

INTERNATIONAL STANDARD

IEC 60601-1-2

Edition 2.1

2004-11

Edition 2:2001 consolidated with amendment 1:2004

Medical electrical equipment –

**Part 1-2:
General requirements for safety –**

**Collateral standard:
Electromagnetic compatibility –
Requirements and tests**

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –**Part 1-2: General requirements for safety – Collateral standard:
Electromagnetic compatibility – 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.
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International Standard IEC 60601-1-2 has been prepared by sub-committee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This consolidated version of IEC 60601-1-2 is based on the second edition (2001) [documents 62A/336/FDIS and 62A/341/RVD] and its amendment 1 (2004) [documents 62A/462/FDIS and 62A/469/RVD].

It bears the edition number 2.1.

A vertical line in the margin shows where the base publication has been modified by amendment 1.

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

- a group of MEDICAL ELECTRICAL EQUIPMENT (e.g. radiological equipment);
- a specific characteristic of all MEDICAL ELECTRICAL EQUIPMENT not fully addressed in the General Standard (e.g. ELECTROMAGNETIC COMPATIBILITY).

In addition, IEC 60601-1-1 has expanded the scope of the general standard to include MEDICAL ELECTRICAL SYSTEMS. In recognition of that expanded scope, this edition of the EMC Collateral Standard takes into account the fact that the general standard now applies to MEDICAL ELECTRICAL SYSTEMS as well as MEDICAL ELECTRICAL EQUIPMENT and includes EMC requirements that are, in most cases, applicable to all parts of the SYSTEM.

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

Subclauses and figures that 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, compliance with which can be tested and definitions: in roman type;
- explanations, advice, general statements, exceptions and references: in smaller type;
- *test specifications: in italic type;*
- TERMS DEFINED IN CLAUSE 2 OF THE GENERAL STANDARD OR OF THIS COLLATERAL STANDARD: SMALL CAPITALS.

NOTE Defined terms are not printed in SMALL CAPITALS in Tables 201-208, in the tables in Annex BBB and in statements required to appear in the ACCOMPANYING DOCUMENTS or instructions for use because they are intended for the customer or user, who may not be familiar with the defined terms of IEC 60601 standards.

The requirements are followed by specifications for the relevant tests.

Some provisions or statements in the body of this Collateral Standard require additional information. Such information is presented in the informative annex AAA, General guidance and rationale. An asterisk (*) in the left margin of a clause or subclause indicates the presence of additional information in Annex AAA.

Annex FFF forms an integral part of this standard.

Annexes AAA, BBB, CCC, DDD, EEE, GGG, HHH and the Bibliography are for information only.

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

The need for establishing specific ELECTROMAGNETIC COMPATIBILITY standards for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS (referred to as EQUIPMENT and SYSTEMS, respectively, in this Collateral Standard) is well recognized.

In particular, the existence of ELECTROMAGNETIC EMISSION standards is essential for the protection of:

- safety services;
- other EQUIPMENT and SYSTEMS;
- non-medical electrical equipment (e.g. computers);
- telecommunications (e.g. radio/TV, telephone, radio-navigation).

Of even more importance, the existence of ELECTROMAGNETIC IMMUNITY standards is essential to assure safety of EQUIPMENT and SYSTEMS. ELECTROMAGNETIC COMPATIBILITY (see definition 2.204) differs from other aspects of safety covered by IEC 60601-1 because the electromagnetic phenomena exist, with varying degrees of severity, in the normal use environment of all EQUIPMENT and SYSTEMS and by definition the equipment must “perform satisfactorily” within its intended environment in order to establish ELECTROMAGNETIC COMPATIBILITY. This means that the conventional single fault approach to safety is not appropriate for application to ELECTROMAGNETIC COMPATIBILITY standards. The ELECTROMAGNETIC DISTURBANCE environment can be compared to ambient temperature, humidity and atmospheric pressure. EQUIPMENT and SYSTEMS may experience environmental conditions within the expected range at any time, and for extended periods of time. As with atmospheric pressure and humidity, the user of the EQUIPMENT or SYSTEM ¹ may not be aware of ambient levels on a continuous basis. The IMMUNITY TEST LEVELS specified in this standard (IEC 60601 TEST LEVELS) represent the range found in the general medical use environment. Therefore, under these conditions, the performance of the EQUIPMENT or SYSTEM would also be expected to be normal.

