Master's Program Biomedical Engineering
Master's Thesis
"Usability validation of a pulse oximeter for use in emergency transport and
homecare applications including improvement of the ear sensor"

Author: Sarah Wandel
1st supervisor: Dr. med. Lühmann
2nd supervisor: M.Sc. Fröhlich
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Abstract

This thesis examines possibilities to improve the bluepoint MEDICAL earprobe sensor to meet the requirements for use outside the hospital as e.g. ambient light conditions. Additionally, the usability of an improved prototype of the earprobe sensor and the new advanced high performance SpO2 monitor OxyTrue® A with the already existing SpO2 sensors is validated for the use in the field of emergency transport and home care.

For the improvement of the Earprobe sensor a smaller detector was tested and filter material with optimized material qualities was analyzed using a spectrometer and implemented in a prototype. This prototype of the earprobe sensor with modified detector and filter material was tested in a breathdown study. The earprobe sensor prototype was finally tested with the SpO2 monitor OxyTrue® A and all corresponding SpO2 sensor types in a formative usability validation, which was elaborated in compliance with the applicable standards IEC 62366, IEC 60601-1-6, IEC 60601-1-12, IEC 60601-1-11, ISO 80601-2-61, ISO 14971 and the FDA Guideline.

The changes made to the Earprobe sensor were not satisfactory, as measurement dropouts occurred for test persons with darker skin during the breathdown study. The reason is the difficult regulation of the red LED, as red light is absorbed more from dark skin than from light skin. A possible solution for this problem could be a filter material which attenuates red light less than infrared light. A filter material with those properties, which is suitable for mass production, could however not be found.

Regarding the formative usability validation, the elaborated questionnaires could be improved and prepared for the summative usability testing. Output of the formative usability validation were recommended design modifications of the instructions for use of the tested sensors, the quick reference guide and the user manual of the OxyTrue® A. These design modifications encompass changes of graphic sizes, changes of instructions and addition of explanations. Change of the OxyTrue® A software to avoid wrong warning messages and change of the colors of certain numbers displayed by the OxyTrue® A were also output of the usability validation. Implementing these changes will allow the tested devices to pass the formative usability validation and to be prepared for the summative usability testing.