SLOVENSKI STANDARD
oSIST prEN IEC 61326-2-6:2023

01-december-2023

Električna oprema za merjenje, nadzor in laboratorijsko uporabo - Zahteve za elektromagnetno združljivost (EMC) - 2-6. del: Posebne zahteve - In vitro diagnostična (IVD) medicinska oprema

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

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

Matériel électrique de mesure, de commande et de laboratoire - Exigences relatives à la CEM - Partie 2-6: Exigences particulières - Matériel médical de diagnostic in vitro (IVD)

Ta slovenski standard je istoveten z: **prEN IEC 61326-2-6:2023**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
19.080	Električno in elektronsko preskušanje	Electrical and electronic testing
33.100.01	Elektromagnetna združljivost na splošno	Electromagnetic compatibility in general

oSIST prEN IEC 61326-2-6:2023 **en,fr,de**

65A/1102/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 61326-2-6 ED4**	
DATE OF CIRCULATION: **2023-09-29**	CLOSING DATE FOR VOTING: **2023-12-22**
SUPERSEDES DOCUMENTS: **65A/1070/CD, 65A/1097/CC**	

IEC SC 65A : SYSTEM ASPECTS

SECRETARIAT: United Kingdom	SECRETARY: Ms Stephanie Lavy
OF INTEREST TO THE FOLLOWING COMMITTEES: TC 77,SC 77A	PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.

FUNCTIONS CONCERNED:

☒ EMC ☐ ENVIRONMENT ☐ QUALITY ASSURANCE ☐ SAFETY

☒ SUBMITTED FOR CENELEC PARALLEL VOTING ☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING

Attention IEC-CENELEC parallel voting

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting.

The CENELEC members are invited to vote through the CENELEC online voting system.

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Recipients of this document are invited to submit, with their comments, notification of any relevant “In Some Countries” clauses to be included should this proposal proceed. Recipients are reminded that the CDV stage is the final stage for submitting ISC clauses. (SEE AC/22/2007 OR NEW GUIDANCE DOC).

TITLE:

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

PROPOSED STABILITY DATE: 2025

NOTE FROM TC/SC OFFICERS:

CONTENTS

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

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

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

This edition includes the following significant technical change 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:

FDIS	Report on voting
65A/XX/FDIS	65A/XX/RVD

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

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: 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 "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE – EMC REQUIREMENTS –

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

1. Scope

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of IN VITRO DIAGNOSTIC MEDICAL ELECTRICAL EQUIPMENT. 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

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

Addition:

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*

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

3. Terms and definitions

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

3.1 Terms and definitions

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

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

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

Note 1 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 2 to entry: IVD: In vitro diagnostic.

Note 3 to entry: PATIENT can receive results and either can self-interpret it or a health care professional needs to translate the result.

Note 4 to entry: MD/MEE: medical device / medical electrical equipment (defined and used in 60601-x).

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 might 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
source reference (defined in 60601-1-11:2020)

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.

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 measurand.

[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: 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 reducing a risk is defective or one fault is present

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

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

3.2 Abbreviations

Subclause 3.2 of IEC 61326-1:2020 applies.

4. General

Clause 4 of IEC 61326-1:2020 applies, except as follows:

Modify final paragraph of Clause to:

The MANUFACTURER shall perform type testing where TYPE TEST is required.

4.101 Essential Performance

During risk analysis, the MANUFACTURER shall identify the performance of the diagnostic function(s) of the IVD MEE, other than that related to BASIC SAFETY, that is necessary to achieve its intended use or that could affect the safety of the IVD MEE were it lost or degraded.

To identify ESSENTIAL PERFORMANCE the MANUFACTURER shall:

1) identify performance of diagnostic function(s), other than that related to BASIC SAFETY, that is necessary to achieve its intended use or that could affect safety;

2) specify performance limits between fully functional and total loss of the identified diagnostic function(s) performance;

3) evaluate the risk from the loss or degradation beyond the specified limits of the fully functional diagnostic function performance. If the resulting risk is unacceptable, then the identified diagnostic function performance constitutes an ESSENTIAL PERFORMANCE of the IVD MEE.

Note 1: ESSENTIAL PERFORMANCE can have multiple aspects

Note 2: Following the principles of risk management, the MANUFACTURER is required to verify the effectiveness of each risk control measure. This can involve demonstrating that the risk control measure will operate in the presence of the conditions that result in the loss or degradation of the identified performance.

Note 3: Each particular standard in the IEC 61010 series can list potential ESSENTIAL PERFORMANCES to guide the MANUFACTURER to identify particular ESSENTIAL PERFORMANCE in accordance with 4.101.

Compliance is checked by inspection of the RISK MANAGEMENT FILE determined by the MANUFACTURER.

Note 4: This particular standard requires the MANUFACTURER to perform a number of activities with regard to electromagnetic DISTURBANCES during the design and realization of their IVD MEE , and to document them in the RISK MANAGEMENT FILE. However, EMC test laboratories cannot be expected to perform or document these activities.

4.102 Basic Safety

During risk analysis, the MANUFACTURER shall identify that the IVD MEE is free from unacceptable risk directly caused by physical hazards.

The MANUFACTURER shall evaluate the risk from the loss or degradation of the general safety functions derived from the IEC 61010 clause 4 to 17 (all tests), or other functions that could affect the safe use of the IVD MEE. If the resulting risk is unacceptable without the implementation of risk controls, then the identified function contributes to BASIC SAFETY of the IVD MEE.

Note 1 More guidance can be found under 6.201.

The MANUFACTURER shall implement risk control measures to reduce the risk from the loss or degradation of the identified performance to an acceptable level.