Usability of Medical Devices

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This chapter gives an overview on how to design medical equipment according to international standards (IEC EN DIN 62366 and IEC EN DIN 60601-1-6) with the user in mind, no matter if physician, nurse or patient. After the definition of the term usability (Sect. 6.1) and widening it to include questions of safety and user satisfaction. In Sects. 6.2 and 6.3 the general questions of usability in medical technology are positively discussed to lead to Sects. 6.4–6.6 outlining in detail the development, testing and assessment of usable devices. The chapter ends with a an illustrative example (Sect. 6.7).

Usability engineering (also called human factors engineering), which is the development of devices which are fit for use, is a subarea of ergonomics. Ergonomics is an interdisciplinary science which concerns itself with adapting work to people. Until the middle of the last century, it was the primary aim of engineers, medical scientists, ergonomists, anthropologists, physiologists, psychologists, and others to reduce the physical exertion of the worker and simultaneously increase production.

6.1 What Is Usability?

As a result also of the increasing digitalization of the working world and of leisure and consumer goods, in recent years the focus has shifted from the reduction of physical exertion to the reduction of mental exertion of the user when using devices, and it could also be said that the devices should not distract the operator’s attention away from the actual task as a result of inexplicable operating concepts. Devices which are particularly simple and intuitive to operate are today described as usable.

Usability is a qualitative attribute which indicates how easy devices are to use. The term usability includes the following properties of a device:

- Effectiveness: Can the goal of the user be fully achieved with the device?
- Efficiency: What is the cost of achieving this goal?
- Satisfaction: What reaction does the device prompt in the operator: does it disturb, or provide assistance?

Another aspect is increasingly gaining in importance in connection with usability in the field of medicine itself, i.e., the aspect of safety. This is important because it has been recognized that risks to the operator or to other people and objects are possible both as a result of potential faulty operation and also as a result of correct use of a device. This recognition gained acceptance early on in the field of aviation and the power plant industry, and in these sectors there is a lot of investment in the development and testing of ergonomic and usable properties.

In other consumer sectors, however, it often becomes apparent that the terms ergonomic and usable
are used as marketing instruments, rather than the corresponding product properties being based on verifiable criteria with a scientific basis.

In contrast, products which are truly intuitive and therefore simple to use have an indisputable competitive advantage. They are accepted by the customer as being top of the line and so become bestsellers. The iPod and iPhone have already become almost proverbial examples of these kinds of products which are extremely successful in the market.

### 6.2 Usability in Medical Technology – Obligation or Opportunity?

To provide all groups involved in health care with a guideline about how usability can be achieved and tested, an internationally valid standard was published in 2006 as a collateral standard for the general provisions for the safety of medical devices. This safety standard for electrical medical devices was authoritatively written by manufacturers of medical devices, scientists, testing institutes, and experts in usability, and has been validated in Germany as a harmonized standard since 1 February 2008 [6.1].

Another international standard for the application of usability for all medical devices gained validity on 1 September 2008 [6.2]: IEC 62366 is increasingly replacing the older IEC 60601-1-6, and for this reason reference will primarily be made below to the content of IEC 62366.

It is first necessary to establish how international standardization defines usability. According to international standardization, usability is the [6.2]:

**character of the user–product interface, which includes the effectiveness, efficiency and learnability and the satisfaction of the user.**

Through this definition alone, the device is accredited with essential features, and the user, in contrast to the manufacturer, is to a certain extent relieved of his responsibility; the device must support the user in operating the device correctly and learning how to do so.

The introduction to this process standard already includes clarification that safe usability is not an unambiguous definition, such as, the paper size according to DIN A, but rather is a challenging task, a method, a process, which demands entirely different capabilities than the (purely) technical realization of this interface. Ergonomics and considerations of usability constitute an interdisciplinary science which primarily involves designing, evaluating, and finally testing the configuration of the operating elements and the man–machine interface, with an external but expert eye, both with impartiality and without blinkers. The usability-orientated developing process should therefore minimize operational errors and risks associated with use. It is closely associated with the established risk management process of ISO 14971 [6.3].

The manufacturer must establish how it specifies the usability of its medical device [6.2] and therefore minimizes risks associated with use. Which risks it accepts is left to the manufacturer according to ISO 14971 [6.3] and is thus the policy of the manufacturer. This provides the manufacturer with the opportunity to position itself in the market according to its concepts, goals, and possibilities. It can determine for itself how it minimizes hazards which it will not accept for its product. It can invest, for example, in an intuitive man–machine interface [6.2]:

*If training is necessary for the medical device in question in order to ensure safe and effective use of the main operating functions by the designated user, the manufacturer must take at least one of the measures – provide the necessary training material itself; – ensure that this material is available; or – provide the training itself.*

*If training of this nature is necessary, the accompanying documentation must describe the available training possibilities and give details of the approximate duration and frequency of training.*

It remains to be seen whether usability will in the future be seen by manufacturers as an inconvenient obligation which must be fulfilled, or as an opportunity to set themselves apart from competitors as a premium manufacturer.

Another advantage for the manufacturers is the result of usability tests which are to be carried out in accordance with IEC EN DIN 62366 and 60601-1-6 during the design and development process and documented in what is known as the usability engineering file. Doing so, the manufacturer can increase the ease of use of his product and can avoid usability issues and risks associated with usability. This reduces the