IEC TS 60601-4-6

Edition 1.0 2024-04

TECHNICAL SPECIFICATION

colour inside

Medical electrical equipment –
Part 4-6: Guidance and interpretation – Voluntary guidance to help achieve basic safety and essential performance with regard to the possible effects of electromagnetic disturbances

IEC TS 60601-4-6:2024-04(en)

IEC Secretariat
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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INTERNATIONAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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MEDICAL ELECTRICAL EQUIPMENT –

Part 4-6: Guidance and interpretation – Voluntary guidance to help achieve basic safety and essential performance with regard to the possible effects of electromagnetic disturbances

FOREWORD

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IEC TS 60601-4-6 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.

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

Draft	Report on voting
62A/1538/DTS	62A/1589/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.

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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:

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– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document.

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

In 2017 it was decided to remove Annex F of IEC 60601-1-2:2014 [1][1] into a separate document and provide guidance to help achieve basic safety and essential performance with regard to the possible effects of ELECTROMAGNETIC DISTURBANCE by a technical specification under the IEC 60601 series of standards.

This IEC document provides voluntary guidance on the assessment and application of techniques and measures that can help reduce the risks associated with the interfering effects of ELECTROMAGNETIC DISTURBANCES on medical equipment and medical systems.

1 Numbers in square brackets refer to the Bibliography.

MEDICAL ELECTRICAL EQUIPMENT –

Part 4-6: Guidance and interpretation – Voluntary guidance to help achieve basic safety and essential performance with regard to the possible effects of electromagnetic disturbances

1 Scope

This document provides practical methods to help achieve BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to the possible effects of EM DISTURBANCES throughout the EXPECTED SERVICE LIFE of ME EQUIPMENT or an ME SYSTEM.

These practical methods attempt to address all of the different types of errors, malfunctions or failures that can be caused by EM DISTURBANCES in ME EQUIPMENT or ME SYSTEMS.

The purpose of this document is to provide recommendations for the techniques and measures used in the design, VERIFICATION, and validation of systems, hardware, software, and firmware used in ME EQUIPMENT or ME SYSTEMS to help achieve BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to the EM DISTURBANCES that could occur throughout the EXPECTED SERVICE LIFE.

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.

IEC 60601-1, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

3 Terms, definitions and abbreviated terms

3.1 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1 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

3.1.1
COMPETENCE
training, technical knowledge, experience, and qualifications relevant to the specific duties to be performed

3.2 Abbreviated terms

AC	alternating current
ANSI	American National Standards Institute
CE	Conformité European (European Conformity)
CISPR	Comité Internationale Speciale des Perturbations Radioélectriques (International Special Committee on Radio Interference)
DC	direct current
EDR	event data recorder
EMI	electromagnetic interference
EMP	electromagnetic pulse
ESD	ELECTROSTATIC DISCHARGE
HEMP	high-altitude electromagnetic pulse
I/O	input/output
IEC	International Electrotechnical Commission
IEMI	intentional electromagnetic interference
ISM	industrial, scientific, and medical
ISO	International Organization for Standardization
JTAG	Joint Test Action Group
NEMP	nuclear electromagnetic pulse
PCB	printed circuit board
PDS	pre-defined state
RF	radio frequency

4 How to use this document

This document makes it possible to create a structured justification to demonstrate adequate mitigation of the effects that can be caused by EM DISTURBANCES for each of the BASIC SAFETY or ESSENTIAL PERFORMANCE issues associated with ME EQUIPMENT or an ME SYSTEM.

Clause 4 describes the use of this document in detail. It is recommended to create a structured justification for each of the BASIC SAFETY or ESSENTIAL PERFORMANCE issues, by completing the cells in the right-hand-most column of the example checklist in Table B.1, plus providing all the documents referenced in those cells.

In general, it is expected that most ME EQUIPMENT or ME SYSTEMS could have several BASIC SAFETY or ESSENTIAL PERFORMANCE issues, each one of which is recommended to be associated with its own, completed, Table B.1 checklist.

In some circumstances two or more different issues for BASIC SAFETY or ESSENTIAL PERFORMANCE might be able to be addressed by a single Table B.1 checklist.

