Using Heuristic Analysis to support Usability Evaluation of a low risk medical device under development process

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Abstract — **New technologies in the healthcare area have increased the possibilities to diagnose and treat the patients but also have added complexity and associated risks by use errors and users dissatisfaction during the use of complex machines. This paper deals with a new medical device under development in Brazil. The device is classified in the country as a low risk, but the device is intended to give comfort and to prevent futures problems to the patient under its use. The manufacture wants to evaluate the usability of the device to provide user satisfaction and efficient use of it. The heuristic analysis was the method chosen to evaluate the device, early as a prototype, in order to identify problems in the developing interface. The analysis was done by six specialists in Human Factor Engineering & Usability Lab in Federal University of Itajuba. We conclude that the heuristic evaluation was appropriate to evaluate the equipment in question, since helped identify relevant points that should be considered by the manufacturer to meet your customer and contribute with safety and efficiency in use.**

Keywords— **Heuristic Analysis; Usability Evaluation; Medical Devices.**

I. Introduction

In Brazil we can highlight two standards internalized by the Brazilian Association of Technical Standards about usability for medical devices: NBR IEC 60601-1-6 [1] and NBR IEC 62366 [2]. Standards of this size are legal requirements for medical equipment registration in some countries, but not yet in Brazil. Such requirements demonstrate the importance of inclusion of usability studies on the product development process. However, these standards can still leave doubts about their actual need and objectives, and "how to do" things in usability evaluation [3].

The Product Development Process (PDP) refers to the steps, activities, tasks, stages and decisions involving the development project of a new product or improvement in an existing one [4]. The process goes since the concept idea until the discontinuation of the product, in order to be systematized. This process identifies the customer desires that are translated into specifications to be described into technical and commercial solutions. All this has to be linked with the strategy, restrictions and operational possibilities of the company and customer needs [5]. According to [6] the PDP is complex and it is not organized as compared with the manufacturing processes. PDP has an iterative characteristic, diversity of cycles and uncertain cooperative. While many companies know the importance of the PDP in the development of long term business, even with efforts towards the improvement of the PDP, the failure rate of new products is still high. There are several reasons for these high failure rates, one of the most significant, the low use of models, tools, approaches and techniques to assist the PDP [7, 8].

Within this context is the Ergonomics, an approach that is related to human factors and usability, which deals with the characteristics, skills and needs of people and the interfaces between people and products [9]. The Ergonomics in PDP is based on understanding how the user is related to the product, the environment, and finally with the system, promoting an understand about the needs that a new system should address. With the knowledge about the user profile, the context of use and the tasks that the product should perform, PDP can clarify the user's perspective on the system and integrate his vision and interaction characteristics.

Inputs from human factors in the PDP can provide competitive advantages for products on the market, and adds what users expect and demands of usability, mainly contributing to increase their satisfaction levels [10]. Consequently, integrate the user's view along the PDP will bring not only the competitive advantages but also financial benefits, by reducing costs from 12% to 1% when human factors are integrated from the beginning of the PDP [11].

To integrate the user's perspective throughout the PDP [12] present a comparison between seven methods: Contextual Research, Task Analysis, Usability Testing, Heuristic Analysis, Cognitive Walkthrough and Delphi Technique.

Among these methods, the Heuristic Analysis was chosen to be used on this application because it is a relatively low cost and low time consuming method. Also it can be performed in a normal room with a product prototype that has the interface with the users already planned. The evaluation of the product under development through Heuristic Analysis will offer information from experts to the manufacture team based on good principals of usability.

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The equipment under evaluation is a low risk device, never produced in Brazil. All the similar and competitors are imported from other countries and this equipment will be the first of this kind to be project and produced in Brazil. With this, a new look about risk and the concern about user satisfaction and usability in general way is a key factors to the company in expanding their marketing and activing success.

II. Methodology

The Heuristic Analysis is based on a comparison of the interface of the object against a list of good usability principles, called heuristics. A set of evaluators, the experts, evaluates the system with regard to heuristics and may have a score of severity or priority classification [13].

According to [13] heuristic analysis is a cheap and fast method, which requires few resources. It is usually applied when the equipment is under post-development review, generating qualitative information resulting from experts. Such an assessment, it requires a moderate level of training specialist researchers who must have well-defined lists of heuristics.

