



BSI Standards Publication

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

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National foreword

This Published Document is the UK implementation of IEC TS 60601-4-6:2024.

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A list of organizations represented on this committee can be obtained on request to its committee manager.

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TECHNICAL SPECIFICATION



**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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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.

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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 TECHNICAL SPECIFICATION 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;
- "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

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