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Usability and Safety of Software Medical Devices: Need for Multidisciplinary Expertise to Apply the IEC 62366: 2007

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Abstract

Software medical devices must now comply with the "ergonomics" essential requirement of the Medical Device Directive. However, the usability standard aiming to guide the manufacturers is very difficult to understand and apply. Relying on a triangulation of methods, this study aims to highlight the need to combine various expertises to be able to grasp the standard. To identify the areas of expertise on which the usability standard relies, an analytical review of this document was performed as well as an analysis of a discussion forum dedicated to it and an analysis of a case study of its application for CE marking. The results show that the IEC 62366 is a usability standard structured as a risk management one. It obviously requires Human Factors/Ergonomics expertise to be able to correctly identify and prevent risks of use errors, but it also requires risk management expertise to be able to grasp the issues of the risk analysis and master the related methods.

Keywords:
Usability; Medical Device Software; Use Error; Risk Management; Standardization.

Introduction

It is widely accepted now that software can be either a component of a medical device (MD) or a medical device [1]. Thus, software for certain purposes is subject to the same regulation as MDs. Since 2010, software MDs must also comply with the "ergonomics" essential requirement aiming to ensure patient and users health and safety by preventing risks of use errors. The manufacturers must now integrate a Usability Engineering Process (UEP) in their MD design and development cycle and document it for CE marking. To comply with this requirement, the IEC 62366 standard [2] has been harmonized with the MD Directive to guide manufacturers.

However, this usability standard proves to be very difficult to be understood and applied by manufacturers, but also by competent authorities or even usability experts [3]. First, the IEC 62366 suffers the same design flaws as most of the standards [4]: references to many other standards, specific terminology, too general descriptions, etc. Futhermore, this standard is at the intersection of several areas of expertise: (i) it is a usability standard relying on a substantial Human Factors/Ergonomics (HF/E) conceptual and methodological expertise and (ii) it specifies a UEP that must be integrated into two other complex processes, the risk management process (RMP) [5] and the quality management process (QMP) [6], each one needing a specific expertise to be mastered.

Relying on a triangulation of methods, this study aims to highlight the need to combine these various areas of expertise to be able to correctly understand and apply the IEC 62366 usability standard. First, an analytical review of the structure and the content of the IEC 62366 standard document was performed to identify the domains of expertise on which it relies. Then, an analysis of a discussion forum dedicated to the IEC 62366 was undertaken to identify the difficulties expressed by the participants and the specific areas of expertise to which these difficulties were related. Finally, we took the opportunity to observe the real expertise-related difficulties for HF/E experts and a manufacturer during a case study of the application of the standard for a MD CE marking.

Methods

Analytical review of the standard document

A detailed analysis of the document was performed; only the results illustrating the purpose are presented here.

References

All the references made by the IEC 62366 to standard documents have been identified and linked to the area of expertise to which they refer for (i) the normative parts of the IEC 62366 (Articles 1 to 7) and (ii) the Bibliography section.

Terms and definitions

For the “Article 3. Terms and definitions”, the analysis goes further with a particular comparison. The terms defined without specific reference, i.e. exclusively decreed by the IEC 62366, were compared with classic HF/E terms defined in the ISO 9241 standards. This series of essential standards in the HF/E field is a reference in the domain and includes a wealth of information that covers every aspect of usability.

Usability Engineering Process

The Article 5 "Usability Engineering Process" describes specifically the requirements for the UEP implementation as well as its documentation. Its analysis also goes further than the analysis of the references with a comparison of the description of the processes between the IEC 62366 and the admitted standards of the different areas of expertise: (i) the ISO 13407:1999 [7] and the ANSI/AAMI HE74:2001 [8] for the UEP process, (ii) the ISO 14971:2007 for the risk management process, and (iii) the ISO 13485:2003 for the quality management process. The comparison was focused on

the objectives of each standard, the required steps and methods for each process and the intended level of requirements (normative or informative requirement).

Analysis of the discussion forum

Data selection and extraction

The queries "*IEC 62366 forum*" and "*IEC 62366 blog*" were performed in the Google® search engine. The first result was a discussion forum named Elsmar Cove with multiple threads on the IEC 62366. In December 2012, the query "62366" was performed in this forum's search engine. All the threads discussing the IEC 62366 standard were included in the study; those that only cited the standard were excluded.

