INTERNATIONAL STANDARD

IEC 60601-1-6

First edition
2004-06

Medical electrical equipment –

Part 1-6:
General requirements for safety –
Collateral standard: Usability

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-6: General requirements for safety – 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 subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This first edition constitutes a Collateral Standard to IEC 60601-1:1998, *Medical electrical equipment – Part 1: General requirements for safety*, hereinafter referred to as the General Standard.

The text of this Collateral Standard is based on the following documents:

FDIS	Report of voting
62A/452/FDIS	62A/458/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.

In the 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. electromagnetic compatibility).

The numbering of sections, clauses and subclauses of this Collateral Standard corresponds with that of the General Standard.

Clauses, subclauses, tables and figures which are additional to those of the General Standard are numbered starting from 201; additional annexes are lettered AAA, BBB, etc., and additional items aaa), bbb), etc.

In this Collateral Standard, the following print types are used:

– requirements and definitions: roman type;

– notes, examples, explanations, advice, general statements and references: smaller roman type;

– *test specifications: italic type;* and

– TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR IN THIS COLLATERAL STANDARD OR AS NOTED IN THE INDEX OF DEFINED TERMS: SMALL CAPITALS.

The requirements are followed by specifications for the relevant tests.

Clause and subclauses for which a rationale is provided in informative Annex AAA are marked with an asterisk (*).

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 part of the PROCESS of RISK CONTROL.

This Collateral Standard describes a USABILITY ENGINEERING PROCESS, and provides guidance on how to implement and execute the PROCESS to provide MEDICAL ELECTRICAL EQUIPMENT SAFETY. 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 safety – Collateral Standard: Usability

SECTION ONE – GENERAL

1 Scope and object

1.201 Scope

This Collateral Standard specifies requirements for a PROCESS to analyse, design, verify and validate the USABILITY, as it relates to SAFETY of MEDICAL ELECTRICAL EQUIPMENT, hereinafter referred to as EQUIPMENT. This standard addresses NORMAL USE and USE ERRORS but excludes ABNORMAL USE.

1.202 Relationship to other standards

1.202.1 IEC 60601-1

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.

1.202.2 Particular Standards

A requirement in a Particular Standard takes priority over the corresponding requirement in this Collateral Standard.

1.202.3 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 60601-1:1988, *Medical electrical equipment – Part 1: General requirements for safety*
Amendment 1 (1991)
Amendment 2 (1995)

IEC 60601-1-8:2003, *Medical electrical equipment – Part 1-8: General requirements for safety – 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*
Amendment 1 (2003)

2 Terminology and definitions

For the purpose of this collateral standard, the terms and definitions given in Clause 2 of IEC 60601-1:1988, as amended by the other collateral standards, Clause 3 of ISO 14971:2000 and the following apply.

NOTE An Index of all defined terms used in this collateral standard is found at the end of the document.

2.201
ABNORMAL USE
intended act or intended omission of an act by the USER or OPERATOR of EQUIPMENT as a result of conduct that is beyond any reasonable means of RISK CONTROL by the manufacturer

NOTE 1 See also Annex BBB. Examples are given in Annex CCC.

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

NOTE 3 ABNORMAL USE is not considered REASONABLY FORESEABLE MISUSE.

2.202
EFFECTIVENESS
accuracy and completeness with which OPERATORS achieve specified goals

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

2.203
EFFICIENCY
resources expended in relation to the accuracy and completeness with which OPERATORS achieve goals

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

2.204
*** OPERATOR-EQUIPMENT INTERFACE**
means by which the OPERATOR and the EQUIPMENT communicate

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

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

2.205
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

2.206
*** PRIMARY OPERATING FUNCTION**
function that involves OPERATOR interaction that is either frequently used or related to the SAFETY of the EQUIPMENT in NORMAL USE

2.207
*** 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 BBB.

2.208
TRAINING
application-specific OPERATOR-oriented instruction or exercises required for the safe and effective use of the EQUIPMENT

2.209
USE ERROR
act or omission of an act that has a different 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 BBB and DDD.1.3.

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

2.210
USE SCENARIO
sequence of events and tasks used to specify and test the USABILITY of the EQUIPMENT

2.211
*** USABILITY**
Characteristic that establishes EFFECTIVENESS, EFFICIENCY and OPERATOR learnability and satisfaction

2.212
USABILITY ENGINEERING
application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of tools, machines, EQUIPMENT, devices, systems, tasks, jobs, and environments to achieve adequate USABILITY

2.213
*** USABILITY ENGINEERING FILE**
set of RECORDS and other documents that are produced by USABILITY ENGINEERING activities

2.214
USABILITY SPECIFICATION
documentation defining the OPERATOR-EQUIPMENT INTERFACE requirements related to USABILITY

2.215
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]

3 General requirements

3.1 *Addition:*

* The EQUIPMENT shall provide adequate USABILITY such that the RISKS resulting from NORMAL USE and USE ERRORS are acceptable.

6 Identification, markings and documents

6.8 ACCOMPANYING DOCUMENTS

6.8.1 * General

Addition:

A brief description of the 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 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 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 inspection of the ACCOMPANYING DOCUMENTS and the USABILITY ENGINEERING FILE.

6.8.2 Instructions for use

Addition:

6.8.201 * TRAINING and materials for TRAINING

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

– provide the necessary materials for TRAINING;

– ensure that these materials are available; or

– provide the TRAINING.

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

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

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

1) Figures in brackets refer to the Bibliography.

SECTIONS TWO TO SIX – NOT USED

SECTION SEVEN – PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER SAFETY HAZARDS

Replacement (title):

46 * USE ERROR and USABILITY

46.201 * 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 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 EQUIPMENT resulting in hearing impairment.

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

46.202 USABILITY ENGINEERING PROCESS

46.202.1 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 EQUIPMENT, its intended OPERATOR and its INTENDED USE/INTENDED PURPOSE (see DDD.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.

In the case of the modification of existing 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 DDD.3.2.2).

NOTE 1 The manufacturer should conduct iterative design and development. USABILITY ENGINEERING should begin early and continue through the EQUIPMENT design and development lifecycle.

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 DDD.2).

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

46.202.2 Input for the USABILITY ENGINEERING PROCESS

46.202.2.1 * EQUIPMENT application specification

The manufacturer shall specify the application of the 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/INTENDED PURPOSE.

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

Compliance is checked by inspection of the USABILITY ENGINEERING FILE and the instructions for use.

46.202.2.2 PRIMARY OPERATING FUNCTIONS

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

NOTE 1 See also DDD.5.2, DDD.5.4, DDD.5.8, DDD.5.9 and DDD.5.13 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 EEE.1 for an example of PRIMARY OPERATING FUNCTIONS for a hypothetical EQUIPMENT.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

46.202.2.3 * RISK ANALYSIS

A RISK ANALYSIS or part of a RISK ANALYSIS that focuses on USABILITY shall be performed according to Clause 4 of ISO 14971:2000. The term and definition of "medical device" in ISO 14971:2000 shall be replaced by the defined term EQUIPMENT. During the RISK ANALYSIS the following shall be considered:

– application specification (see 46.202.2.1);

– OPERATOR PROFILE;

– predictable USE ERRORS (see Annex CCC for a list of predictable USE ERRORS);

– * task related requirements;

– * context of use;

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

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