IEC 60601-1

Edition 3.0 2012-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

colour inside

AMENDMENT 1
AMENDEMENT 1

Medical electrical equipment –
Part 1: General requirements for basic safety and essential performance

Appareils électromédicaux –
Partie 1: Exigences générales pour la sécurité de base et les performances essentielles

IEC 60601-1:2005/A1:2012

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 11.040
ISBN 978-2-83220-227-2

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FOREWORD

This amendment 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.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/805/FDIS	62A/820/RVD

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

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability 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- withdrawn,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.

The contents of the corrigendum of July 2014 have been included in this copy.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

INTRODUCTION TO THE AMENDMENT

The third edition of IEC 60601-1 was published in 2005. At the time of publication, there were 94 National Committee comments on the 2nd CDV and the FDIS that were deferred to a future amendment/revision. Each of their deferred comments was captured in an Issue Sheet by the SC 62A secretariat. By the time of the Auckland meeting in April 2008, the Subcommittees had developed two Interpretation Sheets and the SC 62A secretariat has received an additional 15 issues from National Committees and other interested parties.

At the Auckland meeting, IEC/TC 62 approved a project to develop the 1st amendment to IEC 60601-1:2005 based on the issues outstanding at the time. The TC approved developing the 1st amendment with a view to addressing outstanding issues, including but not limited to:

– those listed in 62A/593/DC and 62A/602/INF;
– the way in which risk management has been introduced into IEC 60601-1:2005; and
– the way the concept of essential performance is used in IEC 60601-1:2005.

Since the Auckland meeting, the secretariat has received 73 additional issues from National Committees or other interested parties for a total of 182 Issues Sheets. This amendment is intended to address those issues.

FOREWORD

Replace the paragraph beginning "This third edition cancels…" with the following:

This third edition cancels and replaces the second edition published in 1988, its Amendment 1 (1991) and Amendment 2 (1995), the second edition of IEC 60601-1-1 published in 2000 and the first edition of IEC 60601-1-4 published in 1996 and its Amendment 1 (1999). This edition constitutes a technical revision. This edition has been significantly restructured. Requirements in the electrical section have been further aligned with those for information technology equipment covered by IEC 60950-1 and a requirement for including a RISK MANAGEMENT PROCESS has been added. For an expanded description of this revision, see Annex A.3.

Add the following note at the end of the Foreword:

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

In the second dash of the existing ninth paragraph, replace the final sentence with:

Compliance with this edition of IEC 60601-1 requires that the MANUFACTURER have in place a RISK MANAGEMENT PROCESS complying with parts of ISO 14971 (see 4.2).

After the last paragraph of the introduction, insert the following new paragraph:

Amendment 1 to this standard is intended to address:

– issues identified by National Committees and other interested parties since the publication of IEC 60601-1:2005;

– the way in which RISK MANAGEMENT has been introduced into IEC 60601-1:2005; and

– the way the concept of ESSENTIAL PERFORMANCE is used in IEC 60601-1:2005.

1 Scope, object and related standards

1.1 * Scope

Renumber the note as Note 1.

Delete the fourth paragraph.

Replace the fifth paragraph with:

The IEC 60601 series does not apply to:

– in vitro diagnostic equipment that does not fall within the definition of ME EQUIPMENT, which is covered by the IEC 61010 series [61];

– implantable parts of active implantable medical devices covered by the ISO 14708 series [69]; or

– medical gas pipeline systems covered by ISO 7396-1 [68].

NOTE 2 ISO 7396-1 applies the requirement of IEC 60601-1-8 to certain monitoring and ALARM SIGNALS.

1.3 * Collateral standards

Replace Note 3 with:

NOTE 3 Collateral standards in the IEC 60601 family are numbered IEC 60601-1-xx. The IEC maintains a catalogue of valid International Standards. Users of this standard should consult this catalogue at "http://webstore.iec.ch" to determine which collateral standards have been published.

1.4 * Particular standards

Replace the note with:

NOTE Particular standards in the IEC 60601 family that are developed by IEC committees are numbered IEC 60601-2-xx. In addition, particular standards developed by joint projects between ISO and IEC can be numbered either IEC 80601-2-xx or ISO 80601-2-xx depending on which committee administered the project. IEC and ISO maintain catalogues of valid International Standards. Users of this standard should consult these catalogues at "http://webstore.iec.ch" and "http://www.iso.org/iso/store.htm" to determine which particular standards have been published.

