropriate actions?
	Location and device identification capability	Does the system allow for recognition of location or individual patients through alarms?

5. Result

This research developed a heuristic guideline for assessing auditory interfaces in formative usability evaluations of medical devices, analyzing standards and annexes to identify evaluation factors categorized by the previously established UEQ-MD scale. The guidelines, refined through expert evaluations into a questionnaire format, introduce the first system capable of integrating auditory interface assessments into medical device usability evaluations—an area previously unexplored. While implementing these guidelines may expose unforeseen issues, marking a limitation of this study, future research aims to use these guidelines for actual evaluations, seeking to create a more systematic and reliable framework.

1 References

1. Donaldson, M. S., Corrigan, J. M., & Kohn, L. T. (Eds.). (2000). To err is human: building a safer health system.
2. Bitkina, O. V., Kim, H. K., & Park, J. (2020). Usability and user experience of medical devices: An overview of the current state, analysis methodologies, and future challenges. International Journal of Industrial Ergonomics, 76, 102932.
3. International Organization for Standardization. (2016). ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes.
4. International Electrotechnical Commission. (2005). IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance. Edition 3.0.
5. International Electrotechnical Commission. (2020). IEC 62366-1:2015/AMD1:2020 Medical devices- Part 1: Application of usability engineering to medical devices. Amendment 1.
6. International Electrotechnical Commission. (2016). IEC TR 62366-2:2016 Medical devices - Part 2: Guidance on the application of usability engineering to medical devices.
7. Ruettgers, N., Naef, A. C., Rossier, M., Knobel, S. E., Jeitziner, M. M., Gerber, S. M. (2022). Perceived sounds and their reported level of disturbance in intensive care units: A multinational survey among healthcare professionals. Plos One, 17(12), e0279603.
8. International Electrotechnical Commission. (2006). IEC 60601-1-8 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems.
9. GE HealthCare. (2020). Alarm Management White Paper. Available online at: https://clinicalview.gehealthcare.com/white-paper/alarm-management-white-paper
10. Ministry of Food and Drug Safety (MFDS). (2017). Practical Guide on Common Standards for Electrical and Mechanical Safety of Medical Devices. Available online at: https://www.mfds.go.kr/brd/m_218/view.do?seq=30856
11. Nielsen, J., & Molich, R. (1990). Heuristic evaluation of user interfaces. In Proceedings of the SIGCHI conference on Human factors in computing systems, pp. 249-256.
12. Food and Drug Administration. (2011). Applying Human Factors and Usability Engineering to Medical Devices. Guidance for Industry and Food and Drug Administration Staff. Available online at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices
13. Roma, M. S. G., & de Vilhena Garcia, E. (2020). Medical device usability: Literature review, current status, and challenges. Research on Biomedical Engineering, 36, pp. 163-170.
14. Sularsa, A., Prihatmanto, A. S., & Nugroho, E. (2015). Evaluasi User Experiences Produk iDigital Museum dengan Menggunakan UEQ. Jurnal Teknologi Informasi, 2(2), pp. 56-62.
15. Laugwitz, B., Held, T., & Schrepp, M. (2008). Construction and evaluation of a user experience questionnaire. In HCI and Usability for Education and Work: 4th Symposium of the Workgroup Human-Computer Interaction and Usability Engineering of the Austrian Computer Society, USAB 2008, Graz, Austria, November 20-21, 2008. Proceedings 4, pp. 63-76. Springer, Berlin Heidelberg.
16. Quiñones, D., Rusu, C., & Rusu, V. (2018). A methodology to develop usability/user experience heuristics. Computer standards & interfaces, 59, pp. 109-129.
17. Lindemann, Magdalena; Weber, Helene (2023). UX in Zahlen: Der User Experience Questionnaire for Medical Devices. In: Usability Professionals 23, Gesellschaft für Informatik e.V., Rapperswil, September 3-6, 2023. DOI: 10.18420/muc2023-up-455.