SLOVENSKI STANDARD
oSIST prEN IEC 61326-2-6:2019

01-oktober-2019

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

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

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 61326-2-6:2019**

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 61326-2-6:2019 **en,fr,de**

65A/928/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 61326-2-6 ED3**	
DATE OF CIRCULATION: **2019-08-23**	CLOSING DATE FOR VOTING: **2019-11-15**
SUPERSEDES DOCUMENTS: **65A/903/CD, 65A/913A/CC**	

IEC SC 65A : SYSTEM ASPECTS

SECRETARIAT: United Kingdom	SECRETARY: Mr Petar Luzajic
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.

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: 2023

NOTE FROM TC/SC OFFICERS:

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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 – Invitro diagnostic (IVD) medical equipment

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International Standard IEC 61326-2-6 has been prepared by subcommittee 65A WG4: System aspects, of IEC technical committee 65: Industrial-process measurement, control and automation.

This third edition cancels and replaces the second published in 2012. 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 IEC 61326-1:202x.

The text of this standard is based on the following documents:

FDIS	Report on voting
65A/631/FDIS	65A/640/RVD

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

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

This part of the IEC 61326 series is to be used in conjunction with IEC 61326-1:202x and follows the same numbering of clauses, subclauses, tables and figures.

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 publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication 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 equipment

1 Scope

In *addition* to the scope of IEC 61326-1, this part of IEC 61326 series specifies minimum requirements for immunity and emissions regarding electromagnetic compatibility for IN VITRO DIAGNOSTIC (IVD) MEDICAL EQUIPMENT, taking into account the particularities and specific aspects of this electrical equipment and their electromagnetic environment.

2 Normative references

Clause 2 of IEC 61326-1:202x applies, except as follows:

Addition:

IEC 61326-1:202x, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

ISO 14971:201x *Medical devices – Application of risk management to medical devices*

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

Addition:

3.101
In vitro diagnostic (IVD) medical equipment
Instruments and apparatus intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease

NOTE to entry: Such instruments or apparatus are intended for use in the collection, preparation, and examination of specimens taken from the human body. No direct or wired patient connection with the device.

3.102
professional healthcare facility environment
an environment where professional healthcare is administered

NOTE 1 to entry: Locations include hospitals, diagnostic laboratories, blood banks, blood donation centres, physician offices, intensive care units, surgical centres, emergency rooms, surgery rooms, clinics, patient rooms, dental offices, limited care facilities, nursing homes, drugstore with trained operator, and first aid rooms.

NOTE 2 to entry: Most environments and locations in the PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT are considered to have a CONTROLLED ELECTROMAGNETIC ENVIRONMENT with regard to fixed electromagnetic sources.

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.

NOTE 3 to entry: Examples of electromagnetic sources that might be used adjacent to IVD medical equipment are:

- High Frequency Surgical Equipment
- Radio Frequency Identification (RFID) systems
- Wireless local area networks (WLAN)
- Handheld mobile radios (e.g. TETRA, two-way radio)
- Paging systems
- Other wireless devices (including consumer devices)

NOTE 4 to entry: It is assumed that IVD equipment is not directly connected to the public mains network.

NOTE 5 to entry: IVD medical equipment should have a suitable level of immunity to ensure the safe and effective performance of the device in its intended use environment. As such, IVD medical equipment used in ambulances, aircraft, cars and helicopters can require a higher level of immunity than the typical PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT.

3.103
home healthcare environment
an environment other than a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT with a much more diverse electromagnetic environment with electromagnetic disturbances that may be more uncontrolled and less well-characterized in terms of amplitude and probability of occurrence.

NOTE 1 to entry: Except in transportation, IVD equipment is usually connected to the public mains network.

NOTE 2 to entry: These reasons justify higher immunity test levels for basic safety and essential performance. Locations include any public setting, including the home of the patient, shops and libraries where anti-theft equipment are used, transportation (e.g. airport security) metal detectors, etc.

NOTE 3 to entry: Examples of electromagnetic sources that might be used near IVD medical equipment in these environments or otherwise expose the IVD equipment to intense electromagnetic disturbances are:

- Small mains frequency transformers (50 Hz and 60 Hz), e.g. in a clock radio on a bedside table
- Mains disturbances
- Mobile phones (often several)
- Fixed radio broadcast stations
- TV transmitting equipment
- Amateur Radio Equipment
- Mobile radio transmitters (e.g. taxi, police)

3.104
analyte
constituent of a sample with a measurable property

EXAMPLES In “mass of protein in 24-hour urine”, “protein” is the analyte and “mass” is the property. In “concentration of glucose in plasma”, “glucose” is the analyte and “concentration” is the property. In both cases, the full phrase designates the measured.

