

## ACMIT

### Austrian Center for Medical Innovation and Technology

#### Programme: COMET – Competence Centers for Excellent Technologies

#### Programme line: K1-Centres

#### COMET subproject, duration and type of project:

#### Optimisation of surgical procedures, 04/2014 – 03/2017, strategic

## Usability engineering and testing for medical device development

Usability engineering and testing is an integral part of state of the art medical device development. It offers several advantages besides fulfilling regulatory requirements such as improved safety, customer acceptance, and reduction of training effort. ACMIT built up a usability lab and created and validated a set of processes, guidelines and templates to support usability oriented development and evaluation of medical technology. Additionally, development of medical phantoms and workflow analysis are strongly interlaced with the ACMITs usability activities and support their successful accomplishment.

### Motivation

Usability engineering according to the international recognized standard IEC 62366 is now an essential part of the medical device development, and regulatory demands in this area will further grow in the future. Research has shown that a huge part of reported critical incidents with medical devices can be traced back to use errors, which is stressing the relevance of an appropriate usability engineering process.

Besides the requirement of a user-oriented development process for CE conformity marking and FDA approval, well performed usability engineering also provides significant advantages, such as:

- improved safety
- improved customer acceptance and satisfaction
- reduced training (costs)
- reduced development costs

### Process and infrastructure

Project focus was on the investigation of fundamental building blocks for the design and realization of a Usability Lab. In particular appropriate processes, document templates and guidelines for usability oriented development of medical technology were created and validated, and equipment for a dedicated observer room with video recording and synchronization systems was built up.

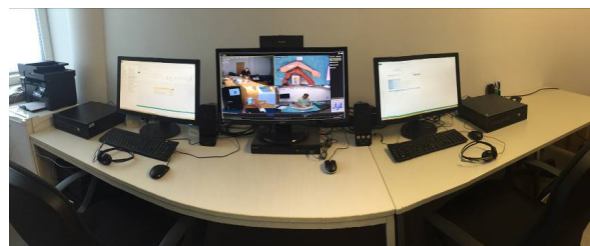


Fig. 1: Observer Room

In addition to the observer room, the configuration for usability studies also comprises a waiting area for the test persons and two rooms for the actual testing.

Testing can be either performed in ACMIT's Experimental Medical Lab in order to mimic hospital settings and/or in a multi-purpose room which resembles home or office environment. Both testing rooms have been upgraded with a dedicated network for video and audio transmission. Two mobile stands equipped with two cameras each, power supply and network switches can be set up easily and used very flexible in different scenarios.



**Fig. 2: Experimental Medical Lab**

In a standard usability setup one camera records the investigated medical device in detail and one

other is showing an overview of the scene including frontal view of the user in order to also record the reactions of the user during the validation.

Besides creating the necessary infrastructure also a team of usability experts was formed.

### **Interconnected activities**

Other building blocks related to usability engineering and testing are ACMIT's work in analysis and documentation of clinical workflows as well as development and creation of medical phantoms. ACMIT's approach is to start usability considerations as well as risk analysis based on the clinical workflow according to which the medical technology should be later used.

Different types of medical phantoms are employed for evaluation of usability of medical devices: in early development stages, rough models are used - during so called cognitive walkthroughs, more sophisticated phantoms mimic (parts of) the patient and allow realistic usability testing.

### **Results**

Based on the project activities described above, ACMIT already successfully accomplished several usability subprojects in different fields and created the environment to high quality usability engineering support for the medical industry.

#### **Contact and information**

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**Further information on COMET – Competence Centers for Excellent Technologies:** [www.ffg.at/comet](http://www.ffg.at/comet)

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