



이름: 이사람 / Saram Lee

직위: 부교수 / Associate Professor

소속: 서울대학교병원 융합의학과 / Transdisciplinary

Department of Medicine & Advanced Technology,  
Seoul National University Hospital

## 강연제목: 의료기기개발과 사용적합성테스트 / Usability testing for medical device development

### Abstract:

IEC 62366-1 defines 'usability' as a feature of the user interface that achieves effectiveness, efficiency and user satisfaction by facilitating the use of medical devices in intended use environments. And it also introduces 'usability engineering' as applying knowledge of human behavior, capabilities, limitations and other characteristics to medical device design to achieve appropriate usability. In Korea, as new medical device manufacturing and quality control standards are applied in 2019, usability is included in GMP screening, and as of January 1, 2022, it is mandatory for all medical devices of grades 1 to 4, which is recognized as a very important requirement for medical device development. In this presentation, it would like to share the experience of usability engineering activities carried out in the process of developing neonatal care units.

### Brief Biosketch

2020-현재 서울대학교병원 융합의학과 부교수 / Transdisciplinary Department of Medicine & Advanced Technology, Seoul National University Hospital, Associate Professor

2021-현재 서울대학교병원 의생명연구원 연구지원본부 담당교수 / Headquarters of Research Administration and Coordination, Biomedical Research Institute, Seoul National University Hospital, Professor in charge

2021-현재 서울대학교병원 의과대학 의학과 겸임부교수 / Department of Medicine, College of Medicine, Seoul National University, Adjunct Associate Professor

2014-2020 서울대학교병원 의생명연구원 연구교수 / Biomedical Research Institute, Seoul National University Hospital, Research Professor

2014 서울대학교 공과대학 협동과정 의용생체공학전공, 박사 / Department of Biomedical Engineering, Seoul National University, Ph.D

2006 경희대학교 공과대학 기계공학전공, 학사 / Mechanical Engineering KyungHee University, B.S.