# INTERNATIONAL STANDARD

# IEC 60601-1-6

Second edition
2006-12

## Medical electrical equipment –

## Part 1-6:
## General requirements for basic safety and essential performance – Collateral standard: Usability



*This **English-language** version is derived from the original **bilingual** publication by leaving out all French-language pages. Missing page numbers correspond to the French-language pages.*

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

# MEDICAL ELECTRICAL EQUIPMENT –

# Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

## FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
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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;

– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

– “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;
- withdrawn;
- replaced by a revised edition, or
- amended.

# INTRODUCTION

Medical practice is increasingly using MEDICAL ELECTRICAL EQUIPMENT for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL ELECTRICAL EQUIPMENT USABILITY have become an increasing cause for concern. The USABILITY ENGINEERING PROCESS is intended to achieve reasonable USABILITY, which in turn is intended to minimise USE ERRORS and to minimise use associated RISKS. Some, but not all, forms of incorrect use are amenable to control by the MANUFACTURER. The USABILITY ENGINEERING PROCESS is an element of the RISK MANAGEMENT PROCESS.

This collateral standard describes a USABILITY ENGINEERING PROCESS, and provides guidance on how to implement and execute the PROCESS to provide BASIC SAFETY and ESSENTIAL PERFORMANCE as it relates to USABILITY of MEDICAL ELECTRICAL EQUIPMENT. It is intended to be useful not only for MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT, but also for technical committees responsible for the preparation of particular standards.

# MEDICAL ELECTRICAL EQUIPMENT –

# Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability

## 1 Scope, object and related standards

### 1.1 Scope

This International Standard specifies requirements for a PROCESS to analyse, design, verify and validate the USABILITY, as it relates to BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT. This collateral standard addresses NORMAL USE and USE ERRORS but excludes ABNORMAL USE.

### 1.2 Object

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

### 1.3 Related standards

#### 1.3.1 IEC 60601-1

For ME EQUIPMENT, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- "the general standard" designates IEC 60601-1 alone;
- "this collateral standard" designates IEC 60601-1-6 alone;
- "this standard" designates the combination of the general standard and this collateral standard.

#### 1.3.2 Particular standards

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

## 2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-8:2006 and the following definitions apply.

NOTE An index of defined terms is found beginning on page 145.

**3.1**
**ABNORMAL USE**
intended act or intended omission of an act by the RESPONSIBLE ORGANIZATION or OPERATOR of ME EQUIPMENT as a result of conduct that is beyond any reasonable means of RISK CONTROL by the MANUFACTURER

NOTE 1 See also Annex B. Examples are given in Annex C.

NOTE 2 It is possible for the PATIENT to be the OPERATOR, e.g. when ME EQUIPMENT is used in the PATIENT'S home.

NOTE 3 ABNORMAL USE is not considered REASONABLY FORESEABLE MISUSE.

**3.2**
**EFFECTIVENESS**
accuracy and completeness with which OPERATORS achieve specified goals

[ISO 9241-11:1998, definition 3.2, modified]

**3.3**
**EFFICIENCY**
resources expended in relation to the accuracy and completeness with which OPERATORS achieve goals

[ISO 9241-11:1998, definition 3.3 modified]

**3.4**
*** OPERATOR-EQUIPMENT INTERFACE**
means by which the OPERATOR and the ME EQUIPMENT communicate

[ANSI/AAMI/HE 74:2001, definition 3.24 modified]

NOTE The ACCOMPANYING DOCUMENTS are considered part of the ME EQUIPMENT and the OPERATOR-EQUIPMENT INTERFACE.

**3.5**
**OPERATOR PROFILE**
summary of the mental, physical and demographic traits of the intended OPERATOR population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements

**3.6**
*** PRIMARY OPERATING FUNCTION**
function that involves OPERATOR interaction that is either frequently used or related to the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME EQUIPMENT in NORMAL USE

**3.7**
*** REASONABLY FORESEEABLE MISUSE**
use by the OPERATOR in a way not intended by the MANUFACTURER but which can result from readily predictable human behaviour

[ISO/IEC Guide 51:1999, definition 3.14, modified]

NOTE 1 REASONABLY FORESEEABLE MISUSE is an intended action.

NOTE 2 Use refers to a product, PROCESS or service.

NOTE 3 Slips, lapses, mistakes and ABNORMAL USE can also be reasonably foreseeable, but are not considered REASONABLY FORESEEABLE MISUSE.

NOTE 4 See also Annex B.

