# IEC TS 60601-4-2

Edition 1.0 2024-03

# TECHNICAL SPECIFICATION

colour inside

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



IEC TS 60601-4-2:2024-03(en)

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

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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

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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IEC TS 60601-4-2 has been prepared by subcommittee 62A: Common aspects of medical equipment, software, and systems, of IEC technical committee 62: Medical equipment, software, and systems. It is a Technical Specification.

This first edition cancels and replaces the first edition of IEC TR 60601-4-2 published in 2016. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to IEC TR 60601-4-2:2016:

a) aligned with IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020,
b) updated references,

c) changed conducted disturbance cable length exclusion (Table 6) from 3 m to 1 m and added a citation of IEC 61000-4-6:2013, Annex B.

The text of this Technical Specification is based on the following documents:

| Draft | Report on voting |
|---|---|
| 62A/1532/DTS | 62A/1560/RVDTS |

Full information on the voting for its approval can be found in the report on voting indicated in the above table.

The language used for the development of this Technical Specification is English.

This document was drafted in accordance with ISO/IEC Directives, Part 2, and developed in accordance with ISO/IEC Directives, Part 1 and ISO/IEC Directives, IEC Supplement, available at www.iec.ch/members_experts/refdocs. The main document types developed by IEC are described in greater detail at www.iec.ch/publications.

In this document, 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 DOCUMENT OR AS NOTED: SMALL CAPITALS.

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

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document; however, we chose to use it in this document 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 document;

– "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 document will remain unchanged until the stability date indicated on the IEC website under webstore.iec.ch in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn, or
- revised.

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# INTRODUCTION

## 0.1 * General

MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS are used in the practice of medicine because they provide functions that are associated with the INTENDED USE. If MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM does not provide these functions because of a lack of IMMUNITY to EM 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 for IMMUNITY of functions of INTENDED USE that are not related to BASIC SAFETY or ESSENTIAL PERFORMANCE.

Examples of functions 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 %.

See Annex A for more information.

In general, the IMMUNITY TEST LEVELS in IEC 60601-1-2 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. Rationale concerning test methodology can be found in Annex A of this document and in Annex A of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020.

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 typical EM 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

This document applies to the performance of MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM in the presence of EM DISTURBANCES. Hereafter, MEDICAL ELECTRICAL EQUIPMENT or a MEDICAL ELECTRICAL SYSTEM are referred to as ME EQUIPMENT or an ME SYSTEM, respectively.

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 EM 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
IEC 60601-1:2005/AMD2:2020

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: EM disturbances – Requirements and tests*
IEC 60601-1-2:2014/AMD1:2020

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 60601-1-8:2006/AMD2:2020

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*
IEC 60601-1-11:2015/AMD1:2020

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 60601-1-12:2014/AMD1:2020

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

IEC 61000-4-3:2006[1], *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

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 61000-4-5:2014/AMD1:2017

IEC 61000-4-6:2013[2], *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[3], *Electromagnetic compatibility (EMC) – Part 4-11: Testing and measurement techniques – Voltage dips, short interruptions and voltage variations immunity tests*
IEC 61000-4-11:2004/AMD1:2017

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*
CISPR 16-1-2:2014/AMD1:2017

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

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1 This publication was withdrawn.

2 This publication was withdrawn and replaced with IEC 61000-4-6:2023.

3 This publication was withdrawn.

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020, IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012, IEC 60601-1-8:2006/AMD2:2020, IEC 60601-1-11:2015, IEC 60601-1-11:2015/AMD1:2020, IEC 60601-1-12:2014, IEC 60601-1-12:2014/AMD1:2020 and the following apply.

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

- IEC Electropedia: available at https://www.electropedia.org/
- ISO Online browsing platform: available at https://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.

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 at the end of the document.

**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 EM 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**
**EMISSION**
**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**
the ability of ME EQUIPMENT or an ME SYSTEM to perform without degradation in the presence of an EM DISTURBANCE

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

**3.9**
**IMMUNITY TEST LEVEL**
level of a test signal used to simulate an EM 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 and IEC 60601-1:2005/AMD1:2012, 3.44, modified — Existing Note 1 to entry deleted and Note 2 to entry converted to Note 1 to entry.]

