이름: 손형국(HyeongGuk SON)
직위: 연구교수 (Research professor)
소속: 고려대학교 구로병원(Korea University Guro-Hospital)
기타소속: 의료기기 사용적합성 연구소(Medical Device Usability Test Center)

강연제목: 의료기기 사용적합성 평가 사례의 후향적 분석을 이용한 위해요인 발굴 연구 소개 (Introduction to a Study on the Identification of Hazard Factors Using a Retrospective Analysis of Usability Test)

Abstract:

With the harmonization of ISO 13485:2016 into domestic regulations, usability engineering has become a mandatory component of the Good Manufacturing Practice (GMP) certification for medical devices. All medical devices are required to undergo usability testing, the design flaws or user errors identified during these tests are part of the design documentation and are not disclosed. Furthermore, both domestic and international regulations have limitations in clearly classifying adverse events and incidents related to device use, making it difficult to identify potential risk factors. Therefore, it is necessary to retrospectively analyze usability test results and identify and assess the risk factors that arise from user characteristics or environmental conditions. In this study, we present two cases of retrospective analysis of usability testing conducted on home-use medical devices and provide insights for future considerations in the design of personal medical devices.

Brief Biosketch

[2021.09~현재] 고려대학교 구로병원 의료기기 분야 의생명연구교수
[2021.09~현재] 고려대학교 구로병원 사용적합성 테스트센터 부센터장
[2022.09~현재] 고려대학교 구로병원 의료기기 안전정보모니터링센터 판별위원장
[2024.02~2025.02] 한국의료기기안전정보원 이상사례 평가 상시위원
[2024.05~2025.04] 한국의료기기안전정보원 혁신의료기기 연구개발 전문위원
[2024.10~2026.10] 서울시 산학협력사업 심의위원