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Usability Based Design of Medical Devices

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Description

Product usability is a crucial feature that must be present for widespread market adoption. The relative scientific literature is heavily normative-oriented, whereas standards on usability are heavily focused on evaluation procedures and specific aspects, such as software issues or human-machine interaction. The few methodological works that focus on usability either view it as one of the many requirements for a given project or present very general approaches. There are currently no design approaches that are systematically geared toward integrating usability and constraints related to usability. LEPRE, a medical device for upper- and lower-limb robotic rehabilitation, is the subject of this paper's application of a usability-oriented model for device design. The device's usability was assessed using two methods: System Usability Scale (SUS) questionnaires were administered to eight physiotherapists, two physiatrists, and 12 patients in order to facilitate a quantitative evaluation. These questionnaires were used to outline qualitative evaluations. The findings back up the plan to provide an integrated methodological approach that can be used early on in the project, saving money and time and resulting in a more linear product development for this application. A product or service's usability, in addition to its safety, is a crucial requirement for widespread market adoption especially in the medical device industry. However, few scientific works and regulations approach usability methodologically, considering it to be one of the many requirements for the project or recommending very general approaches [1,2].

Usability is defined as the extent to which a system, product, or service can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use" by the International Organization for Standardization (ISO). Because of this, the concept of usability is extremely broad, and the scientific literature adds additional attributes to the ISO parameter list, interpreting and giving the ISO definition additional meanings, such as: ease of use, adaptability, adaptability, attitude, and ability to remember. Additionally, because usability can be applied to both software and hardware, it encompasses a wide range of applications, including websites, applications, smartphones, computer mice, and machinery. The ISO definition of usability is used for the purposes of this paper. The scientific literature on usability is heavily normative-oriented, especially in the medical field. Particularly interesting topics include usability risk assessments, usability reports, documentation, and protocols. In addition, the majority of the articles are about software, with a focus on the human-machine interface, evaluation methods, and a large number of very specific application cases. For instance, discussed the difficulties associated with operating room devices' usability and described the usability of a novel robotic bilateral arm rehabilitation device for stroke patients. In addition to being specific to a particular medical field (stroke, operating room, and diabetes), the aforementioned application cases

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Received: 01 October 2022, Manuscript No. Jamk-23-85831; **Editor assigned:** 03 October 2022, PreQC No. P-85831; **Reviewed:** 15 October 2022, QC No. Q-858331; **Revised:** 22 October 2022, Manuscript No. R-85831; **Published:** 29 October 2022, DOI: 10.37421/2168-9601.2022.11.400

frequently do not cover the entire range of design options. For instance, the first application example for stroke technologies is restricted to a robotic bilateral arm rehabilitation device, while the diabetes case is restricted to visually impaired or blind patients. All of the usability-related literature, with the exception of the application cases, focuses primarily on software applications and the human-machine interface, so it does not go beyond the standards. Most importantly, it does not use a methodological approach to discuss usability. There are three references in the normative framework that govern the medical device usability domain for the European market [3,4].

To put it another way, the normative framework examines the usability of a medical device almost as if it were the final product of the design process, providing, for instance, indications regarding its post-hoc evaluation. On the other hand, there are fewer clues about how to actively manage aspects of usability during the design evolution itself. In addition, it is a given that any unanticipated change to a process adds additional costs to a project, such as personnel hours, financial costs, or resources, and that the fulfillment of usability-based requirements could have a significant impact on the final design of a device, particularly in the medical field. Even though they do not contextualize design models into all product design stages, other approaches like Design Thinking and Human-Centered Design are useful, complementary design tools. In fact, Design Thinking is a new way to deal with problems in many professions, especially business and information technology (IT), but it does not specifically address the medical field or refer to specific product design stages. In a similar vein, Human-Centered Design is a method for the development of interactive systems that focuses on the needs and requirements of users and applies human factors/ergonomics and usability knowledge and techniques to make systems usable and useful. This tool is broad and does not define specific engineering tasks, despite the fact that Human-Centered Design does provide guidance on the key aspects to be considered throughout the entire design process, significantly influencing the definition of requirements. As a result, the authors know of no design methods that have been developed to date that are systematically oriented toward the integration of usability and constraints related to usability at all stages of the design process [5].

Conclusion

The application of the usability-oriented model in the design process of the LEPRE medical device for robotic rehabilitation of the upper and lower limbs will serve as a case study for the discussion of the model. The end-effectorbased architecture of this robotic device enables it to carry out a variety of rehabilitation treatments: active with biofeedback, active with active-assisted, or passive (CPM). The monitor, the main body, and the frame are the three main groups that make up it. Any motion profile can be implemented in the desired plane thanks to the compact differential system in the main body. Section 2.2 provides an extended description of the device: Study of Case: LEPRE device for rehabilitation.

Acknowledgement

None.

Conflict of interest

No potential conflict of interest was reported by the authors.

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How to cite this article: Mid, Mahian. "Usability Based Design of Medical Devices." J Account Mark 11 (2022): 400.