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Med-Info

International expert information
for the medical device industry

Usability of medical devices

This Med-Info is directed at

- Manufacturers of medical devices
- Manufacturers of components and accessories for medical devices

Background

User-friendliness and ergonomics have become important quality characteristics for medical devices. Manufacturers and users have taken action: Users of medical devices emphasize a high degree of user-friendliness. The manufacturers of medical devices are responding to the requirements of their users through appropriate measures and improvements. By developing better man-machine interfaces, the avoidance of "user errors" receives more importance.

Now there are standards for usability which determine how usability has to be integrated in the development process. TÜV SÜD Product Service explains what the new standards are all about and illustrates the advantages to the manufacturer.

What standards are there?

- IEC 60601-1-6 (Medical electrical equipment – usability)
- IEC 62366 / IEC 62366-1 (medical devices – usability)

What is the goal of the standards?

- To minimize the risk of use error
- To ensure safety through specific development of suitable man-machine interfaces

What do the standards require?

The standards require of the manufacturers a "usability engineering process". This means that methods from ergonomics must be used during the development phase in order to develop a safe and optimal man-machine interface. It also requires a written "usability specification" which specifies all measures in terms of usability of the device. Among other things, the patient population, the user profile, and use cases beside the indented use have to be specified.

All measures concerning the use of the device must be verified with regard to their implementation and effectiveness. The standards place a special focus on validation. Validation must be planned clearly. The procedures, operating scenarios, environmental scenarios, and test user groups must be specified to permit assessment of the effectiveness of the man-machine interface. The validation must then be carried out in accordance with the specified plan, and, if necessary, measures must be taken to improve the user interface.

The most recent version of IEC 62366-1 from 2015 destinguishes between development parallel "formative testing" and the final "summative testing". Both activities are required for the development of safe and user friendly medical devices.

Link to risk management

The standards have a strong link to risk management. The risks arising from usability have to be handled by the risk management. On the other hand, all risk mitigation measures which involve the user have to be treated in the usability process. An example for this would be a warning message on the display which has to be comprehensible to the user – the evalution of this warning message would be part of a usability validation.

What about legacy user interfaces?

The most recent versions of IEC 62366 and IEC 62366-1 state clear requirements regarding legacy user interfaces or user interfaces of unknown provenance. A central part is the evaluation of market feedback regarding the usability of the device. In case the market feedback does not show any deficiencies with respect to the usability, the usability process can be curtailed.

How can TÜV SÜD help you?

TÜV SÜD Product Service has set up a comprehensive service offer. First of all we offer assessment of your documentation:

- On a voluntary basis
- CB assessments
- In conformity assessment procedures according to directive 93/42/EEC Annex II

Beside the assessment of the usability file we can offer you the following services in cooperation with our partner lab:

- Usability testing under realistic conditions
- Assessment of the usability in parallel with your engineering process
- Training in the new standards and in practical aspects of usability
- TÜV SÜD certification mark for usability

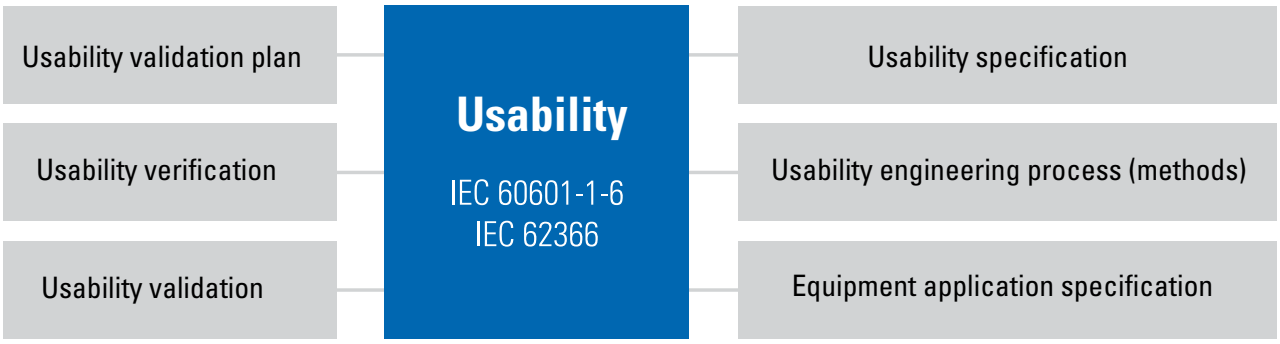
Why should you subject your devices to such a test?

- You achieve optimal protection against use errors.
- You demonstrate that you have developed the man-machine interfaces of your product based on the state of the art in research and technology.
- You have a clear competitive edge through the greater satisfaction of users.
- The trusted and widely recognized TÜV SÜD certification mark represents a marketing advantage.

Your contact partner at TÜV SÜD Product Service can provide further information.

Dr. Andreas Purde
Phone: +49 89 5008-4203
Email: andreas.purde@tuev-sued.de

Dr. Jan Havel
Phone: +49 89 5008-4376
Email: jan.havel@tuev-sued.de



TÜV SÜD Product Service GmbH, Medical and Health Services, Ridlerstr. 65, 80339 Munich
www.tuev-sued.com/medinfo