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# Usability in the lifecycle of medical software development

## A current view on human-centered design activities in German enterprises

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**Abstract:** A close cooperation with users is necessary to ensure that interactive systems are robust, easy to use and accepted. Therefore, in medical technology, standards for usability are of fundamental importance. We investigated with the presented study how the concept of usability is currently understood and implemented in medical software companies. Interviews were conducted with 21 employees of German enterprises. Furthermore we extended an already existing quantitative online survey where 53 companies (including 24 from the health industry sector) participated in. Results show that the importance of usability is recognized by most of the respondents. Moreover, a wide variety of methods and approaches is known and implemented for exploring user needs and evaluating system prototypes. However, it was observed that human-centered design activities mainly focus on functionality, risk prevention and accessibility. Hedonic user needs and subjective perceptions ("user experience") still play a minor role. Based on the results, practical requirements are derived and a "best case" for methodological approach is introduced.

**Keywords:** medical software development process; usability-methods; user experience.

## 1 Introduction

The medical technology market has been growing for many years. Forecasts of annual growth rates confirm that this trend will be maintained in the next 5 years for the global market (5.0%–5.2% per annum) [1]. Medical technology is also one of the most innovative industries with about 11.000 patent applications in Europe [2]. The growing demand is caused by demographic changes, aging societies and an increasing use of interactive technologies, smart devices, software, and mobile applications [i.e. 3–5].

The most important key to success for medical technology is the close cooperation with its users. A human-centered design approach helps to prevent incorrect operations through optimizing the usability at early stages of product development. Usability comprises "the effectiveness, efficiency and satisfaction with which specified users achieve specified goals in particular environments" [6]. The complete documentation of a usability-oriented design process is a necessary precondition for successful authorization procedures of medical devices [6]. Therefore, a conscientious realization of relevant standards is of fundamental importance in medical technology.

However, standards are rather general in this sector, basically determining the main requirements for products and usability-oriented procedures. So it is often up to the developer to decide which methods and instruments will be implemented for exploring specific contexts of usage as well as for evaluating product solutions. Standards neither describe the extent of measures nor when the process will be completed. Moreover, standards do not specify disciplinary background and expertise of the for the sector responsible employees.

These preconditions led to the research question how usability standards are currently implemented in German medical technology. A sub-goal was to identify perceived barriers in the realization of usability-oriented activities. A third goal was to investigate whether the consideration of an appropriate "user experience" is an important aspect in the development of medical software solutions. While usability is mainly performance oriented, user experience also includes "soft criteria" such as appearance and feelings, user emotions and motivation, acceptance as well as integrating the product in everyday life.

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# 2 Material and methods

## 2.1 Method

21 Telephone interviews with German medical software producing companies were conducted. 11 enterprises were small or medium-sized (SME) and 10 were large. For the interview a semi-standardized interview guide was developed. Questions included the main phases of the software development process and the applied usability methods. Furthermore, respondents were asked to assess the importance of different product attributes. At the end, barriers and problems regarding the implementation of usability methods were collected.

## 2.2 Results

The results show that on a scale from 1 ("no knowledge") to 5 ("highest knowledge") respondents evaluate their knowledge about usability slightly higher than their practical experience with usability ($M = 3.48$ vs. $M = 3.10$).

Based on a synopsis of all the information about the three main phases of product development provided by the interviewees a summarized best case model for human-centered design methods was created (see Figure 1).

Post hoc, the main phases were categorized as *context of use and specification* (1), *design and testing* (2) and *reverse engineering* (3). In Figure 1 the applied usability methods are shown next to the main phases. The percentages of the invested resources (time, financial costs and human resources) show that most of the resources are located in the second phase *design and testing*. According to the user-centered design process [7], iteration cycles within the first two phases might be necessary.

When comparing small or medium-sized businesses (SME) with large enterprises, it was apparent that the practical experience of implementing usability measures is significantly higher in case of large enterprises ($d = 1.07$, $p = 0.03$). Moreover, in large medical software enterprises the number of usability employees is significantly higher ($d = 2.39$, $p = 0.03$). While large enterprises employ nine usability professionals on average, SME only employ five.

With respect to the percentage distribution of invested resources, SME tend to invest most of their usability budget in the *design and testing* phase, while large companies use the budget approximately equally distributed over the three main phases. Especially for the *context of use and specification* (phase 1), large enterprises are in a position to