**3.8**
**TRAINING**
application-specific OPERATOR-oriented instruction or exercises required for the safe and effective use of the ME EQUIPMENT

**3.9**
**USE ERROR**
act or omission of an act that has a different ME EQUIPMENT response than intended by the MANUFACTURER or expected by the OPERATOR

NOTE 1 USE ERROR includes slips, lapses, mistakes, and REASONABLY FORESEEABLE MISUSE.

NOTE 2 See also Annex B and D.1.3.

NOTE 3 The physiological response of the PATIENT is not considered part of USE ERROR.

**3.10**
**USE SCENARIO**
sequence of events and tasks used to specify and test the USABILITY of the ME EQUIPMENT

**3.11**
*** USABILITY**
characteristic that establishes EFFECTIVENESS, EFFICIENCY and OPERATOR learnability and satisfaction

**3.12**
**USABILITY ENGINEERING**
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of tools, machines, ME EQUIPMENT, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

**3.13**
*** USABILITY ENGINEERING FILE**
set of RECORDS and other documents that are produced by USABILITY ENGINEERING activities

**3.14**
**USABILITY SPECIFICATION**
documentation defining the OPERATOR-EQUIPMENT INTERFACE requirements related to USABILITY

**3.15**
**VALIDATION**
confirmation, through the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

NOTE 1 The term “validated” is used to designate the corresponding status.

NOTE 2 The use conditions for VALIDATION can be real or simulated.

[ISO 9000:2000, definition 3.8.5]

# 4 General requirements

## 4.1 * Conditions for application to ME EQUIPMENT

The ME EQUIPMENT shall provide adequate USABILITY such that the RISKS resulting from NORMAL USE and USE ERROR are acceptable. See also 7.1.1 and 12.2 of the general standard.

*Compliance with this subclause is considered to exist when compliance with the other clauses and subclauses of this collateral standard is demonstrated.*

## 4.2 * RISK MANAGEMENT PROCESS for ME EQUIPMENT

When performing the RISK ANALYSIS step of the RISK MANAGEMENT PROCESS required by 4.2 of the general standard, the analysis shall consider the following:

– application specification (see 6.2.2.1);

– OPERATOR PROFILE;

– predictable USE ERRORS (see ANNEX C for a list of predictable USE ERRORS);

– * task related requirements;

– * context of use;

– information on HAZARDS known for existing OPERATOR-EQUIPMENT INTERFACES for ME EQUIPMENT of a similar type, if available;

– results of the review of the OPERATOR-EQUIPMENT INTERFACE (see D.2.2 in this document and D.7 of ISO 14971:2000).

*Compliance is checked by inspecting the USABILITY ENGINEERING FILE.*

# 5 ME EQUIPMENT identification, marking and documents

## 5.1 * ACCOMPANYING DOCUMENTS

A brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its USABILITY, shall be included in the instructions for use. The same information shall also be included in the technical description, if this is provided as a separate document.

ACCOMPANYING DOCUMENTS for ME EQUIPMENT may be provided electronically, e.g. by electronic file format or CD-ROM. If the ACCOMPANYING DOCUMENTS are provided electronically, the USABILITY ENGINEERING PROCESS shall include consideration of which information also needs to be provided as hard copy or as markings on the ME EQUIPMENT, e.g. to cover emergency operation.

The ACCOMPANYING DOCUMENTS shall include a description of the OPERATOR PROFILE. The ACCOMPANYING DOCUMENTS shall be written at a level consistent with the intended OPERATOR PROFILE.

*Compliance is checked by inspecting the ACCOMPANYING DOCUMENTS and the USABILITY ENGINEERING FILE.*

### 5.2 * TRAINING and materials for TRAINING

If ME EQUIPMENT specific TRAINING is required for the PRIMARY OPERATING FUNCTIONS of the ME EQUIPMENT, the MANUFACTURER shall:

– provide the necessary materials for TRAINING;

– ensure that these materials are available; or

– provide the TRAINING.

NOTE 1 ME EQUIPMENT-specific TRAINING provides the knowledge and skills required for safe and effective use of ME EQUIPMENT in addition to the OPERATOR PROFILE.

The INTENDED USE shall be the basis for TRAINING and TRAINING material. The instructions for use shall indicate whether specific TRAINING for this ME EQUIPMENT is required and shall indicate the available TRAINING options.

NOTE 2 See IEC 61258 [1]. [1)]

## 6 * USE ERROR and USABILITY

### 6.1 * Safety for the PATIENT, OPERATOR and other persons

A USABILITY ENGINEERING PROCESS shall be conducted to provide safety for the PATIENT, OPERATOR and other persons related to USABILITY of the OPERATOR-EQUIPMENT INTERFACE.

