

INTERNATIONAL STANDARD

NORME INTERNATIONALE



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

**Appareils électromédicaux –
Partie 1-2: Exigences générales pour la sécurité de base et les performances
essentielle – Norme collatérale: Perturbations électromagnétiques – Exigences
et essais**



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CONTENTS

CONTENTS	2
FOREWORD	6
INTRODUCTION	9
1 Scope, object and related standards	11
1.1 * Scope	11
1.2 Object	11
1.3 Related standards	11
1.3.1 IEC 60601-1	11
1.3.2 Particular standards	11
2 Normative references	11
3 Terms and definitions	13
4 General requirements	17
4.1 RISK MANAGEMENT PROCESS for ME EQUIPMENT and ME SYSTEMS	17
4.2 * Non-ME EQUIPMENT used in an ME SYSTEM	17
4.3 General test conditions	17
4.3.1 * Configurations	17
4.3.2 Artificial hand	18
4.3.3 * Power input voltages and frequencies	18
5 ME EQUIPMENT and ME SYSTEMS identification, marking and documents	20
5.1 Additional requirements for marking on the outside of ME EQUIPMENT and ME SYSTEMS that are specified for use only in a shielded location SPECIAL ENVIRONMENT	20
5.2 ACCOMPANYING DOCUMENTS	20
5.2.1 Instructions for use	20
5.2.2 Technical description	21
6 Documentation of the tests	23
6.1 General	23
6.2 Test plan	23
6.3 Test report	23
7 ELECTROMAGNETIC EMISSIONS requirements for ME EQUIPMENT and ME SYSTEMS	23
7.1 Protection of radio services and other equipment	23
7.1.1 * General	23
7.1.2 Operating modes	23
7.1.3 Multimedia equipment	24
7.1.4 * Subsystems	24
7.1.5 ME EQUIPMENT and ME SYSTEMS specified for use only in a shielded location SPECIAL ENVIRONMENT	24
7.1.6 ME EQUIPMENT and ME SYSTEMS that include radio equipment	24
7.1.7 * ME EQUIPMENT whose main functions are performed by motors and switching or regulating devices	25
7.1.8 ME EQUIPMENT and ME SYSTEMS containing X-ray generators	25
7.1.9 PATIENT physiological simulation	25
7.1.10 Artificial hand	25
7.1.11 PATIENT-coupled cables	25
7.1.12 PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS	25
7.2 Protection of the PUBLIC MAINS NETWORK	26

7.2.1	* Harmonic distortion	26
7.2.2	* Voltage fluctuations and flicker	26
7.3	EMISSIONS requirements summary	26
8	Electromagnetic IMMUNITY requirements for ME EQUIPMENT and ME SYSTEMS	27
8.1	* General	27
8.2	PATIENT physiological simulation	30
8.3	Termination of PATIENT-COUPLED parts	30
8.4	HAND-HELD ME EQUIPMENT and parts intended to be HAND-HELD	30
8.5	* Subsystems	31
8.6	PERMANENTLY INSTALLED LARGE ME EQUIPMENT and LARGE ME SYSTEMS	31
8.7	* Operating modes	31
8.8	* Non-ME EQUIPMENT	32
8.9	* IMMUNITY TEST LEVELS	32
8.10	* IMMUNITY to proximity fields from RF wireless communications equipment	39
9	* Test report	41
Annex A (informative)	General guidance and rationale	43
A.1	Safety and performance	43
A.2	Testing of normally non-observable functions	43
A.3	Rationale for particular clauses and subclauses	43
Annex B (informative)	Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS	57
B.1	Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	57
B.2	ACCOMPANYING DOCUMENTS, instructions for use	57
B.3	ACCOMPANYING DOCUMENTS, technical description	57
Annex C (informative)	Guidance in classification according to CISPR 11	59
C.1	General	59
C.2	Separation into groups	59
C.3	Division into classes	60
Annex D (informative)	Guidance on the application of IEC 60601-1-2 to particular standards	61
D.1	General	61
D.2	Recommended modifications	61
D.2.1	Testing requirements	61
D.2.2	ACCOMPANYING DOCUMENTS	61
D.3	Cautions	61
Annex E (informative)	Determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS	63
E.1	General	63
E.2	Summary of method for E.1 a)	66
E.3	Summary of method for E.1 b), c) and d)	66
E.4	Determination of EM DISTURBANCE level reduction	66
E.5	Assessment of EM DISTURBANCE sources	66
E.6	Reasonably foreseeable maximum EM DISTURBANCE levels	67
E.7	Determination of IMMUNITY TEST LEVELS	67
E.8	RF radiators in SPECIAL ENVIRONMENTS	67
E.9	Examples of mitigations and special conditions	68
Annex F (informative)	RISK MANAGEMENT for BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to ELECTROMAGNETIC DISTURBANCES	69