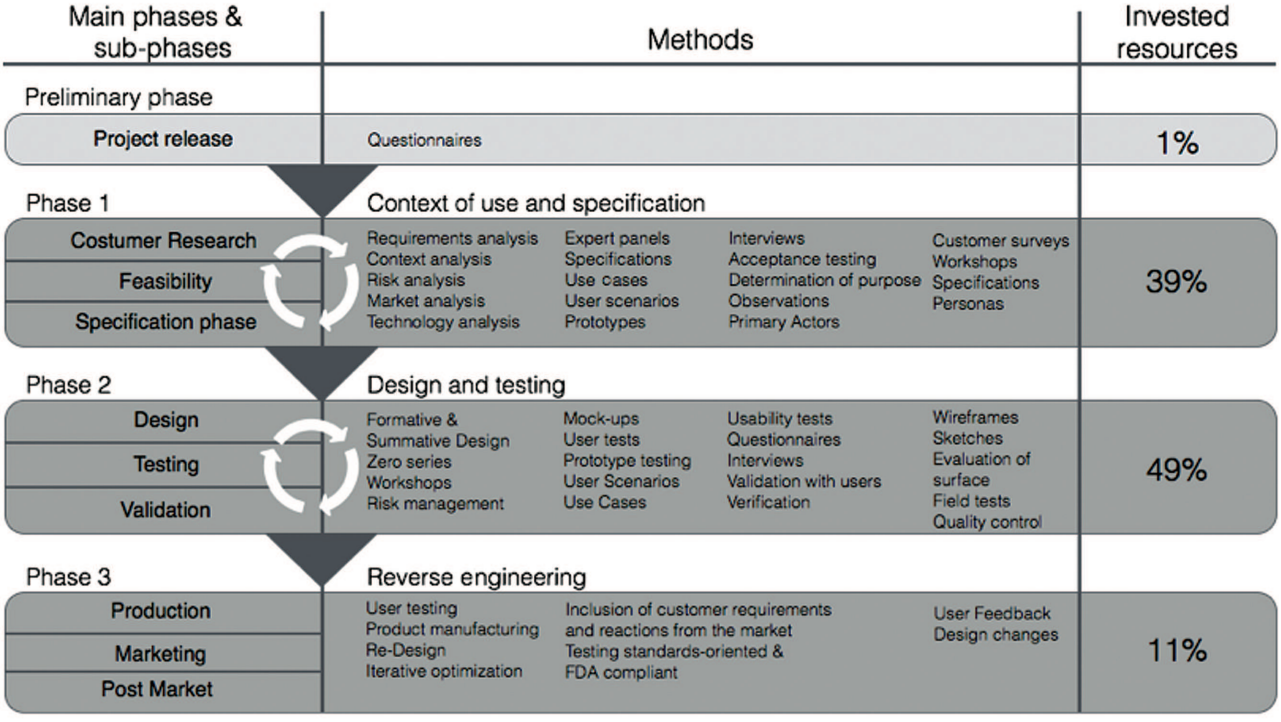


**Figure 1:** Best case model for named human centered design methods divided in main/sub-phases, usability-methods and invested resources.

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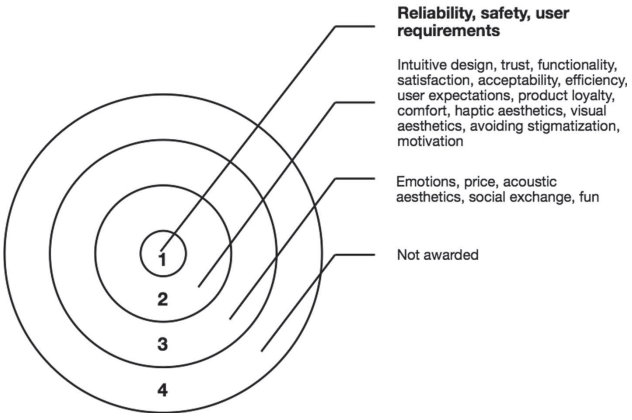


**Figure 2:** Importance of product aspects within usability-practice: 1 = very important; 2 = fairly important; 3 = rather unimportant; 4 = very unimportant (this category is not occupied).

invest a greater proportion of their budget (29% vs. 20.5% for SME).

When asked about the importance of different product related aspects, interviewees assessed *reliability*, *safety* and *user requirements* as most important aspects in the development of medical software solutions, while hedonic product attributes, such as *emotions, fun* and *motivation* are of lower importance (see Figure 2).

The most important problems and barriers of the interviewees for the implementation of usability-methods mentioned were:

- Lack of acceptance of usability
- Lack of resources
- Lack of evidence of the usefulness of usability
- Lack of communication within the organisation
- Early integration of usability in the product development process.

# 3 Online survey

## 3.1 Methods

The online survey aimed to compare the view on usability between the medical technology industry and other industries. For the assessment of usability-related aspects an online self-test developed by the *Usability in Germany e.V.* has been used. This online test is based on the Usability Maturity Model of Woywode et al. [8] and contains 15 items, measuring for example the *usability-acceptance*, and the *use of standards*. The self-test is available under the following link: http://www.usability-in-germany.de/aktuelles/usability-selbsttest. In the present study 24 medical software companies and 29 software companies from a non-medical background participated.

## 3.2 Results

The statistical analysis shows that the usability-acceptance is significantly higher in case of the medical software companies ($p = 0.03$). Furthermore, the interviewed medical software companies evaluated the number of applied methods higher than the companies in other areas ($p = 0.02$). No other differences are statistically relevant.