Data analysis

An automatic textual data analysis of the threads' content was performed with the ALCESTE software [10]. It aims to extract the strongest significant structures of the text, named the "lexical classes", so as to draw the essential information contained in the textual data. After conducting a clean to avoid methodological biases, the ALCESTE software performed the analysis:

i. a basic vocabulary dictionary was created: lexical forms were simplified to gather together forms with the same lexical roots (e.g. "*required*", "*requirement*" or "*requirements*" were turned into "require+");

ii. the corpus was divided into Elementary Context Units (ECU) which correspond to the "units of text" within which ALCESTE was able to calculate words' co-occurence frequencies;

iii. ALCESTE crossed the ECU and the presence/absence of the lexical forms to form classes. The Chi-Square Test revealed the associative strength between a word and a class. For a class, ALCESTE was also able to compute a list of words that were characteristics of the class.

Application of the standard: a case study analysis

Context of the study

MDoloris Medical Systems® had designed an innovative analgesia monitor named PhysioDoloris® (Figure 1). It provided a new pain indicator called A.N.I. (Analgesia Nociception Index) to support better management of the monitoring of a patient's pain during general anesthesia. HF/E experts were asked to (i) perform the usability verification and validation as required by the IEC 62366 standard and (ii) support the UEP documentation for CE marking. The manufacturer and the HF/E specialists had never applied the standard at the time of the study.

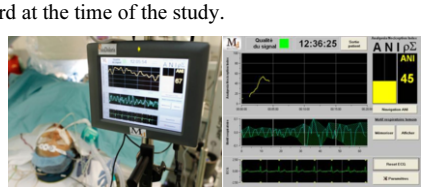

Figure 1 – The PhysioDoloris® monitor in operating room

The HF/E intervention [3] consisted of (i) collecting the mandatory information to prepare the usability plan, (ii) performing the usability verification and validation and (iii) documenting the Usability Engineering File.

HFE experts point of view

An inspection of the Usability Engineering File provided by the HF/E experts to the manufacturer was performed to analyze the type of UEP implemented (steps and methods), the terms used in the document and the reported use error risks. All those elements were compared with the intended classic UEP in the domain of HF/E (ISO 13407) and the intended UEP in the MD regulation (IEC 62366).

Manufacturer point of view

An inspection of the documents provided by the manufacturer to the HFE experts at the beginning of the intervention was performed (accompanying document and first version of the risk management file). The objective was to analyze the usability items already documented by the manufacturer before the HFE experts intervention with regard to the intended IEC 62366 requirements (the application specifications (with the intended user profiles, the intended conditions of use, etc.), the frequently used function, the hazards and hazardous situation related to usability, etc.). Then, the last version of the file given for CE marking by the manufacturer was analyzed to identify the way the items of the Usability Engineering File provided by the HFE experts were integrated: what items have been included? Were they modified and, if yes, how?

Results

Analytical review of the standard document

References

The results show that the ISO 14971 (i.e. the RMP) is the founding reference of the IEC 62366. On the one hand, 93.4% of the references of the normative part refer to the ISO 14971 (the remaining 6.6% concern the IEC 61258 which outlines a generic process for developing materials for education and training for medical electrical equipment). On the other hand, the ISO 14971 is the only referenced document cited as indispensable for the application of the IEC 62366 (Article 2. Normative references).

Table 1 – Distribution of the standards quoted in the IEC 62366 bibliography section by field of expertise

Areas of expertise	Standards cited in the Bibliography section
Quality management system	ISO 9000:2005; ISO 9001:2000; ISO 13485:2003; ISO/TR 16142:2006; EN 1041:1998
Basic safety and essential performance	CEI 61258:1994; ISO/CEI 51:1999; CEI 60601-1:2005; CEI 60601-1-8:2006
Usability (HF/E)	ISO 9241-1:1998; ANSI/AAMI HE48:1993; ANSI/AAMI HE74:2001

The analysis of the Bibliography section shows that references to standards of the HF/E domain are almost non-existent. A total of 75% of the standards cited in the bibliography refer to other fields of expertise as HF/E (Table 1): 5/12 rely on quality management expertise, 4/12 on basic safety and essential performance and, only 3/12 on HF/E expertise.

