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Who are the right users to be involved in the design process of health products?

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Abstract

The misuse of medical products can cause harm to the health of patients and other users. Many international standards are practiced in the medical product development industry to ensure quality and safety, including guides and models with various ways to engage the user in the development process. There are methods that can be performed at any stage of development, which hampers the project-planning phase. Nevertheless, there is a lack of information that helps companies select the most appropriate users, according to a particular profile or attribute. In order to demystify how users can be involved in the development of the product for health and using case studies in the literature as a basis, this research aims to present the recurrent activities that users perform when involved in development of medical devices. The main contribution of this word is the model of user tasks crossed with users characteristics developed.

Keywords: User involvement; User-Centered Design; Medical devices; Product development**.**

1. Introduction

The analysis of incidents caused by medical errors indicates a lack of usability of medical devices. Indeed, the results of a 2013 survey suggest that one in four medical errors during surgeries are consequences of problems of technology or of the equipment itself [1]. The incorrect use of medical equipment may result in the death of patients, depending on the product type and the clinical case [2]. Since the lack of usability is directly related to patient safety, regulatory agencies, like FDA (United States Food and Drug Administration) and Europe Commission Medical Device Directive 93/42/EEC, argue in favor of mandatory norms related to the usability of medical equipment.

The main standard that addresses usability in this sector is the IEC 62366 – Application of usability engineering to medical devices. It establishes the need to employ a usability engineering process in the product design as a way to minimize errors during the use of medical products. Usability, according to the norm is a "feature of the user interface that establishes effectiveness, efficiency, ease of learning and user satisfaction" [3].

In addition to the current regulations, specific process models for medical product development are available in the academic literature [4]. In particular, many authors [5, 6] and all members of the MATCH (Multidisciplinary Assessment of Technology Centre for Healthcare) suggest methods to be used in each phase of product development with the aim of involving the user to guarantee the product usability.

Despite the indications of usability methods came from the norms and reference models of development, companies still find difficulties to plan the user involvement activities. Although the models have recommended methods to involve the users early, Money et al [6] verified that users are usually involved, in practice, just in the end of the project.

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Therefore, it is important to emphasize that the user involvement must be performed since the initial phases and the development team should define which information should be identified, explored and verified with users [3].

This kind of information is mostly related to problems and opportunities that influence the performance of the user in achieving their objectives with the use of the product in a specific context of use [7]. As the users are indeed the people who use and interact with the product, they are the people who have the knowledge of the tasks, behaviors and preferences for the proper functioning of the product [7]. The goal of user involvement during product development is to understand the context of use and the user need in its environment of use [3]. Understanding the context of use means acquiring knowledge about the users, tasks, equipment and the physical and social environment in which the product is used, their prior experience with the product, and the context in which the product will be used [8].

The products of the medical industry also have the peculiarity of having several users interacting with the same product: patients, familiars, caregivers, doctors, nurses, physiotherapists, dentists etc. In the case of infusion pumps, for example, there are at least 5 different users who should be considered: doctors, nurses, nursing technicians and caregivers. It is important to consider the different users because they have different purposes of uses, for example, doctors are responsible for prescribing the procedure with the product, technicians and nurses operate the product to perform the procedure, and patients receive the interventions related with the use of the product. Despite the knowledge about the importance of involving different users, academic researches [6, 10] show that often only senior doctors, who are responsible for the purchase of equipment in hospitals, are the only users involved in the project.

As a regulatory requirement in IEC 62366, design teams must select real users to participate in the development process. Although the norm does not provide information on how to select users, user-centered design theories can be applied to this activity. The lead user theory [10] highlights two characteristics that users must possess to participate in the generation of innovative product concepts: 1) their need must be ahead of the market and 2) as a user, he/she should be highly benefit from the innovative product. On the other hand, testing of guess ability theory emphasizes the importance of involving users without experience of use because they are who realize the greatest quantity and the most serious errors of use [11]. The users called proxy users, who are the people closest to the patients, are also of great importance to product development since they can represent the patients, reporting their difficulties during the use of the product [12].

The IEC 62366 regulation recommends that different characteristics of the users should be considered during their recruitment in order to ensure the representativeness of the information gathered. However, choosing the right users to be involved in the different phases of the project is a difficulty that companies have faced [13].

In view of the above, two research questions were identified: What are the characteristics of the individuals that should be considered when selecting users for their involvement in medical development process? How does the activities performed by users when involved are related to the usability engineering process?