# 4 Discussion

The growing importance of usability is reaching a high level of awareness in the field of medical technology, as our results indicate. Compared to other industries medical companies stated a higher usability acceptance. In addition, respondents assessed their knowledge and practical expertise more than the average. First and foremost human-centered design methods are applied in order to enhance safety and to prevent errors in patient's treatment. Based on the results a best case model was introduced illustrating that a wide range of well-established methods are known and used at different stages of the software development lifecycle.

Nevertheless, the interview study also revealed that certain barriers and problems are perceived. In particular, the lack of acceptance on management level and very limited resources were reported by most of the respondents. In practice, both aspects are frequently interrelated with the lack of an objective, reliable, and holistic criterion of success for human-centered design activities [9]. Future research has to find appropriate solutions in providing low-threshold procedure models which offer the opportunity to gain a realistic view on the outcome of usability measures [10].

Large companies as well as SME have recognized the importance of design and testing medical software solutions. The underlying trend shows that SME invest slightly less of their usability resources in early development phases. Engaging end users in early stages is not only valuable for finding innovative product solutions, but also a fundamental base for determining, validating, and prioritizing functional as well as non-functional requirements from a user's point of view. Since the best case model is a synopsis of all the information provided

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by the interviewees, it should be noted that all companies which participated in the study differ more or less in their individual number of methods and the proportions of invested resources. Therefore, the positive comprehensive view must not hide the fact that some health systems are developed without regard to user requirements, or without the aid of any user-centered design guidelines [11].

Finally, the findings of the study show that the concept of "user experience", including the consideration of non-task related product attributes, is a slightly unattended area in medical technology. However, the systematic investigation, design, and evaluation of a consistent user experience is not only an essential factor for maintaining competitive advantages in the market. For most interactive technologies it rather represents a very important key aspect that determines if a product is used at all and therefore directly influences the effectiveness of a patient's treatment. A coherent experience is necessary for stimulating motivation and intention to use, e.g. in the case of medical products that patients have to apply for themselves over a longer period. Moreover, positive experiences during interaction with a system may contribute to dispel fears and prejudices that may be associated with specific treatments. While by now the concept of usability seems to be widely recognized in medical technology, user experience has to be considered even more in the future. There is a need for adapting and developing specific methods and instruments for measuring subjective experiences with interactive medical products. Extended guidelines and standards should help developers to integrate user experience more efficiently in the product design and evaluation process. Current efforts in bringing together basic requirements for the development of medical software by unifying different standards is a first step (i.e. *Medical Spice, VDI*). However, the consideration of a holistic experiential perspective is a challenging demand that still is to be met in the future.

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## References

[1] Evaluate (n.d.). Total medical technology growth per year from 2008 to 2020. Statista - The Statista Portal. Available from http://www.statista.com/ statistics/320948/worldwide-medical-technology-growth-per-year/. Retrieved April 5, 2016.

[2] MedTech Europe (n.d.). The European Medical Technology industry in Figures. Retrieved April 5, 2016, from http://www.medtecheurope.org/sites/default/files /resource_items/files/MEDTECH_FactFigures_ONLINE3.pdf.

[3] Rieger A, Friess H, Martignoni ME. 15 Augmented Reality–Realität und Virtualität in der Medizin. Der virtuelle Patient 1 2014.

[4] Minge M, Lorenz K, Dannehl S, Trauzettel F, Thüring M. U (X) in Health Design. State-of-the-Art und Herausforderungen bei der nutzer-gerechten Gestaltung therapeutischer Unterstützungssysteme. Mensch und Computer Workshopband; 2015.

[5] Kramme R, Kramme H. Die Rolle der Technik in der Medizin und ihre gesundheitspolitische Bedeutung. Medizintechnik—Verfahren, Systeme und Informationsverarbeitung: Ein anwenderorientierter Querschnitt für Ausbildung und Praxis 3 2013.

[6] DIN EN ISO 62366. Medizinprodukte – Anwendung der Gebrauchstauglichkeit auf Medizinprodukte. Berlin: Beuth Verlag; 2008.

[7] EUROPÄISCHE NORM, E. N. ISO 9241-11: Ergonomische Anforderungen für Bürotätigkeiten mit Bildschirmgeräten; Teil 11: Anforderungen an die Gebrauchstauglichkeit-Leitsätze. DIN Deutsches Institut für Normung eV. 1999.

[8] Woywode M, Mädche A, Wallach D, Plach M. Gebrauchstauglichkeit von Anwendungssoftware als Wettbewerbsfaktor für kleine und mittlere Unternehmen (KMU): Abschlussbericht; 2012.

[9] Reckin R, Schweig J, Brandenburg S. Performance indicators for usability measures – Striving for a working framework beyond Return on Investment. 11. Berliner Werkstatt Mensch-Maschine-Systeme Tagungsband; 2015.

[10] Stade MJ, Reckin R, Brandenburg S, Thüring M. Usability in KMU etablieren: Von schneller Problemlösung zu ressourcenorientiertem Usability Engineering. In: Mensch & Computer Workshopband; 2013. p. 19–27.

[11] Anders SH, Dexheimer JW. Incorporating usability testing into the development of healthcare technologies. Social Media and Mobile Technologies for Healthcare; 2014;32.

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