

# Medical usability engineering with IEC 62366: from requirements to validation

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The IEC 62366 (Application of Usability Engineering to Medical Devices) requires a user-centered design process to minimize risks from hazards due to operator error. The presentation explains the IEC 62366 process, using examples from Medela and Sensile Medical projects, including typical stumbling blocks (e.g. language barriers) and best practice (e.g. conceptual modelling of interaction). It covers requirements specification according to user needs, risk analysis, iterative design and validation with users.

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**Tuesday 13.08.2013 | 18.30 - 20.00**  
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