Terms and defintions

These results are confirmed by the vocabulary listed in Article 3 of the IEC 62366 which relies mainly on other fields of expertise as HF/E. Only 2 terms explicitly refer to standards of the HF/E domain (i.e "effectiveness" to the ISO 9241-11 and "user interface" to the ANSI/AAMI HE74). All other terms (46.2% corresponding to 12/26 terms) refer to standards of other fields of expertise as HF/E (i.e. 9/26 on basic safety and essential performance standards, 2/26 on QMP standards and 1/26 on RMP standards).

Twelve terms have no specific references meaning that they are defined by the IEC 62366 itself. It has to be noted that among these 12 terms, some of them (4/12) have been modified from usual definitions of the HF/E domain: “Usability”, “Use error”, “User” and "Efficiency". For instance, the definition of "Usability" is quite different from the ISO 9241-11 definition (Table 2).

Table 2 – Comparison between the ISO 9241-11 and the IEC 62366 for the definition of the term "Usability"

IEC 62366 (Article 3.17)	**ISO 9241-11** (Article 3.1.)
« *Characteristic of the user interface that establishes effectiveness, efficiency, ease of user learning and user satisfaction* »	« *Extent to which a product can be used by **specified users** to achieve **specified goals** with effectiveness, efficiency and satisfaction in a **specified context of use*** »

Usability Engineering Process

The UEP objectives described in the IEC 62366 differ slightly from those of the ISO 13407. The classic UEP aims to support the design of interactive systems ensuring their usability on the whole while the usability MD regulation aims to identify and prevent risks of use errors. IEC 62366 adopts a safety point of view while the classic usability approach is more global.

This discrepancy obviously impacts the requirements of each standard. The main difference is that the ISO 13407 stresses the importance of understanding and specifying the context of use on the whole (Figure 2), i.e. considering the intended users, their tasks with the device and the corresponding work organization. In contrast, the IEC 62366 emphasizes the need to describe the specifications of the application, the frequently used functions and the identification of hazards and hazardous situations related to usability, getting closer to the risk analysis step of the ISO 14971. Accordingly, the ISO 13407 sets usability objectives related to users and organizational requirements for the evaluation step while the IEC 62366 imposes usability objectives related to frequent and hazardous functions.

Concerning the intended level of requirements, the normative part of the IEC 62366 presents a UEP process similar to the UEP process described in the ISO 14971. The UEP as described in usual HF/E standards (ISO 13407 & ANSI/AAMI HE74) is in an informative section of the IEC 62366 (Annex D).

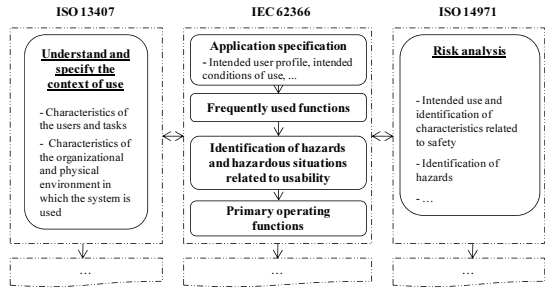

Figure 2 – Description of the first steps of the processes described in the IEC 62366, ISO 13407 and ISO 14971

Analysis of the discussion forum

Twenty-eight threads were included in the analysis corresponding to 295 posts. ALCESTE classified 563 ECU out of 793 created. It revealed 5 stable lexical classes which were pooled into 2 lexical meta-classes (Table 3).

In the first meta-class (45.65% of ECU), the participants want to understand how to reach compliance with the HF/E regulatory requirement. Two lexical classes are included in this meta-class. The first one (Class A, 23.09% of ECU) represents discussions where participants give information about harmonized standards (role and status). It highlights difficulties of the participants to identify the suitable usability standard regarding their MD. In the second class (Class B, 22.56% of ECU), difficulties are expressed with the understanding of the IEC 62366, participants asked for feedbacks and trainings on this purpose.