Note that IEC 60601-1, along with ISO 14971 and ISO TR 24971, provides a well-proven PROCESS for assessing RISKS and by how much they need reduction to be acceptable RISKS, and prescribes well-proven techniques and measures for reducing each of those RISKS.

This document relies on a HAZARD analysis and RISK ASSESSMENT PROCESS as specified in IEC 60601-1 and ISO 14971 having been completed. This document assumes the correct application of the requirements of IEC 60601-1-2:2014 and IEC 60601-1-2:2014/AMD1:2020, and of the requirements in any relevant "particular" standards in the ISO/IEC 60601-2-XX and IEC 80601-2-XX series. This document provides a list of possible techniques and measures that can be used to mitigate the effects that can be caused by EM DISTURBANCES.

5 General

5.1 Mitigation of effects caused by EM DISTURBANCES

There are many well-proven techniques and measures for mitigating the effects that can be caused by EM DISTURBANCES, including in:

a) project management, planning and specification;

b) system design (both hardware and software);

c) operational design (both hardware and software);

d) implementation, integration, installation and commissioning;

e) VERIFICATION and validation of both hardware and software;

f) operation, maintenance, repair, refurbishment and upgrade, and

g) decommissioning.

5.2 Implementing well-proven techniques and measures for mitigating the effects that can be caused by EM DISTURBANCES

5.2.1 General principles

Appropriate techniques and measures for mitigating the effects that can be caused by EM DISTURBANCES are recommended to be identified and applied as necessary throughout the EXPECTED SERVICE LIFE.

The aim of this subclause is to give an informative overview of a range of techniques and measures available for mitigating the effects that can be caused by EM DISTURBANCES. For more detailed information on these techniques and measures, see Annex A.

Figure 1 shows the general principles of this approach.

It will often be the case that some of the techniques and measures listed in Annex A will have already been used by the MANUFACTURER in a given type of ME EQUIPMENT or ME SYSTEM to control RISKS caused by errors, malfunctions and failures that are not directly associated with EM DISTURBANCES. In this case, it is recommended to modify these techniques and measures to help achieve adequate mitigation of the effects that can be caused by EM DISTURBANCES, as described in their entries in Annex A.

However, even where this is done, it is recommended that as appropriate, additional techniques and measures specified in Annex A are used to achieve sufficient mitigation of the effects that can be caused by EM DISTURBANCES, to help achieve the MANUFACTURER's aims for the BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM throughout the EXPECTED SERVICE LIFE.

This is especially so because it is in the nature of EM DISTURBANCES to create a wide range of possible errors, malfunctions, or failures in several locations all at once or in some critical time sequence (see A.1.2).

5.2.2 Choosing design techniques and measures from Annex A

It is recommended to follow the techniques and measures with the following considerations:

a) It has been generally found to be impractical to perform anything more than a general assessment of the EM DISTURBANCES that could possibly occur throughout the EXPECTED SERVICE LIFE. A MANUFACTURER's specification for the maximum ELECTROMAGNETIC ENVIRONMENT of their equipment is generally composed of assessments of EM DISTURBANCES and levels.

b) These assessments are good enough for determining which of the many published EMC EMISSIONS and IMMUNITY standards to apply for the achievement of functionality with adequate uptime, but cannot determine what EM DISTURBANCES, and combinations of them, could foreseeably occur during the EXPECTED SERVICE LIFE.

c) It is necessary to maintain adequate mitigation of the effects that can be caused by EM DISTURBANCES in the operational environment despite all foreseeable faults, misuse, ageing, component tolerances, assembly errors, physical and climatic conditions, etc., that could occur throughout the EXPECTED SERVICE LIFE.

It is recommended that the MANUFACTURER selects an adequate combination of techniques and measures that, together, help achieve adequate mitigation of the effects that can be caused by EM DISTURBANCES. It is recommended that their selection is documented with the reasons for the selections made and for rejecting those that are not used. These decisions are usually documented in the RISK MANAGEMENT FILE.

Table B.1 provides a basic checklist that can be be applied for this purpose. It identifies a number of techniques and measures that can be used at appropriate stages of the EXPECTED SERVICE LIFE. However, Table B.1 is not necessarily exhaustive and it is applicable to use additional techniques and measures to give adequate assurance that the effects that can be caused by EM DISTURBANCES will not cause failure to achieve BASIC SAFETY and ESSENTIAL PERFORMANCE of the ME EQUIPMENT or ME SYSTEM throughout the EXPECTED SERVICE LIFE.

