Usability Engineering in software user interfaces for medical devices

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Abstract:
This paper explains the basics of implementation of usability engineering in the design of medical device interfaces in accordance with international standards. It also presents design factors and guidelines for creating software user interfaces, including the optimization of construction of prototypes and testing process.

Keywords-component: usability of medical software interfaces, prototyping medical interfaces

I. INTRODUCTION

The percentage of medical devices where interaction takes place through software user interfaces is increasing. This situation is caused mainly by lowering the cost of production of devices based on microprocessors and growing market demand. There are new opportunities in this area, for example enriching the functions of the device by updating the operating system without the need for expensive replacement of components. It is of great economic importance to manufacturers. The popularity of modern mobile devices like smartphones or tablets has also a big impact, which resulted in the emergence of new methods of interaction and possibilities. Many users have become accustomed to flexible adjustment of the appearance and features of the user interface to suit their needs. Regardless of the complexity of the medical device interface, it should facilitate user’s tasks, protect against errors, and satisfy customers.

A. Basics of Usability Engineering

According to the ISO 9241 standard, usability is defined as the product’s attribute specifying the ease of use. It is described by the measure of effectiveness (can the goal of user be fully achieved), efficiency (what is the cost of achieving the goal), and satisfaction (which emotions, reactions are triggered in the user interaction with the device). Usability engineering is a subarea of ergonomics - an interdisciplinary science concerning adapting working conditions to human capabilities. It is associated with other sciences, including psychology, human factors, anthropology, etc.

Low usability of the products is a very common cause of their market failure. Users are dissatisfied with the usage of the product and rate it bad. In the end it gives a poor sales and low profit to a developer. In the worst case, it causes the total loss and the need to withdraw the product from the market. It also generates additional costs in dealing with dissatisfied users, complaints, and the necessity to redesign an existing product/service. This situation significantly weakens the image and confidence in the brand.

For medical device manufacturers the stake is much higher. For example, based on the method how medical device interface informs the user about the critical event and what action is proposed, the human health and life may be endangered. Numerous studies have confirmed that the low usability of medical device interfaces has a significant impact on the growth of the use errors and it is a threat to patients [1]. This have led
organizations such as the Food and Drug Administration (FDA), International Electrotechnical Commission (EIC) and the International Organization for Standardization (ISO) to make the following guidelines and standards concerning the process of implementing usability engineering in the design of medical device interfaces.

**B. Basics of the Standard of Usability Engineering for Medical Devices**

The standard ISO/IEC 62366: Medical Devices - Application of Usability Engineering to Medical Devices is replacing the older ISO/IEC 60601-1-6: Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability. The new standard requires that the manufacturers of medical devices deploy Usability Engineering Process based on a User-Centered Design. This standard applies not only to the device itself, but also to documentation and training materials associated with the device. The new norm extends to all medical devices (previously it was applied only to electrical medical devices). The standard can also be a guide in the process of implementation of the principles of usability, because it contains many annexes with detailed examples of the application of the methods.

Ensuring compliance with the standard in order to implement usability engineering is a process where technical skills are only a part of a bigger image. It is an interdisciplinary approach consisting of various stages: design, evaluation, testing, and validation of the proposed solutions. The manufacturer must carefully determine how to ensure high usability and how to minimize the risks associated with interaction with the system.

According to the above standard [2], the implementation of usability engineering process for medical devices is composed of several stages:

- Application of the medical device; it defines the key features associated with the use of devices such as intended medical indication, population and profile of the patients, context of use, and basic operating principle.
- Identification of frequently used functions of the device; it allows paying special attention to these features, which if designed properly could significantly reduce operating errors.
- Identification of risks and hazardous situations associated with the usability; it assumes the analysis of characteristics of the device in terms of impact on the risk of misuse and allows identification of existing and anticipated risks associated with interaction with the device’s interface.
- Identification of the primary operating functions of the device; it concerns features which have a direct impact on the safety of the device, including previously mentioned frequently used functions.