Table 3 – Lexical meta-classes and classes and examples of typical lexical features

Lexical meta-class (ECU %)	**Lexical classes (ECU %)**	**Examples of typical lexical features**
1. Searching the compliance with the ergonomics regulatory requirement (45.65%)	A. Provide information on compliance with the regulatory requirements in general and especially with the usability harmonized standards (23.09%)	iec6060116, standard<, harmonized, adopted, solution+, why, mandatory, regulation+
	B. Search for information and help to understand the IEC 62366 standard (22.56%)	help, thanks, committee, publication, feedback, follow, training, experience, provide+, us, hope
2. Understanding the application of the IEC 62366 (54.35%)	C. Guidance in understanding the UEP principles (27.35%)	user+, design+, error+, interface+, verification, HF, environment+, pati+ent, test+, population+, clear+, real
	D. Search for information about the documentation of the UEF and its link with the RMP (19.36%)	file+, usability, engineering, template+, document+, manage+, plan, existing, procedure, include, risk+, require+, process+, our+

	E. Search for information about the RMP methods to identify risks of use errors (7.64%)	DFMEA, analysis+, detectability, risk+, hazard+, covered, failure+, chang+er, determine+, incorrect+, control+

The second lexical meta-class (54.35% of ECU) includes discussion aiming to understand the application of the IEC 62366 principles. Three classes are part of it. The Class C (27.35% of ECU) includes explanatory utterances about the objectives, the scope and the definitions of the IEC 62366. The Class D (19.36% of ECU) highlights difficulties of participants with the documentation of the UEF. The items "file+" and "document" are the most typical items of this class and one of the most repeated utterance is "usability engineering file" showing that participants are focused on the UEF documentation. Participants try to understand the benefits of the UEP as they don't grasp the relationship between UEP and RMP processes, e.g. how are these two processes different from each other. For example, a representative ECU of this class is: *"Annex of iec14971 takes usability into account, [...] etc. can iec62366 requirements just be implemented in the overall risk plan for the product, or will the auditor want to see a separate usability specification like annex h?"*

Finally, the last class, Class E (7.64% of ECU), includes utterances discussing the methods of the RMP that can be used to identify and prevent the risks of use errors expected by the IEC 62366. The typical lexical features highlight (i) a risk management vocabulary as "hazard", "failure", control", "severity" and "risk" and (ii) a vocabulary related to methods as "determine", "list", "detectability", "analysis", "organized", "method". The primary methods cited are "FMEA" and "FTA", typical risk management methodologies. For example, the most representative ECU of this class is the following: *"My question is whether or not it is recommended to use detectability in an FMEA to comply with iec62366?"* In this class, the ISO 14971 annexes are regularly cited as good guidance to identify use error.

Application of the standard : case study analysis

HFE experts point of view

It has to be noted that the IEC 62366 does not require a specific format for the Usability Engineering File.

In this case study, the results show that the HF/E experts had adopted a classic UEP with comprehensive analysis of the context of use and the evaluation of the designed solutions. Likewise, the documentation of the Usability Engineering File was done following a usual usability report. Although some terms of the IEC 62366 were used (e.g. application specification, frequently used functions, etc.), HF/E experts mainly used specific terms of the classic UEP (e.g. context of use, heuristic analysis, usability testing, etc.).

In regards to the methods, one main difficulty emerged. The HF/E experts have had some difficulties in defining thresholds for the usability goals as they were not used to doing that exclusively in a safety-oriented point of view. These criteria for determining adequacy to the requirements referred to the criteria defined for risk acceptability in the ISO 14971. Moreover, they didn't distinguish in the usability engineering file the safety-oriented usability aspects of the problems, rather they were related to ease-of-use as required by the IEC 62366.

Manufacturer point of view

Analysis of the documentation recovered from the manufacturer shows that only one intended user profile was documented, i.e. the anesthetist, while another major user of the MD was the nurse. In France, indeed, an anesthetist is often in charge of 5-6 patients inside an operating room while nurses are assigned to a given patient. Nurses are also the ones monitoring the patient state and even making some decisions, although obviously the physician is the final decision maker. The manufacturer knew this specific work organization, but in order to be able to control risks associated with this additional user profile, he had decided at the time to consider only the physician's profile as the physician was legally the only one responsible for the drugs administered to a patient. At the end of the study, the nurse profile was added into the documentation by the manufacturer.

