

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: NieprEN 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

oSIST prEN IEC 61326-2-6:2023

iTeh Standards (https://standards.iteh.ai) Document Preview

oSIST prEN IEC 61326-2-6:2023

https://standards.iteh.ai/catalog/standards/sist/47c1e993-6bb5-4c89-be2b-c46bb4c1ed05/osist-pren-iec-61326-2-6-2023

oSIST prEN IEC 61326-2-6:2023

PROJECT NUMBER: IEC 61326-2-6 ED4



Attention IEC-CENELEC parallel voting

CENELEC online voting system.

for Vote (CDV) is submitted for parallel voting.

The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft

The CENELEC members are invited to vote through the

65A/1102/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

	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:		SECRETARY:			
United Kingdom	Ms Stephanie Lavy				
OF INTEREST TO THE FOLLOWING COMMITTEES:		PROPOSED HORIZONTAL STANDARD:			
TC 77,SC 77A					
	Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.				
FUNCTIONS CONCERNED:					
	RONMENT	Quality assura	ANCE	☐ SAFETY	
SUBMITTED FOR CENELEC PARALLE		☐ NOT SUBMITTED		ELEC PARALLEL VOTING	

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:

Copyright © 2023 International Electrotechnical Commission, IEC. All rights reserved. It is permitted to download this electronic file, to make a copy and to print out the content for the sole purpose of preparing National Committee positions. You may not copy or "mirror" the file or printed version of the document, or any part of it, for any other purpose without permission in writing from IEC.

-2-

1

CONTENTS

FC	DREWO	RD	4
1.	Scop	e	6
2.	Norm	native references	6
3.	Term	s and definitions	6
	3.1	Terms and definitions	7
	3.2	Abbreviations	
4.	Gene	eral	9
	4.101	Essential Performance	9
	4.102	Basic Safety	9
5.	EMC	test plan	10
	5.1	General	10
	5.2	Configuration of EUT during testing	10
	5.2.10	1 Subsystems	11
	5.3	Operation conditions of EUT during testing	11
	5.3.10	1 Operation conditions	11
	5.4	Specification of functional performance	
	5.5	Test description	11
6.	Immu		
	6.1	Conditions during the tests	12
	6.101	Conditions during the tests	
	6.2	Immunity test requirements	12
	6.201	Risk assessment and consideration of EMC immunity requirements	
	6.3	Random aspects	18
	6.4	Performance criteria	18
	6.401	Pass/fail criteriagist-press in the control of the control o	18
7.	rd Emis	sion requirements	. 19
8.	Test	results and test report	19
9.	Instru	uctions for use	20
	9.101	General requirements for the IVD MEE instructions for use	20
	9.102		21
	9.103		
		in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT	21
Ar			22
Ar	nex B (informative) General guidance and rationale	23
	B.1	·	
Ar	nex C (
		, , , , , , , , , , , , , , , , , , , ,	
			26
	D.1	Test plan contents	26
Ar	nex E (informative) (leveraged from IEC 60601-1-2:2020 Table 1)	28
	Table I	E.1 – Power input voltages and frequencies during the tests <i>(1 of 2)</i>	28
	1. 2. 3. 4. 5. 6. Ar Ar Ar	1. Scop 2. Norm 3. Term 3.1 3.2 4. Gene 4.101 4.102 5. EMC 5.1 5.2 5.2.10 5.3 5.3.10 5.4 5.5 6. Immu 6.1 6.201 6.3 6.4 6.401 7. Emis 8. Test 9. Instru 9.101 9.102 9.103 Annex A (EQUIF Annex B (Annex D (plan : D.1 Annex E (2. Normative references 3. Terms and definitions 3.1 Terms and definitions 3.2 Abbreviations 4. General 4.101 Essential Performance 4.102 Basic Safety 5. EMC test plan 5.1 General 5.2 Configuration of EUT during testing 5.2.101 Subsystems 5.3 Operation conditions of EUT during testing 5.3.101 Operation conditions 5.4 Specification of functional performance 5.5 Test description 6. Immunity requirements 6.1 Conditions during the tests 6.101 Conditions during the tests 6.201 Risk assessment and consideration of EMC immunity requirements 6.3 Random aspects 6.4 Performance criteria 6.401 Pass/fail criteria 7. Emission requirements 8. Test results and test report 9. Instructions for use 9.101 General requirements for the IVD MEE instructions for use in a HOME HEALTHCARE ENVIRONMENT 9.103 Additional requirements for the instructions for use of equipment to be used in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT Annex A (normative) Immunity test requirements for operations of use for equipment to be used in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT Annex B (informative) General guidance and rationale B.1 Background for maintenance leading to edition 4 of this standard Annex D (informative) General guidance and rationale B.1 Background for maintenance leading to edition 4 of this standard Annex D (informative) (leveraged from IEC 60601-1-2:2020 Annex G) Guidance: Test plan

46	Annex F (informative) Guidance on the application of risk management with regard to				
47	Electromagnetic Disturbances and the Identification of Immunity pass/fail criteria				
48	risks of EUT to identify critical immunity testing	29			
49	F.1 Immunity pass/fail criteria principles	29			
50	F.1.1 General				
51	F.1.2 Immunity pass/fail criteria for non-IVD MEE used in an IVD MEE	29			
52	F.1.3 Immunity pass/fail criteria determination	29			
53	F.2 Basic safety	29			
54	F.3 ESSENTIAL PERFORMANCE	30			
55	F.4 Immunity pass/fail criteria examples	31			
56	F.4.1 General examples	31			
57 58	F.4.2 ESSENTIAL PERFORMANCE Immunity pass criteria examples for IVD Immunoassay Analyzer	32			
59	Bibliography	34			
60					
61					
62 63	Table 101 – Immunity test requirements for equipment intended to be used in the PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT	13			
64 65	Table 102 – Immunity test requirements for equipment intended to be used in the HOME HEALTHCARE ENVIRONMENT	15			
66 67	Table 103 – Test specifications for ENCLOSURE PORT immunity to RF wireless communications equipment				
68 69	Table 104 – Test specifications for ENCLOSURE PORT immunity to proximity magnetic fields	18			
70 71					

