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TECHNICAL REPORT

colour inside

Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

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CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

FOREWORD

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IEC 60601-4-2, which is a technical report, 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.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
62A/1068/DTR	62A/1073A/RVC

Full information on the voting for the approval of this technical report 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 this technical report, the following print types are used:

– Recommendations and definitions: roman type.

– *Test instructions: 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 THIS TECHNICAL REPORT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this technical report, 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 technical report are preceded by the term "Clause" followed by the clause number. References to subclauses within this technical report are by number only.

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

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this technical report; however, we chose to use it in this technical report only as described in 0.3;

– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this technical report;

– "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 this publication will remain unchanged until the stability date indicated on the IEC website 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.

A bilingual version of this publication may be issued at a later date.

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

0.1 * General

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are used in the practice of medicine because they provide needed functions that are associated with the INTENDED USE. If MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM does not provide these needed functions because of a lack of IMMUNITY to ELECTROMAGNETIC DISTURBANCES that are expected to occur in the environment(s) of INTENDED USE, this can interfere with the practice of medicine.

This document provides guidance on assessing IMMUNITY, with regard to the INTENDED USE. Based on the INTENDED USE, MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS should have adequate IMMUNITY to provide the performance specified by the MANUFACTURER in the presence of ELECTROMAGNETIC DISTURBANCES. See Annex A for more information regarding performance.

Guidance for IMMUNITY with regard to INTENDED USE can be useful for MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS for which the BASIC SAFETY AND ESSENTIAL PERFORMANCE do not include the purpose(s) for which the ME EQUIPMENT or ME SYSTEM was purchased. It is important to the OPERATOR or RESPONSIBLE ORGANIZATION and to the delivery of healthcare that these functions operate as intended in the EM ENVIRONMENTS of INTENDED USE.

Examples of performance that might not be BASIC SAFETY or ESSENTIAL PERFORMANCE but that might be INTENDED USE include the following:

– the ability to print an ultrasound image remotely;
– the ability of a scale to accurately measure PATIENT weight;
– accuracy of X-RAY TUBE VOLTAGE in X-ray equipment for radiography and radioscopy, e.g. the error is less than 5 %.

In general in IEC 60601-1-2:2014, the IMMUNITY TEST LEVELS for BASIC SAFETY and ESSENTIAL PERFORMANCE are based on reasonably foreseeable maximum levels of EM DISTURBANCES. In this document, IMMUNITY TEST LEVELS for performance are based on typical levels of EM DISTURBANCES. Rationales concerning test methodology can be found in Annex A of this document and in Annex A of IEC 60601-1-2:2014.

NOTE In general, typical IMMUNITY TEST LEVELS are equal to or lower than reasonably foreseeable maximum levels.

0.2 Purpose of this document

The purpose of this document is to provide a consistent method for evaluating the ability of MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM to perform without degradation of performance in the presence of ELECTROMAGNETIC DISTURBANCES.

0.3 How to use this document

This document can be used in conjunction with IEC 60601-1-2 and testing for conformity to both documents can be done at the same time. This allows IMMUNITY testing of BASIC SAFETY, ESSENTIAL PERFORMANCE and performance of the MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL SYSTEM during one test, concurrently or sequentially. The main difference is the use of performance criteria instead of pass/fail criteria, and differences can also include modes and configurations. For BASIC SAFETY and ESSENTIAL PERFORMANCE, the pass/fail criteria are determined as specified by IEC 60601-1-2. For performance, the criteria are determined by the specifications, instructions and information provided by the MANUFACTURER.

This document uses “recommend” and “should” in place of “shall” in most cases. “Shall” is used where an action is required by other standards or something needs to be done in a

prescribed way in order to be effective. Also, this document has “normative” references. They are “normative” because if you choose to follow the recommendations of this document, they are indispensable for that use. An example of this would be testing for radiated RF IMMUNITY. The test methods of IEC 61000-4-3 would be indispensable for this testing.