IEC 60513 states that the distinction between safety and performance standards is often unclear. EQUIPMENT and SYSTEMS are used in the practice of medicine because they provide needed FUNCTIONS. If an EQUIPMENT or SYSTEM does not provide its needed FUNCTION, because of a lack of IMMUNITY to events expected in the normal use environment, this interferes with the practice of medicine and cannot be considered an acceptable situation. Therefore, this second edition of IEC 60601-1-2 departs from the first edition by establishing a minimum baseline of performance in the presence of expected levels of ELECTROMAGNETIC DISTURBANCE.

This second edition recognizes that there is a shared responsibility between manufacturers, customers and users to ensure that EQUIPMENT and SYSTEMS are designed and operated as intended. The EQUIPMENT or SYSTEM manufacturer’s responsibility is to design and manufacture to meet the requirements of this standard and to disclose information to the customer or user so that a compatible ELECTROMAGNETIC ENVIRONMENT can be maintained in order that the EQUIPMENT or SYSTEM will perform as intended.

Because the practice of medicine involves many specialities, there will by necessity be EQUIPMENT and SYSTEMS that are designed to perform a variety of FUNCTIONS. Some FUNCTIONS involve, for example, measurement of signals from a PATIENT that are of very low levels when compared to ELECTROMAGNETIC NOISE levels that can be coupled into EQUIPMENT and SYSTEMS during the ELECTROMAGNETIC IMMUNITY testing specified in this standard. Because of the proven benefits of many such EQUIPMENT and SYSTEMS, this standard allows the IMMUNITY TEST LEVELS to be lowered, provided there is sufficient justification based on physical, technological or physiological limitations. In this case, the manufacturer is required

¹ In this standard, “or” should be understood to include “and”.

to disclose the levels at which the EQUIPMENT or SYSTEM meets the performance requirements of this standard and to specify the characteristics of the ELECTROMAGNETIC use environment and how this environment is established, in which the EQUIPMENT or SYSTEM will perform as intended.

This standard also recognizes that for certain environments, higher IMMUNITY LEVELS may be required. Research necessary to determine how to identify the environments that may require higher IMMUNITY LEVELS, as well as what the levels should be, is in progress.

Finally, this standard recognizes that for LIFE-SUPPORTING EQUIPMENT and SYSTEMS, higher levels of IMMUNITY are necessary in order to establish a broader safety margin, even for use in the general medical use environment. Therefore, this standard specifies additional requirements for LIFE-SUPPORTING EQUIPMENT and SYSTEMS.

This standard is based on existing IEC standards prepared by SC 62A, TC 77 (Electromagnetic compatibility between electrical equipment including networks) and CISPR (International special committee on radio interference).

The ELECTROMAGNETIC COMPATIBILITY requirements specified by this standard are generally applicable to EQUIPMENT and SYSTEMS as described in 1.201. For certain types of EQUIPMENT and SYSTEMS, these requirements may need to be modified by the special requirements of a Particular Standard. Writers of Particular Standards are encouraged to refer to Annex DDD for guidance in the application of this standard.

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MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests

SECTION ONE – GENERAL

1 Scope and object

*1.201 Scope

This standard applies to ELECTROMAGNETIC COMPATIBILITY of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS, hereinafter referred to as EQUIPMENT and SYSTEMS, respectively.

1.202 Object

This standard specifies requirements and tests for ELECTROMAGNETIC COMPATIBILITY of EQUIPMENT and SYSTEMS and serves as the basis of ELECTROMAGNETIC COMPATIBILITY requirements and tests in Particular Standards.

2 Terminology and definitions

For the purposes of this Collateral Standard, the terms and definitions given in IEC 60601-1:1988, IEC 60601-1-1:2000, IEC 60601-1-8:2003 and ISO 14971:2000 and the following apply:

2.201

(IMMUNITY) COMPLIANCE LEVEL

level less than or equal to the IMMUNITY LEVEL for which the EQUIPMENT or SYSTEM meets the requirements of the applicable subclause of 36.202

NOTE Additional requirements for COMPLIANCE LEVELS are specified in 6.8.3.201.

*2.202

DEGRADATION (of performance)

undesired departure in the operational performance of an EQUIPMENT or SYSTEM from its intended performance

NOTE The term "DEGRADATION" can apply to temporary or permanent failure.

[IEV 161-01-19, modified]

*2.203

EFFECTIVE RADIATED POWER (ERP)

power required at the input of a lossless reference antenna to produce, in a given direction at any specified distance, the same power flux density as that radiated by a given device

NOTE As used by the ITU and as used in Chapter 712 of the IEC, the term "effective radiated power" appears without qualification only when the reference antenna is a half-wave dipole.

