

Usability (IEC 60601-1-6):

Minimization of risks for patients and users

The new standard IEC 60601-1-6 refers to medical electric devices and their combinations. It describes the process of ergonomic design and gives instructions, as to how this process shall be organized, carried out and documented. The usability of the concerned medical equipment shall be so good that the fundamental safety, as well as its essential performance are secured. The standard refers explicitly to use errors and how these can be reduced to an acceptable value. Though the consequences of faults as result of the irresponsible conduct lie beyond the focus of the standard.

In this context it should be mentioned that steute cooperates closely with a university institute that plays a leading role in the determination of ergonomics and usability of medical equipment.

Risk analysis / risk management for medical equipment

The idea of risk management known by the introduction of the ISO 14971 has characterized the basic concept of the third edition of IEC 60601-1. With it the product standard, as well as the process standard, are considered.

Basically the degree of risk is determined by two factors: degree of damage and possibility of occurrence.

The risk analysis is in the meantime for designing engineers and safety engineers a usual method. The risk management per ISO 14971 and soon also per IEC 60601-1-1 goes beyond this. Beside the pure analysis and determination of risk classes, it contains decisions about the acceptability of the planned safety measurements, as well as the definition, implementation and verification of counter-measures and market observation.

Fig. 1