It is suggested by [14] a procedure for implementing a heuristic analysis. The steps are illustrated in Figure 1.

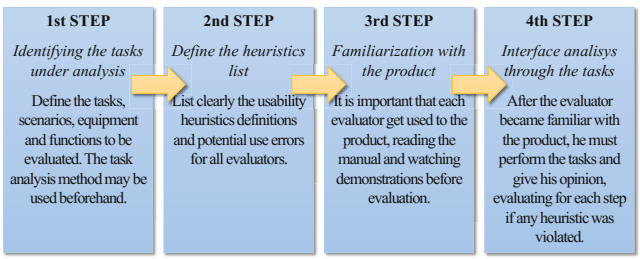


Fig. 1 Steps for Heuristic Analysis

At the end of the evaluation process, the evaluators may also give a priority level of appropriateness of the problem pointing and suggesting improvements.

In 1994, [13] proposed a heuristic list for design concept or product evaluation, at any stage of their development cycle. Nielsen list [13] are presented in Table 1, it has been employed in several areas, from validation of web pages, various software applications, robotic arms reviews, and car dashboard design [14]. It can also be made adaptations and adjustments of Nielsen list for specific applications [14].

Other researchers [15] presented a list of 14 heuristics adapting Nielsen heuristics for evaluation of medical devices, known as Zhang heuristics. Table 2 shows the Zhang heuristic with a brief explanation of each.

Table 1 – Nielsen Heuristic list

1	Visibility of system status
2	Match between system and the real world
3	User control and freedom
4	Consistency and standards
5	Error prevention
6	Recognition rather than recall
7	Flexibility and efficiency of use
8	Aesthetic and minimalist design
9	Help users recognize, diagnose, and recover from errors
10	Help and documentation

Table 2 – Zhang Heuristic for medical devices

Heuristic		Description
1	Consistency and standards	User should have no doubt about the actions, words or situations with different meaning.
2	Visibility of system state	Violation of this heuristic occurs when the questions have no clear answers: "What is the current status of the equipment?"; "What can be done in the current status?"; "Where can you go?".
3	Match between system and world	The system and the perception of the user world correspondence. The system uses the user's language, with words, phrases and concepts familiar from day to day. Do the actions provided by the system correspond to the actions performed by the user?
4	Minimalist	"Less is more", "Simple is not always synonymous with abstract or barely functional", "Simple is efficient". Unnecessary extra information is a distraction.
5	Minimize memory load	Minimize the amount of information that the user must remember to use the equipment.
6	Informative feedback	The user should receive immediate feedback about their actions.
7	Flexibility and efficiency	If possible, it should be given the possibility of user customization and create shortcuts to optimize the use of the equipment.
8	Good error messages	Error messages should be informative. Avoid generic messages with codes for outpatient visits, or codes and numbers of errors.
9	Prevent errors	Device must be capable to prevent errors
10	Clear closure	It should be clear for the user that a task has been finished. Sequences of actions should be organized into groups with a beginning and end.
11	Reversible actions	Users should be able to recover from their mistakes, through reversible actions.
12	Use users' language.	Users should use simple language. Should use a language corresponding to the technical field level expected by users and their perspective.
13	Users in control	User should not get the impression that the equipment is controlling his actions. Users should be initiators of actions, not just react to the actions proposed by the equipment.
14	Help and documentation	Offer help always. The help must be present in support documents, labels and equipment identification.

The selection of heuristics is free for each researcher, but must be clearly defined among all evaluators so you can converge and generate consistent in their ratings [14].

In this paper, the steps proposed by Nielsen [14] and the Heuristics from Zhang [15] were used to evaluate the equipment in our case study.

III. Case Study

The equipment evaluated in this case study was a patient heater (thermal blanket). This equipment is under development in Brazil and has no national competitors.

According to the Brazilian National Health Surveillance Agency (ANVISA) the equipment is framed as low risk (class I). The patient heater is micro controlled device that combines a fan and resistor, providing a continuous stream of heated air. The device operates in the prevention and treatment of hypothermia patient. The heating system provides heat to a preset temperature according to the need of each patient, using a light and flexible hose to a specific blanket which covers the patient. This blanket has micro holes spread consistently to allow the heated air outlet to equally on the patient. This model can be used in all clinical settings where it is necessary to control the body temperature of the patient, including in operating rooms.

The equipment was analyzed according to Zhang heuristics [15] for six experts at Human Factors Engineering & Usability Laboratory in Federal University of Itajuba. According to the proposition [14] this work was conducted in the following steps:

A. Identifying the tasks under analysis

The first step to run the heuristic analysis was to do a task analysis, listing the tasks on the interface that would be evaluated against the heuristics.

We identified 14 tasks from the installation of equipment in hospital bed.

B. Defining the heuristic list

The heuristic used on this study was from Zhang. A protocol with an explanation and description about each heuristic was handled to all the experts from Table 2.

C. Familiarization with the product

Although the equipment was still under development, the manufacturer did not provide an explanation of the operation of the equipment. The familiarization with the equipment was made by each expert directly with the product intuitively and using the draft operating manual.

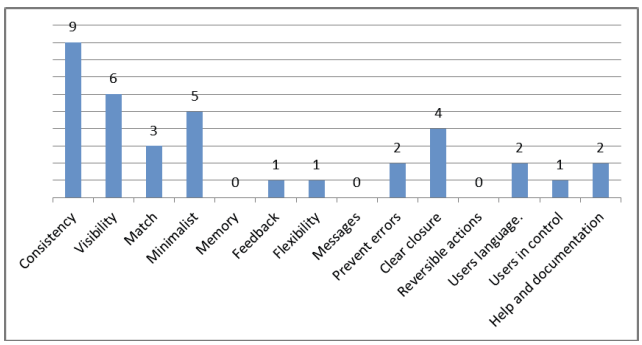
D. Interface analysis through the tasks

Every expert had two hours with the equipment under analysis in private. The tasks were performed with the equipment and the expert compared each difficulty against the heuristic analysis, marking the heuristic violated. The form to write the analysis had an open field for comments and problem description.

After all this steps, the experts discussed about their consideration and analysis together. At the end, they defined the priorities ranking the problems founded.

IV. Results e Discussion

The results of all the experts' analysis are presented in Graf 1. From the 14 heuristics, 10 heuristics were violated and in total, the experts pointed 36 violations.



Graf. 1 Heuristic Violations

According to these violations results, it is shown that the heuristic with the greatest number of violations was the consistency. About consistency we had 9 violations in the 14 evaluated tasks. Lack of consistency was identified in the hose connection to the blanket, label, the panel and the equipment language.

Regarding the visibility heuristic, we had 6 violations, the location of buttons and status of equipment. Information overload on the equipment panel was responsible for violating the minimalist heuristic in 5 times. The heuristic clear closure was violated 4 times on the hose connection, in the labels and on the panel. Some heuristics: messages, reversible actions and memory were not violated.

To make the prioritization of issues raised, the experts considered the basic activities for the proper use of the equipment. Based on the evaluations of the experts, the manufacture should have greater attention on the consistency heuristic, since the hose connection task with the blanket generated questions and problems for all experts.

This difficulty can also affect the performance of the equipment once installed incorrectly and the user satisfaction. The heuristic visibility was also considered a priority since the location of the on/off switch was difficult to locate and access. This implies postural problems in the user's position while installing the equipment.

Another heuristic prioritized by experts was flexibility, which was considered the length of the hose is limiting the use of equipment in different scenarios where there may have beds in different heights.

V. Conclusions

This application on Heuristic Analysis was the first experience with this methodology for the experts from the laboratory and for the manufacture team. As it was the first time performing this analysis, the experts have not enough experience running this kind of evaluation. Even with this fragility, the results were satisfactory for the manufacture, as the equipment was under development and a lot of problems reported will be modified.

The device in this study was considered a low risk device, so the focus of this study was to provide feedback about the usability in terms of user satisfaction, user performance on tasks and use efficiency.

The heuristic analysis was appropriated to evaluate the device helping the identification of gaps to review on the device interface. This method requires low time and resources, so it can be performed by the manufacture team while project the product with a good understanding of the good principals of usability, the heuristics.

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Conflict of Interest

The authors declare that they have no conflict of interest.

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