IEC 60601-1-2

Edition 4.1 2020-09
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014-02+AMD1:2020-09 CSV(en)

IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and definitions clause of IEC publications issued between 2002 and 2015. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC 60601-1-2

Edition 4.1 2020-09
CONSOLIDATED VERSION

INTERNATIONAL STANDARD

colour inside

Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 11.040.01; 33.100.10; 33.100.20

ISBN 978-2-8322-8836-8

Warning! Make sure that you obtained this publication from an authorized distributor.

IEC 60601-1-2

Edition 4.1 2020-09
CONSOLIDATED VERSION

REDLINE VERSION

colour inside

Medical electrical equipment –
Part 1-2: General requirements for basic safety and essential performance –
Collateral Standard: Electromagnetic disturbances – Requirements and tests

IEC 60601-1-2:2014-02+AMD1:2020-09 CSV(en)

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

____

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

This consolidated version of the official IEC Standard and its amendment has been prepared for user convenience.

IEC 60601-1-2 edition 4.1 contains the fourth edition (2014-04) [documents 62A/916/FDIS and 62A/924/RVD] and its amendment 1 (2020-09) [documents 62A/1390/FDIS and 62A/1405/RVD].

In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions are in green text, deletions are in strikethrough red text. A separate Final version with all changes accepted is available in this publication.

International standard IEC 60601-1-2 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 fourth edition constitutes a technical revision.

This fourth 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.

The most significant changes with respect to the previous edition include the following modifications:

– specification of IMMUNITY TEST LEVELS according to the environments of INTENDED USE, categorized according to locations that are harmonized with IEC 60601-1-11: the professional healthcare facility environment, the HOME HEALTHCARE ENVIRONMENT and SPECIAL ENVIRONMENTS;
– specification of tests and test levels to improve the safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS when PORTABLE RF communications equipment is used closer to the MEDICAL ELECTRICAL EQUIPMENT than was recommended based on the IMMUNITY TEST LEVELS that were specified in the third edition;
– specification of IMMUNITY tests and IMMUNITY TEST LEVELS according to the PORTS of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM;
– specification of IMMUNITY TEST LEVELS based on the reasonably foreseeable maximum level of ELECTROMAGNETIC DISTURBANCES in the environments of INTENDED USE, resulting in some IMMUNITY TEST LEVELS that are higher than in the previous edition; and
– better harmonization with the RISK concepts of BASIC SAFETY and ESSENTIAL PERFORMANCE, including deletion of the defined term “life-supporting”;

and the following additions:

– guidance for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS;
– guidance for adjustment of IMMUNITY TEST LEVELS when special considerations of mitigations or INTENDED USE are applicable;
– guidance on RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES; and
– guidance on identification of IMMUNITY pass/fail criteria.

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

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. 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 collateral standard, the term

– “clause” means one of the numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 1 includes 1.1, 1.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 1.1, 1.2 and 1.3.1 are all subclauses of Clause 1).

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

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

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this collateral standard;

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

– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex A.

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

The committee has decided that the contents of the base publication and its amendment 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.

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 publication in which to make products in accordance with the new requirements and to equip them 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.

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 publication using a colour printer.

INTRODUCTION

The need for establishing specific standards for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS is well recognized.

The requirements and tests specified by this collateral standard are generally applicable to MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS as defined in 3.63 and 3.64 in the general standard. For certain types of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, these requirements might need to be modified by the special requirements of a particular standard. Writers of particular standards are encouraged to refer to Annex D for guidance in the application of this collateral standard.

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are expected to provide their BASIC SAFETY and ESSENTIAL PERFORMANCE without interfering with other equipment and systems in the ELECTROMAGNETIC ENVIRONMENTS in which they are intended by their MANUFACTURER to be used. The application of ELECTROMAGNETIC EMISSION standards is essential for the protection of:

– safety services;
– other MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS;
– non-ME EQUIPMENT (e.g. computers);
– telecommunications (e.g. radio/TV, telephone, radio-navigation).

Of even more importance, the application of ELECTROMAGNETIC IMMUNITY standards is essential to ensure safety of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS. To ensure safety, MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are expected to provide their BASIC SAFETY and ESSENTIAL PERFORMANCE in the ELECTROMAGNETIC ENVIRONMENTS of INTENDED USE throughout their EXPECTED SERVICE LIFE.

This collateral standard specifies IMMUNITY TEST LEVELS for safety for ME EQUIPMENT and ME SYSTEMS intended by their MANUFACTURER for use in the professional healthcare facility environment or the HOME HEALTHCARE ENVIRONMENT. It recognizes that RF wireless communications equipment can no longer be prohibited from most PATIENT ENVIRONMENTS because in many cases it has become essential to the efficient provision of healthcare. This collateral standard also recognizes that, for certain SPECIAL ENVIRONMENTS, higher or lower IMMUNITY TEST LEVELS than those specified for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT might be appropriate. This collateral standard provides guidance in determining appropriate IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS.