0.4 IMMUNITY TEST LEVELS

The IMMUNITY TEST LEVELS specified in this document are typical for the locations of INTENDED USE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS. However, Annex C provides a method for modifying the specified typical IMMUNITY TEST LEVELS for performance if necessary or for particular environments (e.g. SPECIAL ENVIRONMENTS) for which this document does not specify IMMUNITY TEST LEVELS.

MEDICAL ELECTRICAL EQUIPMENT –

Part 4-2: Guidance and interpretation – Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

1 Scope and object

1.1 Scope

This part of IEC 60601 applies to the performance of MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM in the presence of ELECTROMAGNETIC DISTURBANCES. Hereafter, MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM are referred to as ME EQUIPMENT or an ME SYSTEM.

1.2 Object

The object of this document is to provide guidance on the assessment of the performance of ME EQUIPMENT or an ME SYSTEM in the presence of ELECTROMAGNETIC DISTURBANCES.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply.

IEC 60417:2002, *Graphical symbols for use on equipment* (available from: http://www.graphical-symbols.info/equipment)

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012 [1)]

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*
IEC 60601-1-8:2006/AMD1:2012

IEC 60601-1-11:2015, *Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment*

1) There exists a consolidated edition 3.1, including IEC 60601-1:2005 and its Amendment 1:2012.

IEC 60601-1-12:2014, *Medical electrical equipment – Part 1-12: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment*

IEC 61000-4-2:2008, *Electromagnetic compatibility (EMC) – Part 4-2: Testing and measurement techniques – Electrostatic discharge immunity test*

IEC 61000-4-3:2006, *Electromagnetic compatibility (EMC) – Part 4-3: Testing and measurement techniques – Radiated, radio-frequency, electromagnetic field immunity test*
IEC 61000-4-3:2006/AMD1:2007
IEC 61000-4-3:2006/AMD2:2010[2)]

IEC 61000-4-4:2012, *Electromagnetic compatibility (EMC) – Part 4-4: Testing and measurement techniques – Electrical fast transient/burst immunity test*

IEC 61000-4-5:2014, *Electromagnetic compatibility (EMC) – Part 4-5: Testing and measurement techniques – Surge immunity test*

IEC 61000-4-6:2013, *Electromagnetic compatibility (EMC) – Part 4-6: Testing and measurement techniques – Immunity to conducted disturbances, induced by radio-frequency fields*

IEC 61000-4-8:2009, *Electromagnetic compatibility (EMC) – Part 4-8: Testing and measurement techniques – Power frequency magnetic field immunity test*

IEC 61000-4-11:2004, *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques –Voltage dips, short interruptions and voltage variations immunity tests*

CISPR 16-1-2:2014, *Specification for radio disturbance and immunity measuring apparatus and methods – Part 1-2: Radio disturbance and immunity measuring apparatus – Coupling devices for conducted disturbance measurements*

ISO 7637-2:2011, *Road vehicles – Electrical disturbances from conduction and coupling – Part 2: Electrical transient conduction along supply lines only*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012, IEC 60601-1-8:2006 and IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-11:2015, IEC 60601-1-12:2014 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

NOTE 1 Where the terms “voltage” and “current” are used in this document, they mean the RMS values of an alternating, direct or composite voltage or current unless stated otherwise.

2) There exists a consolidated edition 3.2, including IEC 61000-4-3:2006 and its Amendment 1:2007 and Amendment 2:2010.

NOTE 2 The term “electrical equipment” is used to mean ME EQUIPMENT or other electrical equipment. This document also uses the term “equipment” to mean ME EQUIPMENT or other electrical or non-electrical equipment in the context of an ME SYSTEM.

NOTE 3 *The dictionary definition of “performance” applies.

NOTE 4 An index of defined terms is found beginning on page 56.