2 * Normative references

Update the following normative references:

IEC 60065:2001, *Audio, video and similar electronic apparatus – Safety requirements* [1)]
Amendment 1:2005
Amendment 2:2010

IEC 60068-2-2:2007, *Environmental testing – Part 2-2: Tests – Test B: Dry heat*

IEC 60227-1:2007, *Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements*

IEC 60245-1:2003, *Rubber insulated cables – Rated voltages up to and including 450/750 V – Part 1: General requirements*[2]
Amendment 1:2007

IEC 60335-1:2010, *Household and similar electrical appliances – Safety – Part 1: General requirements*

IEC 60417, *Graphical symbols for use on equipment.* Available from: <http://www.graphical-symbols.info/equipment>

IEC 60601-1-3, *Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance: Collateral standard: Radiation protection in diagnostic X-ray equipment*

IEC 60664-1:2007, *Insulation coordination for equipment within low-voltage systems – Part 1: Principles, requirements and tests*

IEC 60730-1:2010, *Automatic electrical controls for household and similar use – Part 1: General requirements*

IEC 60825-1:2007, *Safety of laser products – Part 1: Equipment classification and requirements*

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1) There exists a consolidated edition 7.2 including IEC 60065:2001 and its Amendment 1 (2005) and Amendment 2 (2010).

2) There exists a consolidated edition 4.1 including IEC 60245-1:2003 and its Amendment 1 (2007).

IEC 60851-3:2009, *Winding wires – Test methods – Part 3: Mechanical properties*

IEC 60851-5:2008, *Winding wires – Test methods – Part 5: Electrical properties*

IEC 61058-1:2000, *Switches for appliances – Part 1: General requirements*[3)]
Amendment 1:2001
Amendment 2:2007

ISO 7010:2011, *Graphical symbols – Safety colours and safety signs –Registered safety signs*

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

Replace the existing references to ISO 11135, ISO 11137, ISO 13852 and ISO 15223 by the following:

ISO 11135-1:2007, *Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 11137-1:2006, *Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices*

ISO 13857:2008, *Safety of machinery – Safety distances to prevent hazard zones being reached by the upper and lower limbs*

ISO 15223-1:2012, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

Delete the following normative references:

IEC 60878:2003, *Graphical symbols for electrical equipment in medical practice*

IEC 61558-1:1997, *Safety of power transformers, power supply units and similar – Part 1: General requirements and tests*
Amendment 1:1998

ISO 31 (all parts), *Quantities and units*

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units*

ISO 11134, *Sterilization of health care products – Requirements for validation and routine control – Industrial moist heat sterilization*

Add the following new normative references:

IEC 62133, *Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications*

IEC 62304:2006, *Medical device software – Software lifecycle processes*

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3) There exists a consolidated edition 3.2, including IEC 61058-1:2000 and its Amendment 1 (2001) and Amendment 2 (2007)

ISO 17665-1:2006, *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 80000-1:2009, *Quantities and units – Part 1: General*

3 * Terminology and definitions

Add a new Note 3 and renumber the existing Note 3 to Note 4:

NOTE 3 When the term "safety" is used in this document in roman or italic type, it does not mean "safety" as defined in ISO 14971, but rather is used to mean "the state of being protected from or guarded against hurt or injury; freedom from danger".

3.5
AIR CLEARANCE

Replace the existing note with the following:

NOTE Adapted from IEC 60664-1:2007, definition 3.2.

Figure 2 – Example of the defined terminals and conductors

In the key, replace "⑩ MAINS CONDUCTOR" by "⑩ MAINS CONNECTOR".

3.15
CLEARLY LEGIBLE

Add an asterisk before the term and replace the existing note by the following:

NOTE See the test in 7.1.2.

3.25
EARTH LEAKAGE CURRENT

Replace the existing definition with the following:

current flowing from the MAINS PART through or across the insulation into the PROTECTIVE EARTH CONDUCTOR or a functional earthed connection according to 8.6.9

3.27
*** ESSENTIAL PERFORMANCE**

Replace the existing definition with the following:

performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified by the MANUFACTURER results in an unacceptable RISK

3.28
EXPECTED SERVICE LIFE

Replace the existing definition with the following:

time period specified by the MANUFACTURER during which the ME EQUIPMENT or ME SYSTEM is expected to remain safe for use (i.e. maintain BASIC SAFETY and ESSENTIAL PERFORMANCE)

NOTE Maintenance can be necessary during the EXPECTED SERVICE LIFE.