Developing usability specification. This step defines the testable requirements for verification of the usability of the interface. For this purpose there should be prepared use scenarios and goals that must be achieved by the user. The most important element is to provide requirements determining whether the user has any difficulties in understanding the basic functionality of the device.

- Preparation of usability validation plan; it defines the methods and criteria for evaluation and validation of the primary functions of the device in terms of the predetermined usability specification. It is also necessary to determine a representative group of users of the device. Validation methods can be both
qualitative and quantitative. Tests should be carried out in a laboratory environment that simulates the real environments.

- Design and implementation of the user interface; it is the iterative process of user interface design including frequent verification, which takes place during whole development cycle.

- Verification of the user interface usability. This process is carried out on the basis of a predetermined specification of usability. It can be based on user tests and heuristic evaluation.

- Validation of the medical device usability. This task takes place at the last stage of development and assumes that the usability test will be conducted based on a validation plan. The validation should be carried out by people who are not directly involved in the design and development of the user interface. In the case of a negative assessment, the producer must redesign the device and repeat the processes of verification and validation.

The steps presented above concerning implementation of the usability engineering process must be documented in the Usability Engineering File, especially prepared for this purpose. It is a proof that the manufacturer complies with the guidelines described in the standard, and it provides an effective audit of the entire process. The process itself and its elements are iterative.

II. METHODS FOR DETERMINING THE INITIAL REQUIREMENTS FOR A MEDICAL DEVICE USER INTERFACE

Teams responsible for the design and construction of a new medical device must work in parallel on the development of the technology and the implementation of the interface. Requirements related to the usability should be a part of the functional and technical specification of the device. Unsynchronized cooperation between experts of different fields often leads to the necessity of making changes, which is especially costly if introduced in the late development stages of the project. According to the above standard it is necessary to determine requirements related to the primary functions and applications of the device, the context of its use, the requirements of users, patients’ population and potential risks arising from improper interaction with the interface. There are many helpful methods such as focus groups (consisting of future device users, experts and developers), the participatory observation of users in their real working environment, and cognitive walkthrough (usability experts run through specially designed tasks within interface). The proposed methods allow better understanding the users, who often have problems with articulation of what features they really need and how they expect to interact with the interface.

The designers of software user interfaces for medical devices must also be aware of the initial conditions, which are independent of the users' requirements.

III. BASIC FACTORS INFLUENCING SOFTWARE USER INTERFACES FOR MEDICAL DEVICES

One of the main criteria which influence the design of the software user interfaces is the functional complexity of medical devices.

Another important factor is the size of the device, mostly because it affects the size of the interface screen. Large displays provide more information on one screen, while the smaller ones force designers to use a series of related screens for this purpose.
Another hardware factor is the type of power supply unit; the device can be permanently connected to the AC power or be battery operated. This may determine the type of the display technology.

Development tools used for implementation have also significant impact on the design of medical interfaces. This explains the similarity of many interface elements to those known from the popular operating systems. The positive side of this process is production cost savings and the ability to utilize user’s habits. The negative side is further propagation of the shortcomings of existing interfaces and the lack of optimization of the specific requirements for medical devices.

IV. GUIDELINES FOR THE DESIGN OF SOFTWARE USER INTERFACES FOR MEDICAL DEVICES

Guidelines concerning the design of software user interfaces for medical devices are largely based on norms and standards concerning Human-Computer Interaction. The literature [3] presents very precise specifications and requirements for the various elements of the user interface. The most important aspects that are essential in the process of determining guidelines for the medical device are:

- Conceptual model. It should be created at the beginning of the development process of the interface; it allows determining how the target audience imagines interacting with the device. Such a model should assume the use of a minimum number of features and components necessary to operate the device. The interface model should focus on the user task rather than on the internal structure and logic of the device.

- Structure of the interface; it should depict the conceptual model and be in line with the perceptual abilities of users. Particularly noteworthy is the screen hierarchy and navigation through it, which should support the user in finding critical and frequently used functions.