Another major finding was that the manufacturer only focused on technical risks (e.g. related to electrical problems). Even if they knew the problems identified by the HF/E experts, they had not identified them as risks of use errors. For instance, Figure 3 illustrates a severe usability problem identified by the HF/E experts generating a risk of misinterpretation of the index which was potentially dangerous for patient safety.

Figure 3 – Example of a dangerous usability problem identified by HFE experts

From the manufacturer's point of view, it was not a risk as the choice of the direction of the index relied on a clinical explanation (the A.N.I. indicates the proportion of parasympathetic tone in the autonomous nervous system). According to the manufacturer, once the care providers have understood it (during MD training), it would no longer be a problem. He did not consider that training was a low-level risk control measure while an easy high-level countermeasure could have been implemented with the redesign of the Graphic User Interface (GUI). They had difficulties in linking a design choice of the GUI with a potential risk of use error.

Discussion/Conclusion

This study highlights the need of multiple expertises to be able to understand and apply the IEC 62366 standard; it especially shows the need of a double expertise: the HF/E and the risk management expertises. The results show that the QMP expertise is not essential to grasp the content of the IEC 62366 as the standard does not really rely on the ISO 13485.

Firstly, even if the IEC 62366 standard claims to be a usability standard, it has little explicit elements about usability (few references to HF/E, key usability elements only in informative parts). Moreover, it clearly looks like the ISO 14971standard (a lot of references to it and a normative part dedicated to the description of a process very close to the RMP).

Secondly, these results are confirmed by those of the discussion forum analysis. Participants have difficulty understanding the distinctive feature of the IEC 62366 since, for them, the process is similar to the process of the ISO 14971. They also tend to interpret the IEC 62366 based on the risk management process which make easier things for them. As the risk management requirements have been mandatory since the 1990s, it is a process already systematized for most of the manufacturers and thus, well-known by them.

Thirdly, the analysis of the case study reveals that the manufacturer does not really understand the usability-related risks as shown by their not considering the nurse's user profile. As in many French operating rooms, nurses have a major role in the process of anesthesia, and as such cannot be ruled out. A problem would be considered as a use error and not as an abnormal use (i.e. outside the manufacturer's obligations).

Finally, problems of misinterpretation of the IEC 62366 were also observed with the HF/E experts. Spontaneously, they have adopted a classic UEP and have not emphasized the safety-oriented point of view of the identified usability problems (no clear distinction of the usability problems linked to risks of use errors).

Based on all these results, it seems that the IEC 62366 is a usability standard presented and structured as a risk management one. It requires the RMP expertise to be able to grasp the issues of the risk analysis and to master the related methods, but it also requires HF/E expertise to be able to correctly apply the UEP with the identification and prevention of the major risks of use errors.

The Health Information Technology (HIT) community must today be attentive to the MD regulation which has a strong impact on the software MD design and development. The major risk with the IEC 62366 standard lies in the problem of misinterpreting the requirements without realizing because each person understands the standard based on his/her own expertise. The recent focus on patient and user safety related to HF/E aspects makes the usability engineering aspects in development, implementation, and use of medical software a key issue that requires the development of good practice guidelines and standards in this area.

Standards are designed by several international or national standardization organizations (e.g. ISO or IEC) involving many technical committees. HF/E standards are developed and published by these standardization groups [10]. In the HF/E domain, the International Ergonomics Association (IEA) initiates in 1974 was the first HF/E technical committee (TC 159) for the ISO. Today, every standardization organization has a technical committee dedicated to HF/E. But it seems that the international Standard IEC 62366 has been prepared by a joint working group of three committees (subcommittee 62A: Common aspects of electrical medical equipment used in medical practice; IEC technical committee 62: Electrical medical equipment in medical practice and technical committee; ISO/TC 210: Quality management and corresponding general aspects for medical devices) not by integrating HF/E committees. Moreover, the technical committees are usually composed of manufacturers and customers [11]. One action to be taken is to ensure that at least domain experts understanding the issues discuss them within the committees.

From the practical and organizational perspective, we need to make the HF/E and risk management expertises and guidance more visible and accessible to the IEC 62366 intended users and to support all forms of education and training of stakeholders for HIT and MD.

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