Finding usability problems in development phase magnetic brain stimulation device

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In her master's thesis with the title “Regulation and implementation of usability engineering for medical device”, Melissa Holopainen, a student of Life Science Technologies in Aalto University, researched medical device regulation in different regions and implemented a usability engineering (UE) process for a next-generation navigated transcranial magnetic stimulation (nTMS) device. The process was conducted as part of the product development in Nexstim Plc, company developing and manufacturing nTMS devices. The conducted process revealed several usability deficiencies that arose from the graphical user interface (GUI).

Medical devices are regulated by national governments and international authorities to give the best possible treatment for patients. The control ensures that medical devices entering the market are both safe and effective. The usability of a medical device is an important factor to ensure correct use and safety of the user and the one receiving the treatment. Complex medical devices that have inadequate usability can cause use errors that possibly lead to dangerous situations. Regulatory authorities in several regions have approved standard IEC 62366-1:2015 describing the UE process for proving conformance with the usability requirements of their regulations and laws.

In her thesis, Melissa Holopainen applied the UE process for the new nTMS medical device to identify and minimize the use errors and thereby reduce use-associated risks. The risk analysis performed in the process revealed that use errors, when operating the device, could possibly lead to ineffective treatment or seizure.

As part of the process, Holopainen conducted a usability evaluation study where nine participants used the system in the most frequent tasks in the depression treatment process in realistic clinical environment. The study resulted in finding several usability problems that were mostly created by unclear instruction texts and ambiguous GUI components. None of the findings generated possible harm for the user or the patient but less severe problems were identified.

More information:

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