IEC 60601-1-2

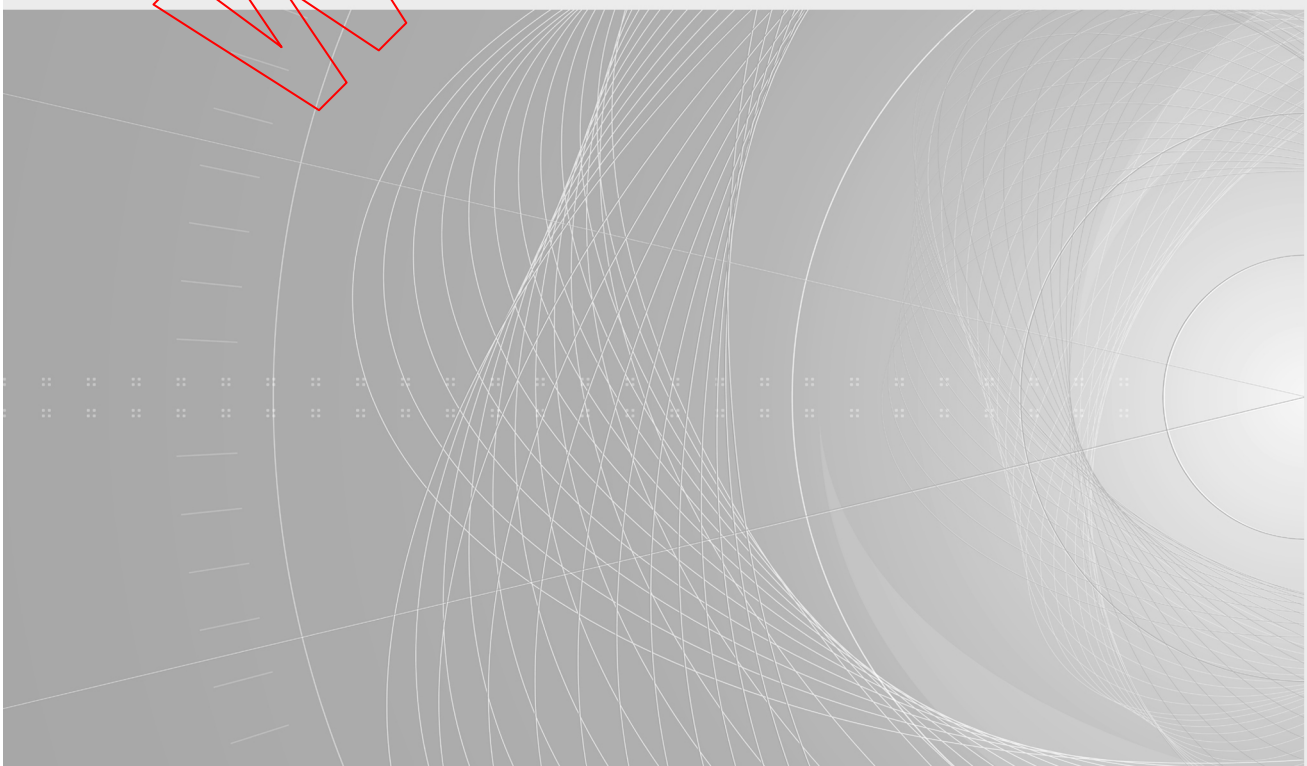
Edition 3.0 2007-03

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

Appareils électromédicaux –
Partie 1-2: Exigences générales pour la sécurité de base et les performances essentielles – Norme collatérale: Compatibilité électromagnétique – Exigences et essais



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MEDICAL ELECTRICAL EQUIPMENT –

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

INTERPRETATION SHEET

This interpretation sheet has been prepared by SC 62A: Common aspects of electrical equipment used in medical practice.

The text of this interpretation sheet is based on the following documents:

ISH	Report on voting
62A/685/ISH	62A/694/RVD

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

Subclause 6.2.2.2 e) (ESD IMMUNITY)

(This is also applicable to Subclause 36.202.2 b) 5) in IEC 60601-1-2:2001[1)].)