The objective of this work is to present the most recurrent activities that users perform when involved in the development of medical products and a description of the characteristics of the selected users. For this, multiple cases research was employed. In total, 15 cases were selected, in which were identified the tasks performed by users during their involvement, and the relevant characteristics of the users relate to each task performed. Finally, a model synthesizing the results obtained was elaborated.

2. Challenges of user involvement in medical products

The theory of user involvement (UI), in fact, is not new. Early research on user engagement was published in the late 1940s. According to Siatri [14], the development of UI theory started in the field of information science and software development. In the late 1980s, two important concepts were established, Lead User and User-Centered Design. The concept of Lead User, proposed by von Hippel [10], establishes that there are users who stand out because they are in the vanguard of some tendencies, whose needs will be on the market in the future. The concept of User-centered design (UCD), cited by Norman and Draper [15], has become widely known for the diffusion of the usability concept, which explores users cognitive aspects. In this way, the author emphasizes the essential role of the design project so that the use of the product is intuitive. According to Campese, Amaral and Costa [16], the user involvement is one of the most important element of UCD.

Damodaran [17] stated that if the user is effectively involved in the development process the main benefits that can be achieved are: improvement in product quality due to the collection of more accurate user requirements; elimination of

unnecessary products characteristics, which the customer does not want; increased product acceptance by the end-user; and greater product use efficiency.

While these benefits are widely recognized, companies have a number of difficulties in involving users. One of them is related to the selection of methods to be used in each phase of the project [18]. Without knowledge of such information, the most common practice among companies is to engage the user only to capture information about their preferences on the solutions created by the development team [17]. Even in situations where an entirely new product is launched on the market, the first product evaluations with the users, most of the time, only happen at the prototyping stage, or even in the final stages of product development [19].

Another difficulty companies face in involving the user, according to Lettl [13], is to choose the right users to be involved in the different phases of the project. However, it is not only the companies that have difficulties in knowing which users to engage, but also the theory is not conclusive in telling which types of users can be involved in product development [20]. In cases of radical innovation, for example, the Lead User methodology is certainly best known for recruiting users. On the other hand, several other authors differ on this view. Weber [20] reports that the main lead users characteristic is to be professionals in the use of the product. Lightbody et al. [21], for example, considered the user lead as a user with a university degree. Thus, the characteristics of who are the lead users, or the appropriate users for the generation of innovative ideas, is not consensus in the literature.

2.1. Usability engineering for medical products

Shah et al. [9] through a theoretical survey on the users involvement in cases of medical products, mapped and categorized several medical products and their users found in the literature. It is possible to verify a wide variety of medical products, ranging from equipment of high technological complexity, such as neuromagnetic meter systems, to products of low technological complexity, such as syringes. In addition, it was also verified the large number of users of a medical product: patients, nurses, doctors, therapists, caregivers, technicians, etc.

According to a recent survey [22], medical errors, which are not included in the death causes rankings, contributed approximately two hundred and fifty thousand deaths per year in the United States the third largest cause of death in the country. Medical error can be categorized as an unintentional act, execution error, planning error or a deviation from the treatment process [22].

In order for medical errors not to be caused by problems related to the use of the product, various laws and regulations are practiced in the health product development industry to guarantee quality and safety to the patient. These regulations, in order to ensure product usability and patient safety, require the use of methods that involve users in the design process [6]. The FDA, for example, specifies that companies must demonstrate that human factors have been considered in the design of medical equipment and also ensure that risks associated with product use are identified, understood, and resolved [6].

3. Research methodology

To reach the proposed goal, a multiple case study research was carried out. In order to conduct the collection of the case studies, a systematic literature review procedure [23] was used. Two research scripts were elaborated and applied. The first aimed to identify, analyze and validate the activities performed by users during their involvement in the project in each selected case, and the second intended to catalog the user's characteristics. Both scripts followed a coding approach proposed in Grounded Theory [24].

The search for the articles was carried out from June 2020 to October 2020, and it was performed in the Scopus database. It included PubMed and journals related to human factors. The search string used was: ("user involvement" OR "user-driven innovation" OR "lead user") AND ("product development" OR "user-centered design" OR "user-centred design" OR "participatory design").