- Style of interaction; it has a very large impact on intuitiveness and efficiency of the user interface. In many cases the type of interaction depends on the chosen technological solutions. For this reason the decision of choosing the style of interaction should be taken at an early stage of the development of the interface concept. Interaction style should be tailored to the context of its use and the aspects of ergonomics.

- Layout of screen; it determines not only aesthetic values but also the quality of interaction with the device. It is difficult to describe one specific pattern that has proved to be good in every situation.

Therefore, it is important to take into account basic guidelines related to the design of a useful user interface, then make several prototypes, and test them in order to find the best solution.

- Legibility of interface elements; misreading critical information displayed on the screen may have very serious consequences for the patient. Because of this it is necessary to ensure high readability of both text elements and graphics.

- Aesthetics of the interface; it has positive influence on the assessment of the device, and it helps users focus on the task being performed. Therefore, the process of designing a graphical user interface should incorporate people having experience in the field of industrial design.

- Data entry. This task should not only be easy and efficient, but also must guarantee that the data will be made accurate, complete and in the correct order.
• Color of the interface; it is important for both functional and aesthetic quality of the interface. The proper use of color allows drawing attention to important elements and determines the readability of visual aspects of the user interface. The key is to follow accepted conventions of encoding information using color for medical devices. Color should not be used as the only factor responsible for information coding because of people with impaired color vision.

• Display of dynamic data. Some values must be monitored and displayed in real time; it is necessary to determine the details of their animation, refresh rate, signal changes, and showing emergencies.

• Interactive mechanisms. The interface can be controlled by different mechanisms: buttons near the screen, knobs, touch screens, keyboards, keypads, etc. The method of control should be ergonomically designed and adapted to the conditions of use of the device.

• User support. Due to the fact that users may differ in terms of knowledge about how the device works, there should be provided with easily accessible assistance. Support may take the form of dialog system, information strips or additional help section where the user can find simplified instructions. Worth considering is the use of graphic descriptions or animations, which in some cases are easier in perception.

V. PROCESS OF PROTOTYPING SOFTWARE USER INTERFACES FOR MEDICAL DEVICES

The predefined requirements and guidelines should be used during the process of prototyping interfaces. In the early stages of prototyping standard methods such as paper prototypes (that allow determining the arrangement of the interface and the basic concepts of interactions) and sorting cards (that help the designer to define the logic and structure of the menu) may be good solutions. The next step is to build an interactive mock-up that allows pre-verifying and assessing the level of ergonomics/usability of interaction with the device and identification of the potential sources of error. For this purpose the designed interfaces are subjected to initial usability testing. If there is a need to carry out tests with the doctors and medical staff, the proposed prototypes should be really similar to the target interfaces in terms of visual and interaction aspects. It is crucial to optimize the process of user interface prototyping because at this stage there may be introduced a number of key changes, which in turn lead to the need of frequent retests. An important element of this optimization is to choose the efficient and effective technology for building prototypes. It has a huge impact on the speed and ease of construction of such interactive mock-ups. It is also responsible for particular fidelity level of appearance and interaction with the device. Designers often choose solutions like Adobe Director, Adobe Flash, Visual Basic, Java, HTML.

One of the newer technologies which provides graphical and programming environment is the Adobe AIR SDK [4]. Given the ease of publishing on mobile devices and rapidly growing capabilities of this technology, it can optimize and speed up the process of building prototypes of advanced user interfaces quite well. The main use of it is to create cross-platform Rich Internet Applications (RIA). It combines several technologies: HTML, JavaScript, Adobe Flash, Flex and ActionScript. From the point of view of the prototyping process the most important features of Adobe AIR are:

• The ability to create highly interactive prototypes based on graphical user interfaces for different types of devices: computers with Windows/MacOS, a wide range of mobile devices (running Android OS, iOS) and selected models of TV. This provides a fast and convenient way to adapt and take advantage of a wide...
range of equipment, including popular mobile devices (tablets, smartphones). Large selection of this type of devices can help the designer to choose the right size screen tailored to the needs.