This subclause states the following:

The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages and frequencies.

This is clarified by the following:

The test may be performed at any input power voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.3.2 j) (Radiated RF IMMUNITY)

(This is also applicable to Subclause 36.202.3 b) 10) in IEC 60601-1-2:2001.)

This subclause states the following:

The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages and frequencies.

This is clarified by the following:

1) A consolidated edition 2.1 exists (withdrawn) including IEC 60601-1-2:2001 and its Amendment 1 (2004).

The test may be performed at any power input voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the EQUIPMENT or SYSTEM is tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.4.2 e) (EFT/burst IMMUNITY)

(This is also applicable to Subclause 36.202.4 b) 5) in IEC 60601-1-2:2001.)

This subclause states the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test is performed at the minimum and maximum RATED input voltages. The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL power frequencies.

This is clarified by the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test shall be performed at the minimum and maximum ME EQUIPMENT or ME SYSTEM RATED power input voltages. The test may be performed at any power input frequency within the ME EQUIPMENT or ME SYSTEM RATED range. If the ME EQUIPMENT or ME SYSTEM is tested at power input voltages and a power input frequency meeting these specifications, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.5.2 f) (Surge IMMUNITY)

(This is also applicable to Subclause 36.202.5 b) 6) in IEC 60601-1-2:2001.)

This subclause states the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test is performed at the minimum and maximum RATED input voltages. The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL power frequencies.

This is clarified by the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test shall be performed at the minimum and maximum ME EQUIPMENT or ME SYSTEM RATED power input voltages. The test may be performed at any power input frequency within the ME EQUIPMENT or ME SYSTEM RATED range. If the ME EQUIPMENT or ME SYSTEM is tested at power input voltages and a power input frequency meeting these specifications, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.6.2 j) (Conducted RF IMMUNITY)

(This is also applicable to Subclause 36.202.6 b) 10) in IEC 60601-1-2:2001.)

This subclause states the following:

The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL input voltages and frequencies.

This is clarified by the following:

The test may be performed at any power input voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the EQUIPMENT or SYSTEM is

tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.7.2 c) (Voltage dips and interruptions IMMUNITY)

(This is also applicable to Subclause 36.202.7 b) 4) in IEC 60601-1-2:2001.)

This subclause states the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test is performed at the minimum and maximum RATED input voltages. The test is performed at the minimum RATED power frequency.

This is clarified by the following:

For ME EQUIPMENT and ME SYSTEMS that have, for power input, multiple voltage settings or autoranging voltage capability, the test shall be performed at the minimum and maximum ME EQUIPMENT or ME SYSTEM RATED input voltages. The test shall be performed with the ME EQUIPMENT or ME SYSTEM powered at the minimum RATED power frequency. If the ME EQUIPMENT or ME SYSTEM is tested at power input voltages and a power input frequency meeting these specifications, it is not necessary to re-test at additional voltages or frequencies.

Subclause 6.2.8.1.2 (Power-frequency magnetic field IMMUNITY)

(This is also applicable to Subclause 36.202.8.1 b) in IEC 60601-1-2:2001.)

This subclause states the following:

a) *(Item 1) in IEC 60601-1-2:2001)*

   Only the continuous field test shall be performed.

   – *The test is performed at both 50 Hz and 60 Hz, with the exception that ME EQUIPMENT and ME SYSTEMS RATED for use only at one of these frequencies need only be tested at that frequency. In either case, during the test, the ME EQUIPMENT or ME SYSTEM is powered at the same frequency as the applied magnetic field.*

   – *If the ME EQUIPMENT or ME SYSTEM is INTERNALLY POWERED or powered from an external d.c. supply, the test is performed at both 50 Hz and 60 Hz, with the exception that ME EQUIPMENT and ME SYSTEMS intended for use only in areas supplied at one of these frequencies need be tested only at that frequency.*

b) *(Item 2) in IEC 60601-1-2:2001))*

   The test may be performed with the ME EQUIPMENT or ME SYSTEM powered at any one of its NOMINAL power voltages.

