BS EN IEC 61326-2-6:2025

BSI Standards Publication

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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Full document details: BS EN IEC 61326-2-6:2025

National foreword

This British Standard is the UK implementation of EN IEC 61326-2-6:2025. It is identical to IEC 61326-2-6:2025. It supersedes BS EN IEC 61326-2-6:2021, which will be withdrawn on 31 August 2028.

The UK participation in its preparation was entrusted to Technical Committee GEL/65/1, System considerations.

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

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Supersedes EN IEC 61326-2-6:2021

English Version

Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical electrical equipment (IEC 61326-2-6:2025)

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) (IEC 61326-2-6:2025)

Elektrische Mess-, Steuer-, Regel- und Laborgeräte - EMV-Anforderungen - Teil 2-6: Besondere Anforderungen - Medizinische In-vitro-Diagnosegeräte (IVD) (IEC 61326-2-6:2025)

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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European foreword

The text of document 65A/1174/FDIS, future edition 4 of IEC 61326-2-6, prepared by SC 65A "System aspects" of IEC/TC 65 "Industrial-process measurement, control and automation" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 61326-2-6:2025.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2026-08-31
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2028-08-31

This document supersedes EN IEC 61326-2-6:2021 and all of its amendments and corrigenda (if any).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

This document is read in conjunction with EN IEC 61326-1:2021.

This document has been prepared under a standardization request addressed to CENELEC by the European Commission. The Standing Committee of the EFTA States subsequently approves these requests for its Member States.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice

The text of the International Standard IEC 61326-2-6:2025 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standard indicated:

IEC 60601-1-2:2014	NOTE	Approved as EN 60601-1-2:2015 (not modified)
IEC 60601-1-11:2015	NOTE	Approved as EN 60601-1-11:2015 (not modified)
IEC 61010-2-101:2018	NOTE	Approved as EN IEC 61010-2-101:2022 (not modified)
ISO 18113-1:2022	NOTE	Approved as EN ISO 18113-1:2024 (not modified)
ISO/TR 24971:2020	NOTE	Approved as CEN ISO/TR 24971:2020 (not modified)
ISO 14971:2007	NOTE	Approved as EN ISO 14971:2019 (not modified)

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Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cencenelec.eu.

Annex ZA of Part 1 is applicable except as follows:

Addition:

Publication	Year	Title	EN/HD	Year
IEC 61010	series	Safety requirements for electrical equipment for measurement, control, and laboratory use	EN IEC 61010	series
IEC 61326-1	2020	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	EN IEC 61326-1	2021
ISO 14971	2019	Medical devices – Application of risk management to medical devices	EN ISO 14971	2019

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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 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.

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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.

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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

For the purposes of this document, the following terms and definitions 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

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Addition:

3.101
in vitro diagnostic medical electrical equipment
IVD MEE
instruments and apparatus intended for use in the examination of specimens intended for diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease

Note 1 to entry: IVD MEE includes all items/parts, which are needed to perform ESSENTIAL PERFORMANCE and/or BASIC SAFETY of the IVD MEE.

Note 2 to entry: Such instruments or apparatus are intended for use in the collection, preparation, and examination of specimens taken from the human body without direct or wired PATIENT connection with the device.

Note 3 to entry: IVD: In vitro diagnostic.

Note 4 to entry: PATIENT can receive results and either can self-interpret it or a health care professional needs to translate the result.

Note 5 to entry: MD/MEE: medical device / medical electrical equipment (defined and used in the IEC 60601 series).

3.102
professional healthcare facility environment
environment where professional healthcare is administered

Note 1 to entry: Locations include hospitals, diagnostic laboratories, blood banks, blood donation centers, physician offices, intensive care units, surgical centers, emergency rooms, surgery rooms, clinics, PATIENT rooms, dental offices, limited care facilities, drugstores with trained operator, and first-aid rooms.

Note 2 to entry: Such instruments can use wireless communications technology for various purposes such as tracking system components and transferring data.

Note 3 to entry: Most environments and locations in the PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT are considered to have well-characterized and fixed EM sources. However, wireless (mobile) communication devices are widely used by healthcare professionals in providing efficient PATIENT care. For this reason, it is more difficult to control the environment for proximity electromagnetic disturbances. Examples of electromagnetic sources that could be used or located close to IVD MEE are:

– radio frequency-identification systems (RFID);
– wireless local area networks (WLAN);
– handheld mobile radios (e.g. TETRA, two-way radio);
– paging systems;
– electromagnetic security systems such as anti-theft electronic article surveillance (EAS) systems or metal detectors;
– other wireless devices (including consumer devices).

Note 4 to entry: IVD MEE, when used in ambulances, or any ground vehicle or aircraft, can require a higher level of immunity than in the PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT.

3.103
home healthcare environment
dwelling place in which a PATIENT lives or other places where PATIENTS are present, excluding PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENTS where operators with medical training are continually available when PATIENTS are present

EXAMPLES In a car, bus, train, boat, or plane, in a wheelchair or walking outdoors.

Note 1 to entry: Other places where a PATIENT is present include the outdoor environment, while working and in vehicles.

SOURCE: IEC 60601-1-11:2015, 3.1

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3.104
analyte
component represented in the name of a measurable quantity

EXAMPLE In "the type of quantity "mass of protein in 24-hour urine", "protein" is the ANALYTE. In "amount of substance of glucose in plasma", "glucose" is the ANALYTE. In both cases, the long phrase represents the measured.

SOURCE: ISO 18113-1:2022, 3.1.4

3.105
basic safety
freedom from unacceptable risk directly caused by physical hazards when IVD MEE is used

3.106
essential performance
performance of a diagnostic function, other than that related to BASIC SAFETY, where loss or DEGRADATION beyond the limits specified in the user documentation results in unacceptable risk

Note 1 to entry: The term “diagnostic” in this context includes testing performed to diagnose or to monitor a medical condition; the results are used to determine the treatment of PATIENTS.

Note 2 to entry: ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or DEGRADATION would result in unacceptable risk.

3.107
manufacturer
natural or legal person with responsibility for the design, manufacture, packaging, assembling, adapting, or labelling of IVD MEE, regardless of whether these operations are performed by that person or on his behalf by another person(s)

3.108
patient
living being (person or animal) undergoing a medical, surgical or dental procedure

Note 1 to entry: A PATIENT can be an operator.

3.109
normal condition
condition in which all means for protection against hazards are intact

3.110
single fault condition
condition of IVD MEE in which one means for reducing a risk is defective or one fault is present

Note 1 to entry: The context of risk is inclusive of hazards related to BASIC SAFETY and diagnostic function DEGRADATION or loss related to ESSENTIAL PERFORMANCE.

Note 2 to entry: For the testing outlined within this document, BASIC SAFETY and ESSENTIAL PERFORMANCE will be monitored for being maintained, in which a failure can result from a SINGLE FAULT CONDITION induced by sensitivity to electromagnetic disturbances. Refer to 6.201 for guidance.

3.111
EMC risk management file
documentation containing a risk analysis, including documentation specific for electromagnetic disturbances

Note 1 to entry: The context of risk is inclusive of hazards related to BASIC SAFETY and diagnostic function DEGRADATION or loss related to ESSENTIAL PERFORMANCE.

Note 2 to entry: ISO 14971 has to be used to evaluate risk of the IVD MEE.

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