The IMMUNITY TEST LEVELS specified for BASIC SAFETY and ESSENTIAL PERFORMANCE are based on the reasonably foreseeable maximum of the ELECTROMAGNETIC DISTURBANCE phenomena in the applicable environments of INTENDED USE.

Not all ELECTROMAGNETIC DISTURBANCE phenomena are covered by this collateral standard, as it is not practical to do so. MANUFACTURERS of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS need to address this during their RISK ASSESSMENT and evaluate if other ELECTROMAGNETIC DISTURBANCE phenomena could make their product unsafe. This evaluation should be based on the environments of INTENDED USE and the reasonably foreseeable maximum levels of ELECTROMAGNETIC DISTURBANCES expected throughout the EXPECTED SERVICE LIFE.

This collateral standard recognizes that the MANUFACTURER has the responsibility to design and perform VERIFICATION of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS to meet the requirements of this collateral standard and to disclose information to the RESPONSIBLE ORGANIZATION or OPERATOR so that the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM will remain safe throughout its EXPECTED SERVICE LIFE.

This collateral standard provides guidance in incorporating considerations regarding ELECTROMAGNETIC DISTURBANCES into the RISK MANAGEMENT PROCESS.

This collateral standard is based on existing IEC standards prepared by subcommittee 62A, technical committee 77 (ELECTROMAGNETIC COMPATIBILITY between electrical equipment including networks), ISO (International standards organization), and CISPR (International special committee on radio interference).

INTRODUCTION to Amendment 1

The fourth edition of IEC 60601-1-2 was published in 2014. Since the publication of IEC 60601-1-2:2014, the IEC Subcommittee (SC) 62A Secretariat has been collecting issues from a variety of sources including comments from National Committees. At the November 2015 meeting of IEC/SC 62A in Kobe, Japan, the subcommittee initiated a process to identify high-priority issues that need to be considered in an amendment and should not wait until the fifth edition of IEC 60601-1-2, which is presently targeted for publication sometime after 2024.

Those issues selected for inclusion on the final "short list" to be addressed in Amendment 1 were those approved by a 2/3 majority of the National Committees present and voting at the Frankfurt meeting of SC 62A. At the meeting held on 10 October 2016, 15 items were presented to the National Committees present. All 15 items received the required 2/3 majority of the National Committees present and voting and have been included in the "short list" for consideration in preparing Amendment 1. All remaining issues have been placed on a "long list" for consideration in the fifth edition of IEC 60601-1-2.

The "short list" of issues was documented in the design specification for Amendment 1. MT 23 was directed to consider each issue described in Clause 6 of the design specification and develop an appropriate solution for the identified problem. That final solution in this amendment can encompass any technical solution proposed by the author of the issue or it can involve a different solution developed by the expert group. The expert group can also have recommended that no change to the standard was justified by the problem statement.

Because this is an amendment to IEC 60601-1-2:2014, the style in force at the time of publication of IEC 60601-1-2 has been applied to this amendment. The style specified in ISO/IEC Directives Part 2:2018 has only been applied when implementing the new style guidance would not result in additional editorial changes.

Users of this document should note that when constructing the dated references to specific elements in a standard, such as definitions, amendments are only referenced if they modified the text being cited. For example, if a reference is made to a definition that has not been modified by an amendment, then the reference to the amendment is not included in the dated reference.

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests

1 Scope, object and related standards

1.1 * Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereafter referred to as ME EQUIPMENT and ME SYSTEMS.

This collateral standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of ME EQUIPMENT and ME SYSTEMS in the presence of ELECTROMAGNETIC DISTURBANCES and to ELECTROMAGNETIC DISTURBANCES emitted by ME EQUIPMENT and ME SYSTEMS.

BASIC SAFETY with regard to ELECTROMAGNETIC DISTURBANCES is applicable to all ME EQUIPMENT and ME SYSTEMS.

1.2 Object

The object of this collateral standard is to specify general requirements and tests for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES and for ELECTROMAGNETIC EMISSIONS of ME EQUIPMENT and ME SYSTEMS. They are in addition to the requirements of the general standard and serve as the basis for particular standards.

1.3 Related standards

1.3.1 IEC 60601-1

For ME EQUIPMENT and ME SYSTEMS, 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 ~~(IEC 60601-1:2005+A1:2012)~~, including any amendments;

– "this collateral standard" designates IEC 60601-1-2 alone, including any amendments;

– "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 documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.