**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

Note 1 to entry: Examples of types of coupling include conductive, capacitive, inductive and optical.

[SOURCE: IEC 60601-1-2:2014, 3.15]

**3.15**
**PATIENT COUPLING POINT**
a sensing or treatment point of ME EQUIPMENT that is necessary to achieve the INTENDED USE of the ME EQUIPMENT or an ME SYSTEM and that provides a path for transfer of electromagnetic energy to or from the PATIENT, whether intended or unintended

Note 1 to entry: Examples of types of coupling include conductive, capacitive, inductive and optical.

[SOURCE: IEC 60601-1-2:2014, 3.16]

**3.16**
**PORT**
access to a device or network where electromagnetic energy or signals can be supplied or received or where the device or network variables can be observed or measured

Note 1 to entry: Examples of PORTS include terminal pairs, PATIENT cables (PATIENT CONNECTIONS), SIGNAL INPUT/OUTPUT PARTS such as data PORTS and USB connections, battery charger connections, and the ENCLOSURE itself (i.e. ENCLOSURE PORT).

[SOURCE: IEC 60601-1-2:2014, 3.17]

**3.17**
**PUBLIC MAINS NETWORK**
LOW VOLTAGE electricity power lines to which all categories of consumers have access

[SOURCE: IEC 60601-1-2:2014, 3.18]

**3.18**
**RADIO FREQUENCY**
**RF**
a frequency in the portion of the electromagnetic spectrum that is between the audio-frequency portion and the infrared portion; frequency useful for radio transmission

[SOURCE: IEC 60601-1-2:2014, 3.19]

**3.19**
**SIGNAL INPUT/OUTPUT PART**
**SIP/SOP**
part of ME EQUIPMENT, not being an APPLIED PART, intended to deliver or receive signals to or from other electrical equipment, for example, for display, recording or data processing

[SOURCE: IEC 60601-1:2005, 3.115]

**3.20**
**SPECIAL ENVIRONMENT**
EM ENVIRONMENT with electromagnetic characteristics different from those specified in this document in Table 2 through Table 6 or that requires IMMUNITY TEST LEVELS or test methods that are different from those specified for the professional healthcare facility environment and the HOME HEALTHCARE ENVIRONMENT

Note 1 to entry: The definition also implies the locations where SPECIAL ENVIRONMENTS are found.

Note 2 to entry: For ME EQUIPMENT and ME SYSTEMS intended for use in SPECIAL ENVIRONMENTS, special IMMUNITY TEST LEVELS can be applicable.

[SOURCE: IEC 60601-1-2:2014, 3.20, modified – references to the source document have been changed to refer to this document, and Notes 1 and 2 to entry have been added.]

**3.21**
**TRANSIENT**
phenomenon or quantity which varies between two consecutive steady states during a time interval short compared with the timescale of interest

[SOURCE: IEC 60050-161:2019 [1][4], 161-02-01.]

## 4 General recommendations

### 4.1 Concurrent and sequential testing

IMMUNITY testing according to this document can be performed concurrently or sequentially with the IMMUNITY testing specified in IEC 60601-1-2.

If the IMMUNITY performance criteria determined according to this document are met at the IMMUNITY TEST LEVELS specified in IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, Clause 8, no further testing is needed to demonstrate conformity to the recommendations of this document.

### 4.2 General test conditions

#### 4.2.1 Configurations

Best practice is that ME EQUIPMENT and ME SYSTEMS are tested in representative configurations and modes consistent with INTENDED USE.

These configurations could include:

– attachment of cables to all PORTS as necessary to achieve the INTENDED USE (including SIP/SOPs and, if applicable, the POTENTIAL EQUALIZATION CONDUCTOR);
– attachment of all tubing and filling of all fluid containers;

[4] Numbers in square brackets refer to the Bibliography.