

# INTERNATIONAL STANDARD

# NORME INTERNATIONALE

**Medical electrical equipment –  
Part 1-6: General requirements for basic safety and essential performance –  
Collateral standard: Usability**

**Appareils électromédicaux –  
Partie 1-6: Exigences générales pour la sécurité de base et les performances  
essentielles – Norme collatérale: Aptitude à l'utilisation**





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ELECTROTECHNICAL  
COMMISSION

COMMISSION  
ELECTROTECHNIQUE  
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## INTERNATIONAL ELECTROTECHNICAL COMMISSION

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**MEDICAL ELECTRICAL EQUIPMENT –****Part 1-6: General requirements for basic safety  
and essential performance –  
Collateral Standard: Usability**

## FOREWORD

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International standard IEC 60601-1-6 has been prepared by IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice of IEC technical committee 62: Electrical equipment in medical practice.

This second edition constitutes a collateral standard to IEC 60601-1: *Medical electrical equipment – Part 1: General requirements for safety and essential performance* hereafter referred to as the general standard.

This document cancels and replaces the first edition of IEC 60601-1-6.

This edition of IEC 60601-1-6 was revised to structurally align it with the 2005 edition of IEC 60601-1 and to implement the decision of IEC Subcommittee 62A that the clause numbering structure of collateral standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in IEC 60601-1:2005.

The text of this collateral standard is based on the following documents:

| FDIS         | Report on voting |
|--------------|------------------|
| 62A/550/FDIS | 62A/557/RVD      |

Full information on the voting for the approval of this collateral standard can be found in the report on voting indicated in the above table.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

In the IEC 60601 series of publications, collateral standards specify general requirements for safety applicable to:

- a subgroup of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment); or
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT, not fully addressed in the general standard (e.g. alarm systems).

In this collateral standard, the following print types are used:

- Requirements and definitions: roman type.
- *Test specifications: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
- TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS COLLATERAL STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

- “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes subclauses 6.1, 6.2, etc.);
- “subclause” means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.2.1 are all subclauses of Clause 6).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
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- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (\*).

A list of all parts of the IEC 60601 series, under the general title: *Medical electrical equipment*, can be found on the IEC website.

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "<http://webstore.iec.ch>" in the data related to the specific publication. At this date, the publication will be

- reconfirmed;
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