

A method framework for usability testing of medical devices

erik.prytz@liu.se

Erik Prytz<sup>1</sup>

<sup>1</sup>Swedish ICT, SICS East, Linköping

## **Background**

The usability of medical devices is important for the delivery of safe and qualitative care. Poor usability can lead to use errors that endanger patient safety. Healthcare providers are therefore interested in establishing a measure of device usability, e.g. when making purchasing decisions. However, establishing whether a specific product is usable for a specific user population and intended use is not trivial. The current project sought to aid healthcare providers in basic usability testing by establishing a method framework that can be used by e.g. a medical testbed at a hospital to provide a standardized process for usability testing a wide range of medical devices.

## **Method**

An existing method framework developed to American standards was adopted and modified. Modifications were made to ensure compliance with European standards, in particular those related to CE-certification for medical devices. The adapted framework was tested on a medical device prototype by an interdisciplinary team with representatives from industry, academia, and a hospital testbed.

## **Result**

Following the process of the framework resulted in an extensive usability analysis of the tested prototype. The end product of the process, a usability report, was considered valuable to the testbed (e.g., as a base for purchasing decisions) and was also extensive enough to cover several CE-certification usability engineering requirements. The framework was iterated and modified based on lessons learned.

## **Conclusions**

The method framework developed in the current research project provided useful guidance to the usability testing process. It was noted that some level of usability testing expertise is required from the analyst interested in applying the framework. The output from the framework covers some but far from all CE-certification requirements. In conclusion, the framework can be a helpful tool for medical device developers and testbeds to support the usability testing process.