

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Electrical equipment for measurement, control and laboratory use - EMC requirements -

Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical equipment

Matériel électrique de mesure, de commande et de laboratoire - Exigences relatives à la CEM -

Partie 2-6: Exigences particulières - Matériel électromédical de diagnostic in vitro (DIV)



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

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

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CONTENTS

FOREWORD.....	3
1 Scope.....	5
2 Normative references.....	5
3 Terms, definitions and abbreviations.....	5
3.1 Terms and definitions.....	5
3.2 Abbreviations.....	8
4 General.....	8
4.101 ESSENTIAL PERFORMANCE.....	8
4.102 BASIC SAFETY.....	8
5 EMC test plan.....	9
5.1 General.....	9
5.2 Configuration of EUT during testing.....	9
5.2.101 Subsystems.....	9
5.3 Operation conditions of EUT during testing.....	9
5.3.101 Operation conditions.....	9
5.4 Specification of FUNCTIONAL PERFORMANCE.....	10
5.5 Test description.....	10
6 Immunity requirements.....	10
6.1 Conditions during the tests.....	10
6.101 Conditions during the tests.....	10
6.2 Immunity test requirements.....	10
6.201 Risk assessment and consideration of EMC immunity requirements.....	11
6.3 Random aspects.....	16
6.4 Performance criteria.....	17
6.401 Pass/fail criteria.....	17
7 Emission requirements.....	17
8 Test results and test report.....	17
9 Instructions for use.....	17
9.101 General requirements for the IVD MEE instructions for use.....	18
9.102 Additional requirements for the instructions for use for equipment to be used in a HOME HEALTHCARE ENVIRONMENT.....	19
9.103 Additional requirements for the instructions for use for equipment to be used in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT.....	19
Annex A (normative) Immunity test requirements for PORTABLE TEST AND MEASUREMENT EQUIPMENT powered by battery or from the circuit being measured.....	20
Annex B (informative) General guidance and rationale for updating the IEC 61326-2- 6:2020 – Background for maintenance leading to edition 4 of this document.....	21
Annex C (informative) How to apply this document and its intended use environments.....	22
Annex D (informative) Guidance: Test plan.....	23
Annex E (informative) Power input voltages and frequencies during tests.....	25
Annex F (informative) Guidance on the application of risk management with regard to electromagnetic disturbances and the Identification of immunity pass/fail criteria risks of EUT to identify critical immunity testing.....	26
F.1 Introductory remarks.....	26
F.2 Immunity pass/fail criteria principles.....	26
F.2.1 General.....	26

F.2.2	Immunity pass/fail criteria for non-IVD MEE used in an IVD MEE	26
F.2.3	Immunity pass/fail criteria determination.....	26
F.3	BASIC SAFETY.....	27
F.4	ESSENTIAL PERFORMANCE.....	27
F.5	Immunity pass/fail criteria examples	27
F.5.1	General examples	27
F.5.2	Examples and guidance for developing test plan immunity pass/fail criteria for ESSENTIAL PERFORMANCE and BASIC SAFETY for IVD Immunoassay Analyzer.....	28
Annex G (informative)	Guidance on how to apply Table 104.....	30
Bibliography	31
Figure C.1	– Standard/environment decision	22
Figure F.1	– ESSENTIAL PERFORMANCE evaluation.....	27
Figure F.2	– Relation of risk analysis and test plan	29
Figure G.1	– Steps for evaluation of immunity to proximity magnetic fields	30
Table 101	– Immunity test requirements for equipment intended to be used in the PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT.....	12
Table 102	– Immunity test requirements for equipment intended to be used in the HOME HEALTHCARE ENVIRONMENT.....	13
Table 103	– Test specifications for ENCLOSURE PORT immunity to RF wireless communications equipment	15
Table 104	– Test specifications for ENCLOSURE PORT immunity to proximity magnetic fields.....	16
Table D.1	– Recommended minimum test plan contents.....	23
Table E.1	– Power input voltages and frequencies during the tests.....	25
Table F.1	– Examples of ESSENTIAL PERFORMANCE Immunity pass criteria for an IVD immunoassay analyzer.....	29

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**Electrical equipment for measurement, control and laboratory use -
EMC requirements - Part 2-6: Particular requirements -
In vitro diagnostic (IVD) medical electrical equipment**

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IEC 61326-2-6 has been prepared by subcommittee 65A: System aspects, of IEC technical committee 65: Industrial-process measurement, control and automation. It is an International Standard.

This fourth edition cancels and replaces the third edition published in 2020. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

- Update of the document with respect to test levels and documentation.

The text of this International Standard is based on the following documents:

Draft	Report on voting
65A/1174/FDIS	65A/1180/RVD

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 International Standard 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:

Terms used throughout this document which have been defined in Clause 3 of this document and of IEC 61326-1:2020 are printed in SMALL CAPITALS.

This part of IEC 61326 is to be used in conjunction with IEC 61326-1:2020 and follows the same numbering of clauses, subclauses, tables and figures.

If an IEC 61326-2-6 report is available, the report of IEC 61326-1 is integrated.

When a particular subclause of IEC 61326-1 is not mentioned in this part, that subclause applies as far as is reasonable. When this standard states "addition", "modification" or "replacement", the relevant text in IEC 61326-1 is to be adapted accordingly.

NOTE The following numbering system is used:

- subclauses, tables and figures that are numbered starting from 101 are additional to those in IEC 61326-1;
- unless notes are in a new subclause or involve notes in IEC 61326-1, they are numbered starting from 101 including those in a replaced clause or subclause;
- additional annexes are lettered AA, BB, etc.

A list of all parts of the IEC 61326 series, under the general title *Electrical equipment for measurement, control and laboratory use – EMC requirements*, 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.

1 Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of IN VITRO DIAGNOSTIC MEDICAL ELECTRICAL EQUIPMENT (IVD MEE). This part of IEC 61326 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of IVD MEE in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by IVD MEE.

BASIC SAFETY with regard to electromagnetic disturbances is applicable to all IVD MEE.

NOTE 1 Performance with respect to electromagnetic disturbances other than ESSENTIAL PERFORMANCE is the subject of IEC 61326-1:2020

NOTE 2 IT equipment can be a part of an IVD MEE, if it is required to maintain BASIC SAFETY or ESSENTIAL PERFORMANCE.

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.

Clause 2 of IEC 61326-1:2020 applies, except as follows:

Addition:

IEC 61010 (all parts), *Safety requirements for electrical equipment for measurement, control, and laboratory use*

IEC 61326-1:2020, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

ISO 14971:2019, *Medical devices – Application of risk management to medical devices*

3 Terms, definitions and abbreviations

For the purposes of this document, the terms and definitions given in IEC 61326-1 apply, except as follows.

3.1 Terms and definitions

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