3.1
ACCESSIBLE PART
part of electrical equipment other than an APPLIED PART that can be touched by means of the standard test finger

Note 1 to entry: See also 5.9.2.1 of IEC 60601-1:2005.

[SOURCE: IEC 60601-1:2005, 3,2, modified — the original NOTE has been modified to add a reference to IEC 60601-1:2005.]

3.2
APPLIED PART
part of ME EQUIPMENT that in NORMAL USE necessarily comes into physical contact with the PATIENT for ME EQUIPMENT or an ME SYSTEM to perform its function

Note 1 to entry: See Figure 3, Figure 4 and Figure A.1 to Figure A.7 (inclusive) of IEC 60601-1:2005.

[SOURCE: IEC 60601-1:2005, 3.8, modified — Note 1 has been modified to add a reference to IEC 60601-1:2005 and Note 2 and Note 3 have been deleted.]

3.3
ELECTROMAGNETIC DISTURBANCE
EM DISTURBANCE
any electromagnetic phenomenon that could degrade the performance of a device, equipment or system

Note 1 to entry: An ELECTROMAGNETIC DISTURBANCE can be ELECTROMAGNETIC NOISE, an unwanted signal or a change in the propagation medium itself.

[SOURCE: IEC 60601-1-2:2014, 3.3]

3.4
(ELECTROMAGNETIC) EMISSION
the phenomenon by which electromagnetic energy emanates from a source

[SOURCE: IEC 60601-1-2:2014, 3.4]

3.5
ELECTROMAGNETIC ENVIRONMENT
EM ENVIRONMENT
the totality of electromagnetic phenomena existing at a given location

Note 1 to entry: In general, the EM ENVIRONMENT is time dependent and its description might need a statistical approach.

[SOURCE: IEC 60601-1-2:2014, 3.5]

3.6
ELECTROSTATIC DISCHARGE
ESD
a transfer of electric charge between bodies of different electrostatic potential in proximity or through direct contact

[SOURCE: IEC 60601-1-2:2014, 3.6]

3.7
ENCLOSURE PORT
physical boundary of the ME EQUIPMENT or ME SYSTEM that electromagnetic fields can radiate through or impinge on

[SOURCE: IEC 60601-1-2:2014, 3.7, modified – Note 1 to entry has been deleted.]

3.8
IMMUNITY (TO A DISTURBANCE)
the ability of ME EQUIPMENT or an ME SYSTEM to perform without degradation in the presence of an ELECTROMAGNETIC DISTURBANCE

[SOURCE: IEC 60601-1-2:2014, 3.8]

3.9
IMMUNITY TEST LEVEL
the level of a test signal used to simulate an ELECTROMAGNETIC DISTURBANCE when performing an IMMUNITY test

[SOURCE: IEC 60601-1-2:2014, 3.9]

3.10
INTENDED USE
INTENDED PURPOSE
use for which a product, PROCESS or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

Note 1 to entry: 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, service, transport, etc. as well.

[SOURCE: IEC 60601-1:2005 + IEC 60601-1:2005/AMD1:2012, 3.44]

3.11
LARGE ME EQUIPMENT
ME EQUIPMENT that cannot fit within a 2 m × 2 m × 2,5 m volume, excluding cables

[SOURCE: IEC 60601-1-2:2014, 3.12]

3.12
LARGE ME SYSTEM
ME SYSTEM that cannot fit within a 2 m × 2 m × 2,5 m volume, excluding cables; this includes distributed ME SYSTEMS

[SOURCE: IEC 60601-1-2:2014, 3.13]

3.13
LOW VOLTAGE
line-to-line or line-to-neutral voltage that is less than or equal to 1 000 V AC or 1 500 V DC

[SOURCE: IEC 60601-1-2:2014, 3.14]

3.14
PATIENT-COUPLED
term referring to the presence of a path for the transfer of electromagnetic energy to or from the PATIENT, whether intended or unintended