[SOURCE: ISO 18113-1:2009, 3.3]

200

201 **3.105**
202 **basic safety**
203 freedom to unacceptable risk to the operator directly caused by physical hazards when IVD
204 medical equipment is used under normal condition and single fault condition

205 NOTE to entry: Caused to operators by physical hazards.

206 **3.106**
207 **essential performance**
208 performance necessary to achieve freedom from unacceptable RISK

209 NOTE to entry: essential performance is most easily understood by considering whether its absence or degradation
210 would result in an unacceptable risk.

211 Subclause 3.2 of IEC 61326-1:202x applies.

212

213 # 4 General

214 Clause 4 of IEC 61326-1:202x applies.

215 # 5 EMC test plan

216 ## 5.1 General

217 Subclause 5.1 of IEC 61326-1:202x applies.

218 ## 5.2 Configuration of EUT during testing

219 Subclause 5.2 of IEC 61326-1:202x applies.

220 ## 5.3 Operation conditions of EUT during testing

221 Subclause 5.3 of IEC 61326-1:202x applies, except as follows:

222 *Addition:*

223 **5.3.101 Operational conditions**

224 The device shall be set to conditions specified by the manufacturer in accordance with the
225 intended use.

226 When different input power modes are available (e.g. battery, a.c. options), the manufacturer
227 shall specify these mode(s) of operation, which cover(s) the most severe condition in
228 accordance with the product risk analysis.

229 ## 5.4 Specification of functional performance

230 Subclause 5.4 of IEC 61326-1:202x applies.

231 ## 5.5 Test description

232 Subclause 5.5 of IEC 61326-1:202x applies.

6 Immunity requirements

6.1 Conditions during the tests

Subclause 6.1 of IEC 61326-1:202x is replaced as follows.

6.101 Conditions during the tests

The configuration and modes of operation during the tests shall be precisely noted in the test report.

Tests shall be applied to the relevant ports in accordance with Table 101 or Table 102 of this standard, as applicable.

The tests shall be conducted in accordance with the basic standards. The tests shall be carried out one at a time. If additional methods are required, the method and rationale shall be documented in the test report.

6.2 Immunity test requirements

Subclause 6.2 of IEC 61326-1:202x and its title are replaced as follows.

6.201 Risk assessment and consideration of EMC immunity requirements

Powerful electromagnetic emission sources can lead to malfunctions in nearby medical equipment under certain circumstances. Different types of medical electrical equipment have different levels of risk with a malfunction. IVD medical equipment however is not intended to keep alive or resuscitate patients, so a malfunction would not directly cause the death or serious injury of a patient. Such a malfunction in IVD medical electrical equipment can result in an incorrect reading, which can in turn lead to a wrong therapeutic decision (misdiagnosis). For some ANALYTES and in some circumstances, an incorrect result could result in serious harm to the patient. In the case of larger IVD electrical equipment, electromagnetic disturbances can also cause malfunctions that pose a direct threat to the operator, for example through unexpected mechanical movements.

The manufacturer shall perform risk management according to ISO 14971 for guidance in assessing risk associated with direct hazards as well as ISO 14971:201x, Annex H for guidelines for assessing the risk to patients from incorrect IVD test results.

NOTE As a rule, results from IVD medical equipment are checked for plausibility by medical personnel or followed-up by decisions of a healthcare professional. IVD medical equipment for self-testing by lay users is always provided with advice on action to be taken in case of indeterminate results. The users are urged to contact their medical practitioner first before making any decision of medical relevance.

For equipment intended to be used in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT the immunity requirements of Table 101 shall be applied.

Table 101 – Immunity test requirements for equipment intended to be used in PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT

PORT	Phenomenon	Basic standard	Test value	Performance criterion
ENCLOSURE.1	Electrostatic discharge	IEC 61000-4-2	± 4 kV contact ± 2 kV, ± 4 kV, ± 8 kV air	B B
	Electromagnetic field	IEC 61000-4-3	3 V/m (80 MHz to 6 GHz)	A
	Power-frequency magnetic field [a)]	IEC 61000-4-8	3 A/m (50 Hz, 60 Hz)	A