Item *b)* is clarified by the following:

The test may be performed at any power input voltage within the ME EQUIPMENT or ME SYSTEM RATED power input voltage range. If the EQUIPMENT or SYSTEM is tested at one power input voltage, it is not necessary to re-test at additional voltages.

For EMISSIONS, IEC 60601-1-2 references CISPR 11. IEC 60601-1-2 does not add any clarification regarding the power input voltage and frequency during EMISSIONS testing.

Subclause 7.5.3 of CISPR 11:2009 states the following:

Mains power at the nominal voltage shall be supplied.

This is clarified by the following:

The test may be performed at any input power voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

Subclause 9.1 of CISPR 11:2009 states the following:

Power at the nominal voltage shall be supplied.

This is clarified by the following:

The test may be performed at any input power voltage and frequency within the ME EQUIPMENT or ME SYSTEM RATED voltage and frequency range. If the ME EQUIPMENT or ME SYSTEM is tested at one power input voltage and one power input frequency meeting this specification, it is not necessary to re-test at additional voltages or frequencies.

These clarifications will remain valid until a new version of IEC 60601-1-2 is published.

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 1-2: General requirements for basic safety and essential performance – 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 IEC subcommittee 62A: Common aspects of electrical equipment used in medical practice, of IEC technical committee 62: Electrical equipment in medical practice.

This third 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.

This document cancels and replaces the second edition of IEC 60601-1-2, and constitutes a technical revision.

This edition of IEC 60601-1-2 was revised to structurally align it with the 2005 edition of IEC 60601-1 and to implement the decision of IEC subcommittee 62A that the clause numbering structure of collateral standards written to IEC 60601-1:2005 would adhere to the form specified in ISO/IEC Directives, Part 2:2004. The principle technical changes are in Clause 4, which now recognizes that there is a general requirement for a risk management process in IEC 60601-1:2005.

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

FDIS	Report on voting
62A/560/FDIS	62A/567/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.

NOTE Defined terms are not printed in SMALL CAPITALS in Table 1 through Table 8, in the tables in Annex C and in statements required to appear in the technical description or instructions for use because they are intended for the OPERATOR or RESPONSIBLE ORGANIZATION, who may not be familiar with the defined terms of IEC 60601 standards.

In referring to the structure of this standard, the term

– "clause" means one of the six numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 6 includes 6.1, 6.2, etc.);
– "subclause" means a numbered subdivision of a clause (e.g. 6.1, 6.2 and 6.2.1 are all subclauses of Clause 6).

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

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

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

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

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

Clauses, subclauses, items and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

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

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

The need for establishing specific ELECTROMAGNETIC COMPATIBILITY standards for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS is well recognized.

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

– safety services;

– other MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS;

– electrical equipment that is not ME 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 MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS. ELECTROMAGNETIC COMPATIBILITY (see Definition 3.4) 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 MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL 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. MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL 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 OPERATOR of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM may not be aware of ambient levels on a continuous basis. The IMMUNITY TEST LEVELS specified in this collateral standard (IEC 60601 TEST LEVELS) represent the range found in the general medical use environment. Therefore, under these conditions, the performance of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM would also be expected to be normal.

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are used in the practice of medicine because they provide needed FUNCTIONS. If MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL 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.

This edition recognizes that there is a shared responsibility between MANUFACTURERS, RESPONSIBLE ORGANIZATIONS and OPERATORS to ensure that MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are designed and operated as intended. The MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM MANUFACTURER'S responsibility is to design and manufacture to meet the requirements of this collateral standard and to disclose information to the RESPONSIBLE ORGANIZATION or OPERATOR so that a compatible ELECTROMAGNETIC ENVIRONMENT can be maintained in order that the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM will perform as intended.