

3rd Edition of IEC/EN 60601-1:2005.

This Med-Info is addressed to:

- manufacturers of medical electrical equipment
- manufacturers of components of medical electrical equipment

Background

The IEC 60601-1:2005 (3rd edition) was published in December 2005. It is the third edition of the basic standard, replacing the previous version IEC 60601-1:1988+A1:1991+A2:1995.

As basic standard for medical electrical equipment, this standard deals with the general requirements concerning basic safety and the essential performance.

What is the new standard called?

IEC 60601-1:2005 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance)

Why did a new edition of the basic standard become necessary and which are the most important changes compared to the second edition?

- a) User protection was adjusted to the requirements of IEC 60950-1 for information technology. This has essentially led to alleviated requirements and allows the use of components already approved in IEC 60950-1.
- b) Introduction of risk management as an alternative for compliance of individual aspects of the standard and for covering risks not subject to a standard.

- c) More precise adjustment of the insulation coordination to environmental conditions (e.g. degree of pollution, overvoltage category etc.).
- d) Integration of some collateral standards into the basic standard (e.g. IEC 60601-1-1 systems).
- e) Expansion of the scope of application of the standard beyond basic safety by integration of the essential performance (= functional safety).
- f) The term "under medical supervision" from the scope of application of the second edition has not been included in the third edition. Therefore, medical equipment for household use are now within the scope of application of the basic standard.
- g) The national deviations for America (previously in UL 60601-1) have been included in the third edition.
- h) Introduction of the term "expected service life".
- i) Completely new structure of the standard.
- j) Section 9, "Mechanical hazards", has been expanded significantly.
- k) Extensive explanations in the informative Appendix A.

When will the new standard be introduced and what does this imply?

- a) **MDD conformity assessment procedure, CE marking:** You probably know that according to the "New concept of the EU", the application of harmonizing standards proving the observance of the "Essential Requirements" is not obligatory, but is recommended. For this reason, when fulfilling the third edition of EN 60601-1 after its publication in the Official Journal (OJ) of the EU, complying to the Essential Requirements of MDD 93/42/EEC can also be assumed.

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The IEC 60601-1:2005 was issued as EN 60601-1:2006 in October 2006. The listing within the OJ as "harmonized standard" has not occurred to date (7 September 2007).

Transition periods:

- products without applicable particular part 2 standard: 12 December 2009.
- products with applicable particular part 2 standard: according to the transition period as defined in the relevant part 2 standard.

Since the publication of the IEC standard it can be applied as state of the art.

However, this does not imply the above-mentioned assumption of adherence.

b) **CB procedure:** The use of IEC standards is mandatory as part of the CB scheme. IEC 60601-1:2005 has been adopted as a valid standard in the CB procedure, but is currently still on hold. In addition, the second edition of IEC 60601-1 may also be applied.

c) **NRTL approval (National Recognized Test Laboratory):** As part of the NRTL program, TÜV SÜD Product Service is enjoying consistent growth of its testing business and opens up direct access to the American market for manufacturers. TÜV SÜD Product Service has been accredited as a NRTL by the United States OSHA (U.S. Department of Labor: Occupational Safety & Health Administration). Currently OSHA has not incorporated the third edition into the scope of the NRTL procedure. Consequently, the second edition continues to apply, along with the national deviations for the U.S. and Canada.

d) **Product-specific standards:** If a particular standard for a medical electrical equipment exists (e.g. IEC 60601-2-27 for ECG equipment), which has not yet been adapted to the structure of the third edition, the second edition of the general standard continues to be binding. At this it must be considered that product-specific part 2 standards may define a transition period which may continue to delay the mandatory application of the third edition for the kind of equipment concerned.

e) **DIN EN:** Published in July 2007 as DIN EN 60601-1:2007.

Where can I get a test protocol form?

The test protocol has been provided as part of the CB procedure by the IECEE since August 2006. The protocol can be purchased on the Internet. It is available at www.iec.ch, under "Search Site", enter "TRF 60601" and click on the button "Webstore".

How can TÜV SÜD Product Service assist you?

Due to our longstanding work in the relevant standards committees we have profound knowledge of the requirements defined by the standard. Our service for you:

- training sessions on the third edition of IEC 60601-1:2005;
- definition of the additional requirements of the third edition concerning your product;
- product tests (complete or delta tests).

Specialists from TÜV SÜD Product Service will be pleased to discuss further details with you:

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