No techniques and measures with regard to EM DISTURBANCES, such as those described in this document, can be assumed to guarantee complete protection against every possible type of EM DISTURBANCE, combination of EM DISTURBANCES, fault or misuse that could result in EMI.

The exact combination of techniques and measures that a MANUFACTURER might select for a particular ME EQUIPMENT or ME SYSTEM depends on many factors specific to the medical application in question. Except where stated otherwise, the techniques and measures specified in Annex A are appropriate for both "continuous" and "on-demand" functions.

Depending on the nature of the project, different techniques and measures might be used in its various stages, for example:

a) if a project does not involve any software design, then no software design techniques and measures would be selected for any of the project's stages; likewise,

b) if there is no circuit design, then circuit design techniques and measures would not be needed.

c) If ME EQUIPMENT or an ME SYSTEM does not need to maintain its functionality or be safe after a nuclear explosion that created EMP (such as HEMP or NEMP), then the techniques and measures described in this document that are intended to provide protection against EMP, HEMP or NEMP, need not be applied.

Knowledge of the extent to which robust conventional ELECTROMAGNETIC COMPATIBILITY (EMC) management techniques (such as high-specification electromagnetic mitigation including shielding, filtering, and transient suppression) are able to prevent EM DISTURBANCES from affecting the BASIC SAFETY and ESSENTIAL PERFORMANCE during the EXPECTED SERVICE LIFE can be used during the selection and application of the techniques and measures, where this is justified.

Each technique or measure described in this document is described in more detail in Annex A, based on its relevance to the stage of the project, under the headings: Aim; Description; Identification; Mitigation, and Effectiveness.

Aim	The overall purpose of the technique or measure.
Description	Broadly how the technique or measure achieves its aim.
Identification	The effectiveness of the technique or measure in revealing the presence of an error or malfunction that could be caused by EM DISTURBANCES
Mitigation	The behaviour of the system function in response to the detected errors or malfunctions that could have been caused by EM DISTURBANCES.

"Effectiveness" specifies the value of each technique or measure for mitigating the effects that can be caused by EM DISTURBANCES, using the attributes:

Not Effective (NE);

Effective (E);

Highly Effective (HE).

In this document, the "effectiveness" of a technique or measure listed in Table B.1 as NE, E, or HE (see above) is graded by the RISK level resulting from the application of the PROCESS described in Annex C of ISO TR 24971:2020 [3] by the MANUFACTURER of the ME EQUIPMENT or ME SYSTEM.

Three RISK levels are used in this document, taken from C.4 of ISO TR 24971:2020 [3]:

1 = Insignificant or negligible risk

2 = Investigate further RISK reduction

3 = Unacceptable risk

It is recommended that if a technique or measure rated as HE for the relevant ME EQUIPMENT or ME SYSTEM is not used, a detailed technical explanation of why it was not used is documented. For example, the technique or measure might not actually be relevant for the design being implemented, or it might be that an alternative technique or measure is used instead that provides the same benefits regarding mitigation of the effects of EM DISTURBANCES for the design issue concerned.

Where a technique or measure applies to a technology that is not relevant to the ME EQUIPMENT or ME SYSTEM concerned, and the effectiveness is shown in Table B.1 as being HE, it is recommended that a justification for why that technique or measure was not applied is documented.

The "effectiveness" levels (E, HE) listed in Table B.1 are generic starting points, and it is recommended that the MANUFACTURER makes an informed application consistent with expectations of the medical application.

It is important to understand that ME EQUIPMENT and ME SYSTEMS cannot be said to achieve BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to EM DISTURBANCES simply on the basis of the system parts from which they are composed.

Other techniques and measures not listed in Table B.1 might also be able to assist in demonstrating that the effects that can be caused by EM DISTURBANCES, have been sufficiently mitigated to achieve BASIC SAFETY and ESSENTIAL PERFORMANCE throughout the EXPECTED SERVICE LIFE, and space has been allowed in that table for them to be written in.