3.30
FIXED

Add the following note after the examples:

NOTE See the taxonomy in the rationale for definition 3.63.

3.37
HAND-HELD

Replace the existing definition with the following:

term referring to equipment that, once installed and placed into service, is intended to be supported by the hand

NOTE 1 Equipment can refer to ACCESSORIES or equipment parts.

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.38
HARM

Replace the source citation with the following:

[ISO 14971:2007, definition 2.2, modified]

3.39
HAZARD

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.3]

3.40
HAZARDOUS SITUATION

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.4]

3.43
INSULATION CO-ORDINATION

Add a note to the existing definition as follows:

NOTE This includes insulation types, CREEPAGE DISTANCES, AIR CLEARANCES, distance through insulation, coatings, encapsulation, environmental aspects, etc.

3.44
*** INTENDED USE**
INTENDED PURPOSE

Delete the asterisk in front of the term and replace the existing definition and note with the following:

use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

[ISO 14971:2007, definition 2.5]

NOTE INTENDED USE should not be confused with NORMAL USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

3.49
*** MAINS PART**

Replace the existing definition and the notes with the following:

part of electrical equipment forming a circuit that is intended to be connected to the SUPPLY MAINS

NOTE 1 The MAINS PART includes all conductive parts that are not separated from the SUPPLY MAINS by at least one MEANS OF PROTECTION.

NOTE 2 For the purpose of this definition, the PROTECTIVE EARTH CONDUCTOR is not regarded as a part of the MAINS PART (see Figure 2 and Figure 3).

3.55
MANUFACTURER

Replace existing Note 4 with:

NOTE 4 Adapted from ISO 14971:2007, definition 2.8.

3.65
MOBILE

Replace the existing definition with the following:

term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while supported by its own wheels or equivalent means

NOTE See the taxonomy in the rationale for definition 3.63.

3.67
MULTIPLE SOCKET-OUTLET
MSO

In the existing definition, replace "cables or cords or ME EQUIPMENT for" with "cables, cords or ME EQUIPMENT providing".

3.71
NORMAL USE

In the existing note, delete the term "service" in the last line of the sentence.

3.72
OBJECTIVE EVIDENCE

Replace the existing definition with the following:

data supporting the existence or verity of something

NOTE Objective evidence can be obtained through observation, measurement, testing or other means.

[ISO 14971:2007, definition 2.10]

3.76
PATIENT

Add a note to the definition as follows:

NOTE A PATIENT can be an OPERATOR.

3.81
PEAK WORKING VOLTAGE

Replace the existing source citation with the following:

[IEC 60950-1:2005, definition 1.2.9.8, modified]

3.85
PORTABLE

Replace the existing definition with the following:

term referring to TRANSPORTABLE equipment that, once installed and placed into service, is intended to be moved from one location to another while being carried by one or more persons

NOTE 1 Equipment can refer to ACCESSORIES or equipment parts.

NOTE 2 See the taxonomy in the rationale for definition 3.63.

3.88
PROCEDURE

Replace the existing definition with the following:

specified way to carry out an activity or a PROCESS

[ISO 14971:2007, definition 2.12]

3.89
PROCESS

Replace the existing definition with the following:

set of interrelated or interacting activities which transforms inputs into outputs

[ISO 14971:2007, definition 2.13]

3.98
RECORD

Replace the existing definition with the following:

document stating results achieved or providing evidence of activities performed

[ISO 14971:2007, definition 2.14]

3.100
RESIDUAL RISK

Replace the existing definition with the following:

RISK remaining after RISK CONTROL measures have been taken

[ISO 14971:2007, definition 2.15]

3.102
RISK

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.16]

3.103
RISK ANALYSIS

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.17]

3.104
RISK ASSESSMENT

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.18]

3.105
RISK CONTROL

Replace the existing definition with the following:

PROCESS in which decisions are made and measures implemented by which RISKS are reduced to, or maintained within, specified levels

[ISO 14971:2007, definition 2.19]

3.106
RISK EVALUATION

Replace the existing definition with the following:

PROCESS of comparing the estimated RISK against given RISK criteria to determine the acceptability of the RISK

[ISO 14971:2007, definition 2.21]

3.107
RISK MANAGEMENT

Replace the existing definition with the following:

systematic application of management policies, PROCEDURES and practices to the tasks of analyzing, evaluating and controlling RISK

[ISO 14971:2007, definition 2.22]

NOTE For the purposes of this standard, RISK MANAGEMENT does not include planning for or monitoring of production and post-production information; whereas this is required for compliance with ISO 14971 (see 4.2.2).

