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## Med-Info

International expert information  
for the medical device industry

## 3<sup>rd</sup> edition of IEC 60601-1:2005+A1:2012

### This Med-Info is addressed to

- Manufacturers of medical electrical equipment and systems
- Manufacturers of components of medical electrical equipment

### Background

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

Amendment 1 (A1:2012) was published in July 2012. The current version of the standard is thus called IEC 60601-1:2005+A1:2012, also known as Edition 3.1.

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+A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. The German version is published as DIN EN 60601-1:2013.

### 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 often led to alleviated requirements and thus allows, under certain conditions, 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 most national deviations for America (previously in UL 60601-1) have been included in the 3<sup>rd</sup> edition.
- g) Introduction of the term "expected service life".
- h) Section 9, "Mechanical hazards", has been expanded significantly.
- i) Key changes in A1:2012:
  - correction of problems that emerged when the standard was applied
  - reduction of references to risk management
  - clarification of the term "Essential Performance"

# Iec 60603rd Edition Amendment 1

**Rachel S Tattersall**



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