

# Usability Engineering to IEC 62366-1



User Research  
Human Factors  
Usability Testing  
Compliance



Future-proofing medical devices



# Usability Engineering to IEC 62366-1

Understanding your intended users to create usable medical devices.

THAY Medical are a natural choice of partner when developing medical devices, where ease of use, efficiency, effectiveness and user satisfaction is required. We specialize in collaborating with medical device developers to provide the usability and human factors engineering elements that are now critical in maximizing device safety, and in particular—use safety.

## IEC 62366-1 Elements

What THAY Medical can do for you:

- USABILITY PLANNING
- USE SPECIFICATION
- USE HAZARDS AND SITUATIONS
- USE SCENARIOS
- USABILITY RISK ASSESSMENT
- USER INTERFACE DESIGN
- USABILITY VERIFICATION
- FORMATIVE USABILITY TESTING
- RESIDUAL RISK
- ITERATION
- USABILITY VALIDATION
- SUMMATIVE USABILITY TESTING
- USABILITY ENGINEERING FILE

Use environments we can test in:

- Hospitals
- Doctor Surgeries
- Home—use environments
- Simulation Centres
- Ambulances
- Clinics

NOTE: Usability Testing may be referred to as “Human Factors Testing” in some countries.



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## Working together on usability

Developing devices efficiently.

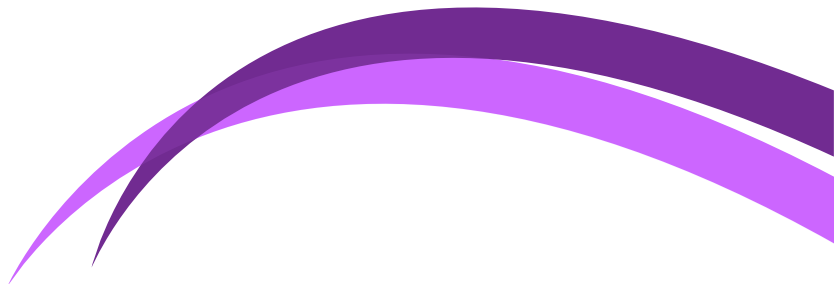
THAY Medical are focused on effective device development, and to do this we work within project schedules to the medical device developer requirements. We focus on working closely with key development staff to provide the research, design, testing and documentation elements required by IEC 62366-1 to either internal quality system requirements or to our own.

The good news is that we are able to work globally in countries such as France, Spain, Portugal, Italy, Ireland, Sweden, Denmark, Holland, Germany, Brazil, Mexico, Australia, New Zealand, South Korea, India, Israel, South Africa, Canada, the USA and the UK. We can perform usability testing in all of these countries and since IEC 62366-1 does not specify where to test, it can be performed where the device is most frequently expected to be used, or to match a sales launch strategy.

## Creating usable devices

Where a good product can become a great product.

Usability engineering is a method of developing a medical device with focus on the intended users. With focus on the user, the risk of use errors can be minimised and the use safety maximised. This can be the difference between a good device, and a great device. For more details, please visit our website or contact us.



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