NOTE 1 To guide the application of USABILITY ENGINEERING principles, the HAZARDS to PATIENTS, OPERATORS and other persons as listed in ISO 14971 should be considered.

NOTE 2 The following are examples of HAZARDS for the PATIENT:

– unintentional setting of the diagnostic or therapeutic ME EQUIPMENT, e.g. inappropriate X-ray exposure setting requiring an additional exposure;

– unintentional interruption of delivery of therapy;

– misinterpretation of displayed values followed by an inappropriate treatment;

– confusing data presentation contributing to mental fatigue resulting in increased USE ERROR.

NOTE 3 The following are examples of HAZARDS for the OPERATOR:

– poor anthropometric design leading to musculoskeletal injury;

– repetitive-motion resulting in nerve/tendon injuries;

– poor display contrast resulting in eye fatigue;

– loud noise emanating from the ME EQUIPMENT resulting in hearing impairment.

*Compliance with this subclause is considered to exist when compliance with the other clauses and subclauses of this collateral standard is demonstrated.*

### 6.2 * USABILITY ENGINEERING PROCESS

#### 6.2.1 General

The results of the USABILITY ENGINEERING PROCESS shall be recorded in the USABILITY ENGINEERING FILE. The USABILITY ENGINEERING PROCESS may vary in form and extent based on the nature of the ME EQUIPMENT, its intended OPERATOR and its INTENDED USE (see D.3.2). The records and other documents that make up the USABILITY ENGINEERING FILE may form part of other documents and files, e.g. a MANUFACTURER'S product file or RISK MANAGEMENT FILE.



1) Figures in square brackets refer to the Bibliography.

In the case of the modification of existing ME EQUIPMENT design, the USABILITY ENGINEERING PROCESS may be scaled based on the significance of the modification depending on the results of the RISK ANALYSIS (see D.3.2.2).

NOTE 1 The MANUFACTURER should conduct iterative design and development. USABILITY ENGINEERING should begin early and continue through the ME EQUIPMENT design and development life cycle.

NOTE 2 Due to the iterative nature of the USABILITY ENGINEERING PROCESS, the activities described in the following subclauses may be carried out in any convenient order (see D.2).

*Compliance is checked by inspecting the USABILITY ENGINEERING FILE.*

### 6.2.2 Input for the USABILITY ENGINEERING PROCESS

#### 6.2.2.1 * ME EQUIPMENT application specification

The MANUFACTURER shall specify the application of the ME EQUIPMENT in the USABILITY ENGINEERING FILE.

This specification shall include:

– medical purpose (e.g. conditions(s) or disease(s) to be screened, monitored, treated, or diagnosed);

– PATIENT population (e.g. age, weight, region of body, health, condition);

– part of the body or type of tissue applied to or interacted with;

– * intended OPERATOR PROFILE; and

– application (e.g. environment, frequency of use, location, mobility).

NOTE This specification contains elements of the INTENDED USE.

A summary of the ME EQUIPMENT application specification shall be included in the instructions for use.

*Compliance is checked by inspecting the USABILITY ENGINEERING FILE and the instructions for use.*



#### 6.2.2.2 PRIMARY OPERATING FUNCTIONS

The MANUFACTURER shall determine the PRIMARY OPERATING FUNCTIONS and record them in the USABILITY ENGINEERING FILE.

NOTE 1 See also D.5.3, D.5.5, D.5.9, D.5.10 and D.5.14 for a discussion of methods that might be useful in determining PRIMARY OPERATING FUNCTIONS.

NOTE 2 PRIMARY OPERATING FUNCTIONS should be easily recognizable and self-explanatory to the OPERATOR.

NOTE 3 See element 1.2 of Figure E.1 for an example of PRIMARY OPERATING FUNCTIONS for a hypothetical ME EQUIPMENT.

*Compliance is checked by inspection of the USABILITY ENGINEERING FILE.*

#### 6.2.2.3 * Information for safety as a RISK CONTROL

For RISK CONTROL related to USABILITY, the MANUFACTURER shall decide what information is required for BASIC SAFETY or ESSENTIAL PERFORMANCE, e.g. warnings or limitation of use in the ACCOMPANYING DOCUMENTS, marking, etc. Any such information shall be subject to the USABILITY ENGINEERING PROCESS. Disregarding this information shall be considered ABNORMAL USE. See also Annex B.