- In conjunction with the IDE (Integrated Development Environment) such as Eclipse, Flash Builder, Flash Professional, it allows very quick modification of graphics and interaction.
- Using the same code regardless of the platform on which the prototype will be published saves time and gives opportunity to try out different types of equipment, tailored to the requirements of the prototype.
- Easy to install on supported platforms (AIR files for Windows/Mac OS, APK files for Android OS, IPA files for iOS).
- Supports touch gestures, sensors and built-in equipment (like acceleration, camera, microphone, GPS) on mobile devices.
- Possibility to connect external controllers such as Phidgets, which can significantly enrich the interaction methods by adding physical controllers like sliders, buttons and other.
- Supports hardware acceleration for 2D and 3D graphics (3D Stage) for advanced graphics and video.
- Possibility of reading and writing data to the local operating system, XML files, SQLite local database, databases located on servers, and encrypted data storage that came with the AIR.
- Large set of third-party libraries and frameworks that increase the capabilities of the prototypes/applications.
- Using Native Extensions allows implementation of the native functions of the operating system.
- The SDK is free and very actively expanded and supported (for iOS devices it is required to pay for the developer certificate in order to publish applications on these devices).

Adobe AIR described above looks very promising because of its key features. It can be also a good choice for prototyping or even building the full version of health-care or well-being applications, which can be used by patients at home in the process of rehabilitation.

VI. PROCESSES OF VERIFICATION AND VALIDATION OF SOFTWARE USER INTERFACES FOR MEDICAL DEVICES

Usability standards require regular verification and validation of medical devices. Verification applies to individual elements and features of the device at different stages of the product development. In order to verify software user interface, many common methods can be used: heuristic evaluation, inspection of key features, cognitive walkthrough, simple tests with users, etc. Validation however is the final stage of the development and allows assessment of the medical device as a whole in terms of its usability and safety. For this purpose usability tests are carried out in a specially prepared laboratory, which should offer the conditions similar to the real environment where the device will be used. The laboratory is usually equipped with cameras, microphones and usability testing software that allow recording behavior of the users and interaction with the user interface by using screen capture. It is recommended that the test moderators be present in an adjacent room, separated by a semitransparent mirror. Installed recording equipment should not distract participants.
Popular professional programs for image acquisition, registration events and analysis of test data are Noldus ObserverXT [5], TechSmith Morae [6], etc.

In the case of testing the interfaces based on mobile devices additional applications may be helpful for cloning devices’ screens in real time on a computer using Wi-Fi (Reflections [7] for iOS and MyMobiler [8] for Android). One of useful web services that collects and analyzes events occurred in the user interface is Flurry [9]. The big advantage of this service is the possibility of manual implementing which actions will trigger collecting data directly in the code of the application, and the wide range of statistical analysis and data visualization tools.

The test should be conducted with the involvement of representatives of the user group, and use a representative task. In the usability testing of standard interfaces it is assumed that only six users are sufficient to detect 80% of the potential usability problems. In the case of medical device interfaces it is recommended to test the critical functions on a group of ten users who were selected carefully [10]. Although laboratory conditions will never be identical to the real testing, this form of tests has many advantages. It allows repeated performance of even unlikely scenarios with different users in controlled conditions with no risk to patients. Results collected during the test should be carefully examined by experts and available to the project group. In accordance with the usability standard, the test results must be documented in the Usability Engineering File.

VII. SUMMARY

The introduction of standardization in the design process of software user interfaces for medical devices primarily improves the usability and safety of this equipment, and can also bring many benefits to the manufacturers of medical devices. Project groups responsible for the creation of interfaces must follow the required steps of implementation of usability engineering and find ways to optimize the different stages of the process, especially concerning prototyping and user driven development.

REFERENCES

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