[IEV 161-04-16, modified]

*2.204

ELECTROMAGNETIC COMPATIBILITY (EMC)

ability of an EQUIPMENT or SYSTEM to function satisfactorily in its ELECTROMAGNETIC ENVIRONMENT without introducing intolerable ELECTROMAGNETIC DISTURBANCES to anything in that environment

[IEV 161-01-07, modified]

2.205*ELECTROMAGNETIC DISTURBANCE**

any electromagnetic phenomenon that may degrade the performance of a device, equipment or system

NOTE An ELECTROMAGNETIC DISTURBANCE may be an ELECTROMAGNETIC NOISE, an unwanted signal or a change in the propagation medium itself.

[IEV 161-01-05, modified]

2.206**(ELECTROMAGNETIC) EMISSION**

phenomenon by which electromagnetic energy emanates from a source

[IEV 161-01-08]

2.207*ELECTROMAGNETIC ENVIRONMENT**

totality of electromagnetic phenomena existing at a given location

NOTE In general, the ELECTROMAGNETIC ENVIRONMENT is time dependent and its description may need a statistical approach.

[IEV 161-01-01, modified]

2.208**ELECTROMAGNETIC NOISE**

time-varying electromagnetic phenomenon apparently not conveying information and which may be superimposed on or combined with a wanted signal

[IEV 161-01-02]

2.209**ELECTROSTATIC DISCHARGE (ESD)**

a transfer of electric charge between bodies of different electrostatic potential in proximity or through direct contact

[IEV 161-01-22]

2.211*EXCLUSION BAND**

frequency band for intentional receivers of RF electromagnetic energy that extends from -5% to $+5\%$ of the frequency, or frequency band, of reception for frequencies of reception greater than or equal to 80 MHz and from -10% to $+10\%$ of the frequency, or frequency band, of reception for frequencies of reception less than 80 MHz

NOTE Other definitions of this term are sometimes used for other purposes in national radio regulations.

2.212*FUNCTION (of an EQUIPMENT or SYSTEM)**

clinically significant operation that the EQUIPMENT or SYSTEM is intended to perform in the diagnosis, treatment or monitoring of a PATIENT

2.213**IEC 60601 TEST LEVEL**

IMMUNITY TEST LEVEL specified in 36.202 by this standard or a Particular Standard

2.214*IMMUNITY (to a disturbance)**

ability of an EQUIPMENT or SYSTEM to perform without DEGRADATION in the presence of an ELECTROMAGNETIC DISTURBANCE

[IEV 161-01-20, modified]

2.215**IMMUNITY LEVEL**

maximum level of a given ELECTROMAGNETIC DISTURBANCE incident on a particular device, equipment or system for which it remains capable of operating at a required degree of performance

[IEV 161-03-14]

2.216*IMMUNITY TEST LEVEL**

level of a test signal used to simulate an ELECTROMAGNETIC DISTURBANCE when performing an IMMUNITY test

[IEV 161-04-41, modified]

2.217**INFORMATION TECHNOLOGY EQUIPMENT (ITE)**

equipment designed for the purpose of

- a) receiving data from an external source (such as a data input line or via a keyboard);
- b) performing some processing functions on the received data (such as computation, data transformation or recording, filing, sorting, storage, transfer of data);
- c) providing a data output (either to other equipment or by the reproduction of data or images)

NOTE This definition includes electrical or electronic units or systems that predominantly generate a multiplicity of periodic binary pulsed electrical or electronic waveforms and are designed to perform data processing functions such as word processing, electronic computation, data transformation, recording, filing, sorting, storage, retrieval and transfer, and reproduction of data as images.

[IEV 161-05-04]

2.218*LARGE EQUIPMENT OR SYSTEM**

EQUIPMENT or SYSTEM that cannot fit within a 2 m × 2 m × 2,5 m volume, excluding cables; this includes distributed SYSTEMS

2.219*LIFE-SUPPORTING EQUIPMENT OR SYSTEM**

EQUIPMENT or SYSTEM that includes at least one FUNCTION that is intended to actively keep alive or resuscitate PATIENTS and the failure of which to comply with the requirements of 36.202.1 j) is likely to lead to serious injury or death of a PATIENT

2.220*LOW VOLTAGE**

line-to-line or line-to-neutral voltage that is less than or equal to 1 000 V a.c. or 1 500 V d.c.

2.221*MEDICAL ELECTRICAL SYSTEM (hereinafter referred to as SYSTEM)**

combination of items of equipment, at least one of which must be MEDICAL ELECTRICAL EQUIPMENT and interconnected by FUNCTIONAL CONNECTION or use of a MULTIPLE PORTABLE SOCKET-OUTLET

NOTE Equipment when mentioned in connection with a SYSTEM, should be taken to include EQUIPMENT.