F.1	General.....	69
F.2	General requirements for RISK MANAGEMENT	70
F.3	RISK ANALYSIS.....	71
F.4	RISK EVALUATION.....	74
F.5	RISK CONTROL.....	75
	F.5.1 RISK CONTROL option analysis	75
	F.5.2 Implementation of RISK CONTROL measure(s).....	75
	F.5.3 RESIDUAL RISK EVALUATION.....	75
	F.5.4 RISK/benefit analysis.....	76
	F.5.5 RISKS arising from RISK CONTROL measures	76
	F.5.6 Completeness of RISK CONTROL	76
F.6	Evaluation of overall RESIDUAL RISK acceptability	76
F.7	RISK MANAGEMENT report	76
F.8	Production and post-production information	77
Annex G (informative)	Guidance: Test plan.....	78
	G.1 Test plan contents	78
Annex H (informative)	PATIENT-coupled cables EMISSIONS	80
	H.1 * Protection of other equipment from PATIENT cable conducted EMISSIONS	80
	H.2 Test method.....	80
	H.3 Rationale	80
Annex I (informative)	Identification of IMMUNITY pass/fail criteria	82
	I.1 General.....	82
	I.2 IMMUNITY pass/fail criteria principles.....	82
	I.2.1 General	82
	I.2.2 IMMUNITY pass/fail criteria for non-ME EQUIPMENT used in an ME SYSTEM	82
	I.2.3 IMMUNITY pass/fail criteria determination	82
	I.3 IMMUNITY pass/fail criteria examples.....	83
	I.3.1 General examples.....	83
	I.3.2 Example of IMMUNITY pass/fail criteria for a radiological table system.....	84
Bibliography.....		86
Index of defined terms used in this collateral standard		89
Figure 1 – RC element of the artificial hand		18
Figure 2 – PORTS of ME EQUIPMENT and ME SYSTEMS		27
Figure 3 – Examples of environments of INTENDED USE.....		33
Figure A.1 – Examples of PORTS (from IEC 61000-6-1:2005).....		47
Figure A.2 – IEC 61000-4-2 Figure A.1 – Maximum values of electrostatic voltages to which OPERATORS can be charged while in contact with the materials mentioned in A.2		54
Figure E.1 – Test plan development flow when SPECIAL ENVIRONMENTS are known		64
Figure E.2 – Sub-process for determination of IMMUNITY TEST LEVELS for SPECIAL ENVIRONMENTS.....		65
Figure F.1 – Function of this collateral standard in the RISK MANAGEMENT PROCESS.....		69
Figure F.2 – Examples of multiple VERIFICATION methods for improving confidence in RISK levels		70
Figure H.1 – Setup for PATIENT-COUPLED cables conducted EMISSIONS test for ME EQUIPMENT and ME SYSTEMS that conform to IEC 60601-2-27		81

Table 1 – Power input voltages and frequencies during the tests (1 of 2).....	19
Table 2 – EMISSION limits per environment	26
Table 3 – Procedure for continuing to test ME EQUIPMENT or ME SYSTEMS that are damaged by an IMMUNITY test signal	28
Table 4 – * ENCLOSURE PORT	34
Table 5 – * Input a.c. power PORT (1 of 2)	35
Table 6 – Input d.c. power PORT	37
Table 7 – * PATIENT coupling PORT	38
Table 8 – Signal input/output parts PORT	39
Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment.....	40
Table 10 – * Minimum test report contents (1 of 2).....	41
Table A.1 – IEC/TR 61000-2-5 information considered in specifying IMMUNITY TEST LEVELS for each IMMUNITY TEST	49
Table B.1 – Marking on the outside of ME EQUIPMENT, ME SYSTEMS or their parts	57
Table B.2 – ACCOMPANYING DOCUMENTS, instructions for use	57
Table B.3 – ACCOMPANYING DOCUMENTS, technical description.....	58
Table E.1 – Examples of specific mitigations / environmental conditions	68
Table F.1 – Examples of EM phenomena that should be considered in a RISK ANALYSIS	72
Table G.1 – Recommended minimum test plan contents (1 of 2).....	78
Table H.1 – PATIENT-COUPLED conducted EMISSION recommended limit.....	80
Table I.1 – Example of IMMUNITY pass criteria for a radiological table system	85

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

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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 cancels and replaces the third edition of IEC 60601-1-2, published in 2007, and 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 ENVIRONMENT;
- 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

The text of this collateral standard is based on the following documents:

FDIS	Report on voting
62A/916/FDIS	62A/924/RVD

Full information on the voting for the approval of this 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 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.

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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.