In order to collect only case studies in which users were involved during the development of the medical product, the following inclusion criteria were adopted: (1) Articles need to report a description of case where there is activities of user involvement during the design of a medical product; and (2) in the content of the article, it is required to contain information about who were the users involved, their characteristics and what activities they performed.

A total of 430 articles were identified. Three filters were used to select only the articles that met the inclusion criteria. In the first filter, only the titles of the 430 articles were read, and as a result 120 articles were selected that could meet

the criteria. In the second filter, the introductions and conclusions of the 120 articles were read and, then, 49 articles were selected. In the third filter, all 49 articles were read and only 11 articles were selected. Finally, a cross - search of articles was carried out in order to collect other articles that may be relevant to the research but which were not present in the Scopus database or were not found through the search string used. The cross search resulted in the collection of 4 more articles relevant to the research. Thus, in total, 15 articles were identified as relevant to this research.

For the information collection in the case studies, two scripts were used. In the first script the objective was to codify the stage of product development, which users were involved (e.g. doctors, nurses, patients, etc.), which tasks were performed and which user characteristics were most relevant to the task they were performing. The model proposed by the Brazilian standard of usability in medical devices [25] was used as reference for the definition of the development phase to which the user was being involved. In the second script the objective was to codify the characteristics of the users and facts to describe them.

Table 1 Description of the cases selected

Case	Project and product description
Ram et al. [26]	Development of a new product for a genetic and rare disease treatment.
Schmettow et al. [27]	Usability test in an infusion pump prototype used in hospitals.
Garmer et al. [11]	Identification of possible improvements to the interface of a newly designed infusion pump.
Fung et al. [28]	Development of a device for use in residential environments in Obstructive Apnea treatment.
Lang et al. [29]	Identification of the factors that led to a low young public adherence in a device for a Cystic Fibrosis and Chronic Obstructive Lung Diseases treatment.
Bühler [30]	Usability tests performance of a Robotized wheelchair.
Lightbody et al. [21]	Development of an inclusive technology to be used by people with severe weaknesses.
Hanson et al. [31]	Development of a multimedia program to assist families and caregivers in dealing with people diagnosed with dementia.
Conradie et al. [12]	Development of a device that will allow to assist blind people in their movement indoors as in train stations.
Astell et al. [32]	A program development to improve social interaction of people with dementia with their caregivers and family members.
Han et al. [33]	Development of a device to be used by people with limited mobility in the conduct of their hydrotherapy sessions.
Weightman et al. [34]	Development of a game to aid in children rehabilitation with cerebral palsy.
Kittel et al. [35]	Identification of the reasons for the high abandonment of wheelchair use, even those that are customized and have a high price.
Miettinen and Hasu [36]	Development of a magnetoencephalography machine (MEG) to be used in brain research and diagnostics.
Obradovich and Woods [37]	Investigation of how people use a terbutaline infusion pump in preterm labor in women at risk.

Then, a cross analysis of user tasks and their characteristics were developed. The objective of this cross-analysis was to relate the characteristics of the users that the authors recommended to the tasks performed during their involvement

in the medical product development process. In this analysis, it was possible to identify the most appropriate user's characteristics for each task performed in different phases of the medical product development. Table 1 presents the description of the 15 cases selected.

4. Results

4.1. User tasks identification

The multiple case analysis identified 12 tasks performed by users during the product development process. The tasks were grouped according to the usability engineering process proposed by IEC 6236 (Figure 1). These tasks define the activities that can be performed in collaboration with the users. They also ensure that information from users and theirs context of use of medical products, including all regulamentation information requirements, is collected. The tasks descriptions are shown below.

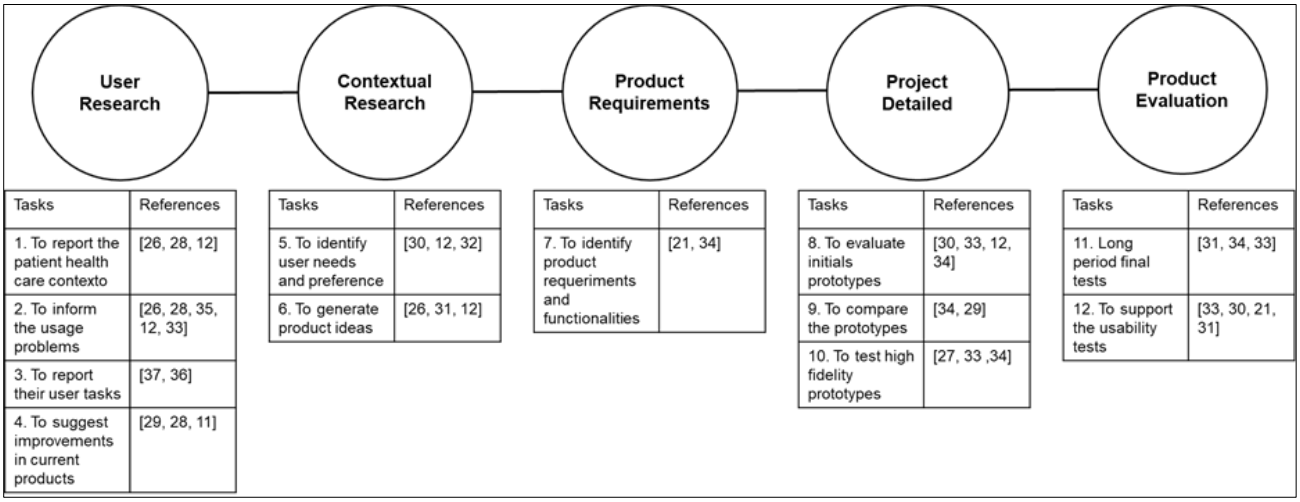

Figure 1 Tasks performed by users during the product development process

4.1.1 Tasks related to User research phase

Task 01: To report the patient health care context. In cases of medical product, the development team may not have all the necessary experience about the challenges to give the medical care in each context of product use [12, 26, 28]. In medical products exists so many types of product medical users, as well different patients impairments. Therefore is important the development team involve users to collect information about different context of use [12], [28] and how this is affected by the patient impairment type and severity [12, 26].

Task 02: To inform the usage problems. There are diverse motives that turn the product difficult to use for some users, for example: the patient's illness can be rare [26, 35], the product is not suitable to the context of use [12, 28] or the patient type of impairment was not considered [33] and so on. A way to understand the discordances of use is asking users about the problems they have with the product [12, 26, 33, 35].

Task 03: To report their user tasks. This task is related with product operation in order to collect the activities the user have to do to use the product. The differences among user types and patient impairments affect the way they use the product and consequently how the user tasks are made [37]. So is important the development team to involve the users and map all the activities the users are doing to use the product [36, 37].

Task 04: To suggest improvements in current products. The development team do not need to depend only on their ideas but can also consider solutions became from users. These solutions can be an improvement in diverse factors of the product, for example: how to resolve discordances of use [29], how to design a completely new concept [28] and how the user experience can improve with same changes [11].

4.1.2 Tasks related to Contextual research phase

Task 05: To identify user needs and preferences

A definition of the target users is crucial to identification of user preferences [12, 30, 32]. Studies about the different levels of user needs are also can be necessary because clarify who are the mainly product users [12, 32]. This information guides the product concepts generations and enable the development team to create concepts that satisfy all user groups and their context of use [12, 32].

Task 06: To generate product ideas

Users that belong to the target user previously defined can be recruited to participate in the sessions of prototype creations [12, 26, 31]. This contact with user enable the development team to incorporate rapidly the user preferences while product concepts are generated.

4.1.3 Tasks related to Product requirements phase

Task 07: To identify product requirements and functionalities

This task is related to the definition of quantitative parameters with users that will guide product the development and also product evaluations [21, 34]. The development team through the interpretations of the information previously collected generally makes these definitions but users also can contribute validating the parameters and their values.

4.1.4 Tasks related to Project detailed phase

Task 08: To evaluate initials prototypes

Some uncertainties and doubts about the product design, for example the posture [12, 30, 33, 34], user interactions [21, 31, 32, 34] and aesthetics [33, 34], can be solved during earlier prototypes evaluations with users. These corrections in product design are important be realized before the construction of a beta prototype to avoid large and possibly late and costly modifications in product development.

Task 09: To compare the prototypes

Users can compare different versions of the product and identify which better meet their needs [29, 34]. Based on the analysis of user preferences among the prototypes for certains product characteristics, the development team can understand if the product meets user needs and then decides if new prototypes will be build or just simply modifications in current prototypes are enough.

Task 10: To test high fidelity prototypes

The development team can invite users to perform activities that represent the operation of the product as a whole [27, 33, 34]. This task enable the development team to fix prototypes before the construction of a costly real product version.

4.1.5 Tasks related to Product evaluation

Task 11: Long period final tests

Users can be invited to test for a long time the product usability in a real context of use. These evaluations aim to ensure that the product have an appropriated usability for the users. The tests are usually done with few users, realized at theirs home [31, 34] and also at the tratament local [33, 34].

Task 12: To support the usability tests

As there are so many types of product medical users and different patient's impairments, sometimes non-patients, for example caregivers or health people, are invited to participate in usability sessions to support the development team. This help can be in any moment of the project: therapy session creation [33], development of questionnaires [30], be a reference and assure the quality of the test results [21, 31].

4.2. User characteristics identification

The characteristics of the users identified in this research were recommended by the authors of the case studies as appropriate for the task that the user performed when being involved in the development of the medical product.

Although the authors consider several criteria for recruiting users, such as age, geographic location, profession and disease or disability, these are information that contribute to the definition of the target users of the project. However, in this study, we sought to map the characteristics that affect the use of the product and, therefore, should be considered during the involvement of users in the development of the medical product. The description of each of the characteristics identified is presented in table 2.

Table 2 Description of user's characteristics

Characteristic	Description	Case
Experience frustrated with current products	The product does not meet the user need for many reasons: a rare disease, context of use not contemplated and so on	[12, 26, 28]
Experience time of product use	Quantity of time (for example, years and months) since the first product utilization by the user	[26, 27, 29, 30, 33, 38]
Experience with a specific brand	Identification if the user has experience with a specific brand in question	[27, 29]
Frequency of use	What is the periodicity of use, for example, if the user use the product one time a month, use daily, sporadic use etc	[12, 21, 26, 27, 30–34, 36–38]
Experience with patient illness or disability	What is the frequency that has the user been in contact with patients with the illness or disability (daily, monthly, never, etc.).	[26, 28, 31, 32, 34]
Practical experience of the difficulties faced by the patient	This indicates if the person is been socializing and caring with patients	[12, 21, 26–28, 30, 31, 33, 37]
Willingness to learn	To know if the health people involved like to learn new things	[21, 34]
Technical ability	the level of product functional knowledge, which can be expressed in various way by the user: realize the use tasks is a less time, ability to fix the product, knowledge about the product components and so on	[12, 21, 30, 34]

4.3. Cross analysis: the model of user tasks and characteristics

In all the cases analyzed in this research, it is possible to note the relation between the characteristics and the tasks that the users were performing. Figure 2 aims to present the relationship between user involvement activities and the characteristics of the users involved. This relationship indicates a criterion that can be used to perform the selection of users in each of the activities.

The height of the valley of each line in figure 2 represents the number of times the characteristic was relevant to the task that the user was performing. In the Garmer [39] study, for example, the author pointed out that users more experienced with the product were more confident and have more competence to suggest improvements in the product, while inexperienced users aided in identifying the most recurrent and more serious problems of product use. Conradie et al. [12] decided, in their researches, to involve users without technical knowledge of the product to evaluate the initial prototypes because they found that lead users, with a lot of technical knowledge, contributed ideas that were inconvenient, according to the authors, to other users of the product.

It is interest to note that there are some user characteristics the development team should consider during all the phases of medical product development: frequency of use, experience with patient illness or disability and practical experience about the difficulties faced by the patient. However, the others characteristics are relevant in just determined moments

of the project. Thus, Figure 2 can be seen as a model representing the most appropriate characteristics that the development team need to consider for each task that the user can perform in the process of usability engineering.

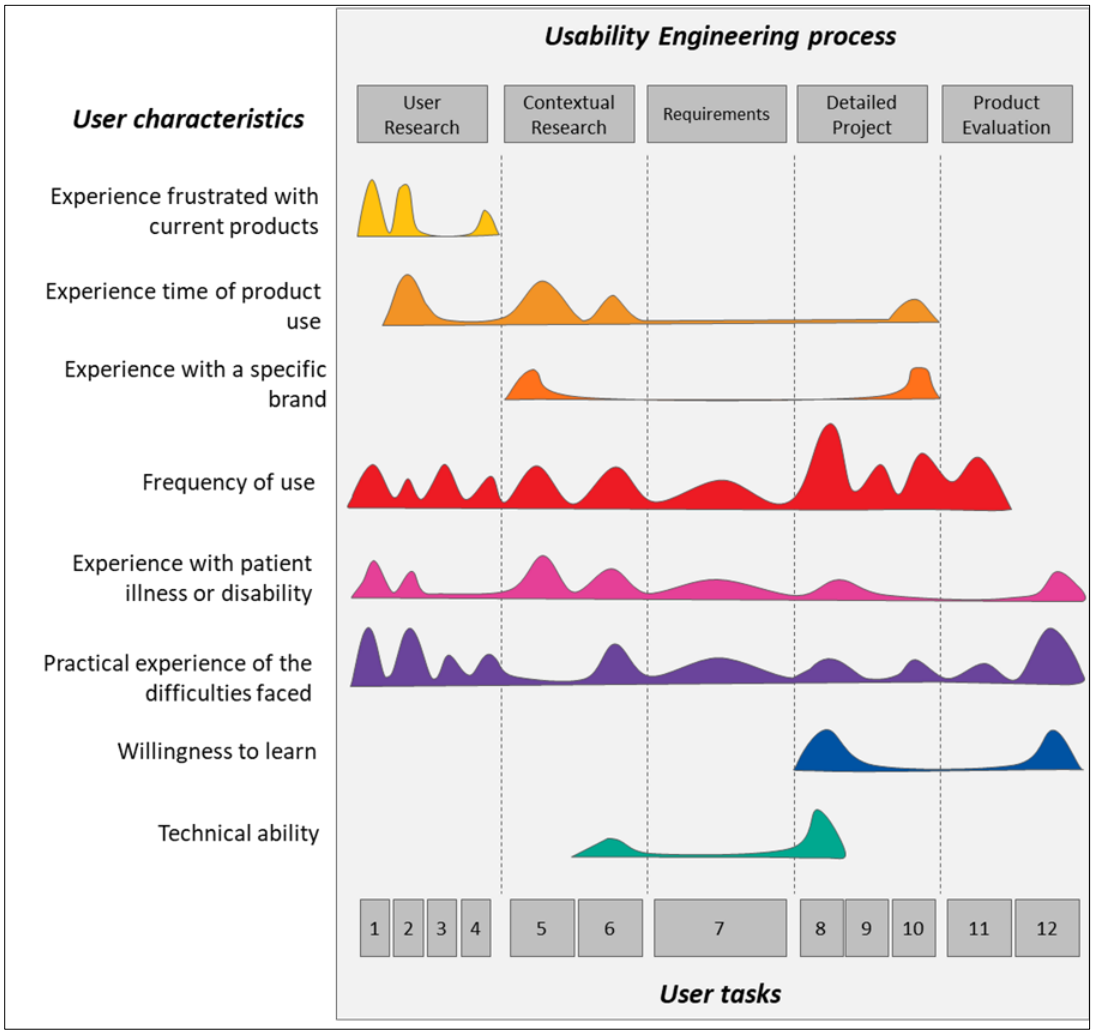

Figure 2 Model for selecting user based on the need characteristic of each user involvement task

5. Conclusion

Based on the creation of this model of the tasks and characteristics of the users, this research presents a diagnosis of the cases of user involvement in the medical industry, in order to demystify the user's role as well as their most important characteristics in the different stages of development and finally helps to enrich the understanding of how usability engineering can act to prevent errors during the use of the products.

In general, the user can be involved in all phases of medical product development. However, the development team should consider the appropriate user characteristics for each task they are performing. When recruiting users to the task of identifying product requirements, it might be more appropriate to involve users with different frequency of use, experiences with patient illness, and practical experiences about the difficulties faced by the patient, than involving users with different technical skills with the product. It is concluded, therefore, that it is not enough to involve any user throughout the development of the product, but that there are more appropriate users than others, depending on the task that will be performed during their involvement.

Although the usability norm and others models present in the literature focuses on the methods that can be performed by the development team to involve the users, this research highlights that the characteristics of the users involved is also an important aspect. The characteristics of the users mapped in this research affect the use of the product and, therefore, can help the development team in the choice of the users that will be involved. The tasks of the users represent the activity performed during their involvement in the development of the medical product. The cross-analysis of user

characteristics and tasks allowed us to understand how the user can be involved and thus contribute to demystify who the right users are to be involved at the right time, as stated by Lettl [13].

Compliance with ethical standards

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Disclosure of conflict of interest

The authors declares that there is no conflict of interest in their research study.

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