[IEC 60601-1-1; definition 2.201]

2.222*OPERATING FREQUENCY**

fundamental frequency of a signal, electrical or non-electrical, that is set in an EQUIPMENT or SYSTEM intended to control a physiological parameter

2.223*PATIENT-COUPLED EQUIPMENT OR SYSTEM**

EQUIPMENT or SYSTEM that contains at least one APPLIED PART whereby contact with the PATIENT provides a sensing or treatment point necessary for the normal operation of the EQUIPMENT or SYSTEM and provides a path for electromagnetic energy, whether coupled conductively, capacitively or inductively and whether intended or unintended

2.224*PHYSIOLOGICAL SIMULATION FREQUENCY**

fundamental frequency of a signal, electrical or non-electrical, used to simulate a physiological parameter such that the EQUIPMENT or SYSTEM will operate in a manner consistent with use on a PATIENT

2.225*PUBLIC MAINS NETWORK**

LOW VOLTAGE electricity power lines to which all categories of consumers have access

2.226*RADIO FREQUENCY (RF)**

frequency in the portion of the electromagnetic spectrum that is between the audio-frequency portion and the infrared portion; frequency useful for radio transmission

NOTE The limits are generally accepted to be 9 kHz to 3 000 GHz.

2.227*PROFESSIONAL EQUIPMENT OR SYSTEM**

EQUIPMENT or SYSTEM for use by healthcare professionals and that is not intended for sale to the general public

[IEV 161-05-05, modified]

2.228**TYPE A PROFESSIONAL EQUIPMENT OR SYSTEM**

PROFESSIONAL EQUIPMENT or SYSTEM that complies with CISPR 11 Group 2 Class B except for the third harmonic of the fundamental frequency of the EQUIPMENT or SYSTEM, in which case the third harmonic complies with the Group 2 Class A electromagnetic radiation disturbance limit

NOTE See 36.201.1 a) 6).

3 General requirements**3.201 General requirements for ELECTROMAGNETIC COMPATIBILITY of EQUIPMENT and SYSTEMS*****3.201.1 ELECTROMAGNETIC COMPATIBILITY**

EQUIPMENT and SYSTEMS shall not emit ELECTROMAGNETIC DISTURBANCES that could affect radio services, other equipment or the essential performance of other EQUIPMENT and SYSTEMS. The essential performance of EQUIPMENT and SYSTEMS shall have adequate IMMUNITY to ELECTROMAGNETIC DISTURBANCES.

Compliance is considered to exist if the requirements of this standard are met.

3.201.2 Essential performance

Either the essential performance of the EQUIPMENT or SYSTEM shall be identified (see Annex GGG for guidance on identifying the essential performance) or the performance of all FUNCTIONS of the EQUIPMENT or SYSTEM shall be considered essential performance for the purpose of IMMUNITY testing (see 36.202.1 j)). The essential performance shall be disclosed in the ACCOMPANYING DOCUMENTS.

Compliance is checked by inspection of the ACCOMPANYING DOCUMENTS or, if this identification is not performed, by inspection of the documents to verify that the performance of all FUNCTIONS of the EQUIPMENT or SYSTEM has been tested in accordance with 36.202.

3.201.3 MEDICAL ELECTRICAL EQUIPMENT

MEDICAL ELECTRICAL EQUIPMENT shall meet the requirements of this standard.

Compliance is considered to exist if the requirements of this standard are met.

3.201.4 Non-medical electrical equipment

Non-medical electrical equipment that is supplied as part of a SYSTEM is exempt from the EMC testing requirements of this standard, provided all of the following conditions are met (see also Annex HHH):

- a) the non-medical electrical equipment complies with applicable international EMC standards;
- b) both the EMISSIONS and IMMUNITY of the non-medical electrical equipment have been determined not to adversely affect the essential performance or safety of the SYSTEM;
- c) the EMISSIONS of the non-medical electrical equipment have been determined not to cause the EMISSIONS of the SYSTEM to exceed applicable limits.

Compliance is checked by inspection of the documents for this determination and other appropriate documents or certificates or, if this determination is not performed, by inspection of the documents to verify that the non-medical electrical equipment has been tested in accordance with this standard.

*3.201.5 General test conditions

For EMC testing, the SINGLE FAULT CONDITION requirements of the General Standard do not apply.

6 Identification, marking and documents

6.1.201 Marking on the outside of EQUIPMENT or EQUIPMENT parts

*6.1.201.1 Marking on the outside of EQUIPMENT or EQUIPMENT parts that include RF transmitters or that apply RF electromagnetic energy for diagnosis or treatment

EQUIPMENT and SYSTEMS that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment shall be labelled with the following symbol for non-ionizing radiation [IEC 60417-5140]:

