European Medical Device Usability Requirements

Manufacturers marketing medical devices in Europe need to be able to demonstrate compliance with the newly clarified usability requirements introduced by Directive 2007/47/EC. This article discusses European usability requirements, relevant European standards and important ethical considerations.

Essential Requirements

The need to ensure that medical devices are designed, manufactured and also used in a way that does not lead to unnecessary risks to patients and users is not new. This need is addressed in a broad manner in the general Essential Requirements of all three medical device directives: the Medical Devices Directive (MDD; 93/42/EEC), Active Implantable Medical Devices Directive (AIMDD; 90/385/EEC) and In Vitro Diagnostic Medical Devices Directive (IVDD; 98/79/EC). In spite of these requirements, some medical device manufacturers fail to recognise that specific activities, such as the incorporation of device use in risk analysis during device design or modification, are needed to prevent unnecessary use errors. As a result, Directive 2007/47/EC, which came into effect in March 2010 and revised the MDD and AIMDD, introduced important revisions and clarifications, including clearer usability requirements. Recital 18 of the revising directive states:

"As design for patient safety initiatives play an increasing role in public health policy, it is necessary to expressly set out the need to consider ergonomic design in the essential requirements. In addition the level of training and knowledge of the user, such as in the case of a lay user, should be further emphasised within the essential requirements. The manufacturer should place particular emphasis on the consequences of misuse of the product and its adverse effects on the human body."

Thus, Essential Requirement 1 of Annex I of the MDD was revised to include two additions to the primary requirement:

- to reduce, as much as possible, the risk of use error due to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety)
- to consider the technical knowledge, experience, education and training and, where applicable, the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

Readers should refer to the MDD for the exact language of the requirement. It is interesting to note that the revised AIMDD does not include clarified requirements related to usability. Also, the IVDD was not revised by Directive 2007/47/EC. Nonetheless, as stated earlier, the need to consider usability in medical device design is inherent in the Essential Requirements of these two directives as well.

Other Essential Requirements also address specific usability concerns in the MDD. For example, Essential Requirement 12.9 requires that the function of the controls and indicators be clearly specified on the devices. Where a device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, it also requires this information to be understandable to the user and, as appropriate, the patient.

Essential Requirement 13.1 requires that each device be accompanied by the information needed to use it safely and properly, taking account of the training and knowledge of the potential users, and that the manufacturer be identified.

Harmonised standards

While the European directives define the Essential Requirements, European harmonised standards provide corresponding technical specifications for meeting the Essential Requirements of the directives. These standards are not mandatory and, as such, alternate methods for meeting the requirements of the directives are possible, but the producer has an obligation to prove his products are in

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conformance with the Essential Requirements. Compliance with European harmonised standards, however, provides a presumption of conformity with the relevant Essential Requirements.

The primary standard for medical device usability is EN 62366, Medical devices – Application of usability engineering to medical devices. This standard specifies a process for analysing, specifying the design, and verifying and validating usability, as it relates to safety of the medical device. It applies to all types of medical devices, both electrical and nonelectrical. EN ISO 14971, Medical devices — Application of risk management to medical devices, the European harmonised standard for device risk management, is closely linked to the application of EN 62366 and necessary for achieving conformity with the usability standard.

EN 60601-1-6, Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability, applies to medical electrical equipment; however, the 2010 edition generally refers to IEC 62366, which is the international standard adopted as the European harmonised standard EN 62366. For example, clause 4.2 of EN 60601-1-6:2010 states that a usability engineering process complying with IEC 62366 shall be performed. For this reason, the principal standard that medical device manufacturers should use to demonstrate compliance with European device usability requirements is EN 62366 in conjunction with EN ISO 14971.

A comprehensive standard

EN 62366 is a 104-page standard that describes a usability engineering process, and provides comprehensive guidance on implementation of the process, in order to minimise the risk of use error in medical devices. The first 17 pages include these seven clauses:

- Scope
- Normative references
- Terms and definitions
- Principles
- Usability engineering process
- Accompanying document
- Training and materials for training

Most of the document consists of informative annexes, which include: general guidance and rationale for various provisions of the standard; categories of user action; examples of use errors, abnormal use and possible causes; guidance on the usability engineering process; questions that can be used to identify medical device characteristics associated with usability that could impact safety; examples of possible usability-related hazardous situations; and usability goals, using an illustrative example for a home parenteral infusion pump.

Usability engineering process

Clause 5 of EN 62366, Usability Engineering Process, describes the steps in the process. As the standard points out in Clause

4.3, Scaling of the usability engineering effort, they can vary in form and extent, depending on the nature of the medical device, its intended user and its intended use. In addition, the standard advises that, because of the iterative nature of the usability engineering process, the activities described in Clause 5 can be performed in any convenient order.

Readers should refer to the standard for a detailed description of usability engineering process activities, which are included in Clause 5 and also in the informative Annex A. Briefly stated, however, the usability engineering process includes the following steps:

- Development of the medical device application specification, which identifies the most important characteristics related to the use of the device, based upon the intended medical indication, intended patient population, intended part of the body or type of tissue with which the device interacts, intended user profile, intended conditions of use and operating principles. The application specification lays the foundation for defining the usability specification.
- Determination of frequently used functions that involve user interaction with the medical device. This is an important step in the process because inadequate usability of frequently used functions can adversely affect safety by increasing the probability of use error.
- An identification of hazards and hazardous situations related to usability, which includes the identification of characteristics related to safety and of known or foreseeable hazards and hazardous situations. These activities are part of risk analysis and are to be conducted according to EN ISO 14971.
- Determination of the primary operating functions with input from frequently used and medical device safety functions.
- Development of the usability specification, which will provide testable requirements for usability verification, and testable requirements for usability of the primary operating functions, including criteria for determining the adequacy of risk control achieved by the usability engineering process.
- Preparation and maintenance of the usability validation plan, which specifies the methods and success criteria for the validation of the usability of primary operating functions and specifies the involvement of representative intended users; it must also address frequent-use scenarios and reasonably foreseeable worst-case use scenarios.
- Design and implementation of the user interface as described in the usability specification employing, as appropriate, usability engineering methods and techniques.
- Verification of the medical device user interface design against the requirements of the usability specification.
- Validation of the usability of the medical device according to the usability validation plan.

The results of the usability engineering process should be recorded in the usability engineering file; however, if the records and documents are part of other documents and files, the usability engineering file can refer to the location of these records and documents.

Protecting human subjects

The last paragraph of the introduction to EN 60601-1-6 states that clinical investigations conducted according to ISO 14155-1 and usability testing for verification or validation according to this standard are two fundamentally different activities and should not be confused.

However, the distinction between usability tests and clinical investigations is not addressed in any detail either in the usability standards or the medical device directives. For example, the medical device directives do not define clinical investigation; however, this term is defined in ISO 14155:2011, the newly revised standard for medical device clinical investigations, which is expected to become a European harmonised standard in the near future. The standard defines clinical investigation as a "systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device." For these reasons, manufacturers should ensure that usability studies that involve patients do not constitute clinical investigations if that is not their intention. In case of doubt, prudent manufacturers will seek an opinion from a Notified Body or Competent Authority.

In addition, Subclause D.4.3.3, Research protocols and informed consent, of EN 62366 states, among other things, that user research can range from broad information gathering processes, focused brainstorming, problem-oriented sessions or more rigorous hypothesis-based approaches. It further states that subject consent should be obtained if there is any risk, if the research makes appreciable time or other demands on the subject or if the results can appear in a peer-reviewed publication. No additional guidance is provided, such as advice on assessing compliance of the study with standard ethical requirements, such as oversight by an ethics committee. However, a usability study involving a non-CE marked device that exposes patients to risks may need to be reviewed not only by ethics committees but also by the relevant competent authorities.

In many cases, the most efficient and cost-effective method of obtaining usability data is to collect these data during a premarket clinical investigation that is being conducted to establish safety and performance as part of device validation. This approach has the advantage of reducing the number of studies needed and also avoiding potential problems in determining ethical and regulatory requirements applicable to the usability aspects of the study.

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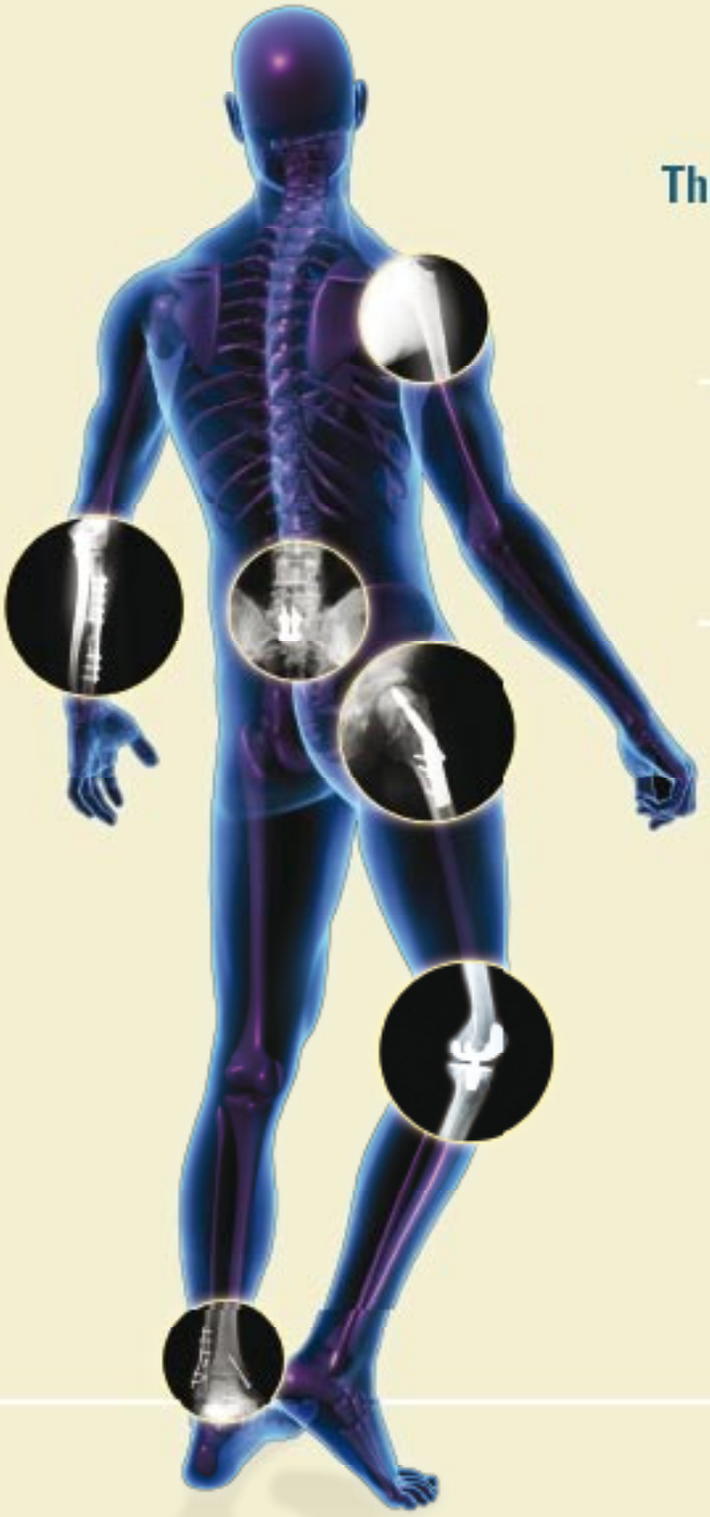

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