3.108
RISK MANAGEMENT FILE

Replace the existing definition with the following:

set of RECORDS and other documents that are produced by RISK MANAGEMENT

[ISO 14971:2007, definition 2.23]

NOTE All safety related information including MANUFACTURER'S calculations, test results, etc. is considered to be part of the RISK MANAGEMENT FILE. See also 4.2.

3.114
SEVERITY

Replace the existing source citation with the following:

[ISO 14971:2007, definition 2.25]

3.116
SINGLE FAULT CONDITION

Replace the existing definition with the following:

condition of ME EQUIPMENT in which a single means for reducing a RISK is defective or a single abnormal condition is present

NOTE See 4.7 and 13.2.

3.118
STATIONARY

Replace the existing definition with the following:

term referring to equipment that, once installed and placed into service, is not intended to be moved from one place to another

NOTE See the taxonomy in the rationale for definition 3.63.

3.130
TRANSPORTABLE

Replace the existing definition with the following:

term referring to equipment that, once installed and placed into service, is intended to be moved from one place to another whether or not connected to a supply and without an appreciable restriction of range

EXAMPLES MOBILE equipment, PORTABLE equipment and BODY-WORN equipment

NOTE See the taxonomy in the rationale for definition 3.63.

3.132
TYPE B APPLIED PART

Delete the reference to "DB" in two places in Note 1.

3.133
TYPE BF APPLIED PART

Delete the reference to "DB" in two places in Note 1.

3.134
TYPE CF APPLIED PART

Delete the reference to "DB" in two places in Note 1 and insert Note 3 as follows:

NOTE 3 See the rationale for the definition of DIRECT CARDIAC APPLICATION (3.22) concerning the applied parts that need to be TYPE CF APPLIED PARTS.

3.136
USABILITY

Replace the existing definition with the following:

characteristic of the OPERATOR interface that establishes effectiveness, efficiency, ease of OPERATOR learning and OPERATOR satisfaction

[IEC 62366:2007, definition 3.17, modified]

3.137
USABILITY ENGINEERING

Replace the existing definition with the following:

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

[IEC 62366:2007, definition 3.18]

3.138
VERIFICATION

Replace the existing definition with the following:

confirmation, through the provision of OBJECTIVE EVIDENCE, that specified requirements have been fulfilled

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

NOTE 2 Confirmation can comprise activities such as:

– performing alternative calculations;
– comparing a new design specification with a similar proven design specification;
– undertaking tests and demonstrations;
– reviewing documents prior to issue.

[ISO 14971:2007, definition 2.28]

3.139
WORKING VOLTAGE

Replace the existing source citation with the following:

[IEC 60950-1:2005, definition 1.2.9.6]

Add the following new definitions:

3.140
AIR KERMA
K
quotient of dE_{tr} by dm, where dE_{tr} is the sum of the initial kinetic energies of all the charged particles liberated by uncharged particles in a mass dm of air, thus

$$K = \frac{dE_{tr}}{dm}$$

Unit: J kg^{-1}

The special name for the unit of AIR KERMA is gray (Gy) (ICRU 60)

[IEC 60601-1-3:2008, definition 3.4]

3.141
ALARM CONDITION
state of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS SITUATION exists for which OPERATOR awareness or response is required

NOTE 1 An ALARM CONDITION can be invalid, i.e. a false positive ALARM CONDITION.

NOTE 2 An ALARM CONDITION can be missed, i.e. a false negative ALARM CONDITION.

[IEC 60601-1-8:2006 / Amendment 1 (2012), definition 3.1]

3.142
ALARM SIGNAL
type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION

[IEC 60601-1-8:2006, definition 3.9]

3.143
ALARM SYSTEM
parts of ME EQUIPMENT or a ME SYSTEM that detect ALARM CONDITIONS and, as appropriate, generate ALARM SIGNALS

[IEC 60601-1-8:2006, definition 3.11]

3.144
BODY-WORN
term referring to TRANSPORTABLE equipment whose INTENDED USE includes operation while being worn by a PATIENT or attached to a PATIENT'S clothing