INTERNATIONAL ELECTROTECHNICAL COMMISSION

73

72

74

75

76 77

78

79 80

81

82

83 84 85 86 87

88 89 90

91

92 93

94 95

96 97

98 99

100 101

102 103 104

105 106

107 108 109

110 111 112

> 113 114

115 116

118

119 120

121

122

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 8) Attention is drawn to the normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
- 9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.
- 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 117 technical revision.
- This edition includes the following significant technical change with respect to the previous
 - 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		

- 5 -

IEC CDV 61326-2-6 © IEC:2023

123

- 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.
- 126 This document has been drafted in accordance with the ISO/IEC Directives, Part 2.
- 127 In this document the following print types are used:
- 128 Terms used throughout this document which have been defined in Clause 3 of this document
- and of IEC 61326-1:2020: SMALL CAPITALS.
- 130 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.
- 132 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.
- 136 Note The following numbering system is used:
- 137 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;
- 140 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
- 146 reconfirmed.
- 147 standar withdrawn, atalog/standards/sist/47c1e993-6bb5-4c89-be2b-c46bb4c1ed05/osist-pren-iec-61326-2-6-2023
- replaced by a revised edition, or
- 149 amended.

150

151

-6-

IEC CDV 61326-2-6 © IEC:2023

ELECTRICAL EQUIPMENT FOR MEASUREMENT, 152 CONTROL AND LABORATORY USE -153 **EMC REQUIREMENTS -**154 155 Part 2-6: Particular requirements -156 In vitro diagnostic (IVD) medical electrical equipment 157 158 159 160 1. Scope 161 This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of IN VITRO 162 DIAGNOSTIC MEDICAL ELECTRICAL EQUIPMENT. This part of IEC 61326 applies to the BASIC SAFETY 163 and ESSENTIAL PERFORMANCE of IVD MEE in the presence of electromagnetic disturbances and to 164 electromagnetic disturbances emitted by IVD MEE. 165 BASIC SAFETY with regard to electromagnetic disturbances is applicable to all IVD MEE. 166 167 Note 1: performance with respect to electromagnetic disturbances other than ESSENTIAL PERFORMANCE is the subject of IEC 61326-1:2020 168 169 Note 2: IT equipment can be a part of an IVD MEE, if it is required to maintain BASIC SAFETY OF ESSENTIAL PERFORMANCE 2. Normative references 170 Clause 2 of IEC 61326-1:2020 applies, except as follows: 171 https://standards.iteh.ai) Addition: 172 IEC 61326-1:2020, Electrical equipment for measurement, control and laboratory use - EMC 173 requirements - Part 1: General requirements 174 175 ISO 14971:2019, Medical devices – Application of risk management to medical devices IEC 61010 (all parts), Safety requirements for electrical equipment for measurement, control, 176 177 and laboratory use 178 3. Terms and definitions 179

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

180

181

182

as follows.

-7-

183

184

3.1 Terms and definitions

- ISO and IEC maintain terminological databases for use in standardization at the following 185 addresses: 186
- IEC Electropedia: available at http://www.electropedia.org/ 187
- ISO Online browsing platform: available at http://www.iso.org/obp 188
- Addition: 189
- 3.101 190
- in vitro diagnostic medical electrical equipment (IVD MEE) 191
- instruments and apparatus intended for use in the examination of specimens intended for 192
- diagnosis of disease or other conditions, including a determination of the state of health, in 193
- order to cure, mitigate, treat, or prevent disease. IVD MEE includes all items/parts, which are 194
- needed to perform ESSENTIAL PERFORMANCE and/or BASIC SAFETY of the IVD MEE. 195
- Note 1 to entry: Such instruments or apparatus are intended for use in the collection, preparation, and examination 196
- of specimens taken from the human body without direct or wired PATIENT connection with the device. 197
- 198 Note 2 to entry: IVD: In vitro diagnostic.
- 199 Note 3 to entry: PATIENT can receive results and either can self-interpret it or a health care professional needs to
- 200 translate the result.
- 201 Note 4 to entry: MD/MEE: medical device / medical electrical equipment (defined and used in 60601-x).
- 202
- professional healthcare facility environment 203
- environment where professional healthcare is administered 204
- 205 Note 1 to entry: Locations include hospitals, diagnostic laboratories, blood banks, blood donation centers, physician
- 206 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. 207
- 208 Note 2 to entry: Such instruments can use wireless communications technology for various purposes such as
- 209 tracking system components and transferring data.
- Note 3 to entry: Most environments and locations in the PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT are 210
- considered to have well-characterized and fixed EM sources. However, wireless (mobile) communication devices are 211
- 212 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 213
- 214 be used or located close to IVD MEE are:
- 215 radio frequency-identification systems (RFID);
- wireless local area networks (WLAN); 216
- handheld mobile radios (e.g. TETRA, two-way radio); 217
- 218 paging systems;
- 219 electromagnetic security systems such as anti-theft electronic article surveillance (EAS) systems or metal 220
- 221 other wireless devices (including consumer devices);
- 222 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. 223
- 224 3.103
- home healthcare environment 225
- source reference (defined in 60601-1-11:2020) 226
- dwelling place in which a PATIENT lives or other places where PATIENTS are present, excluding 227
- professional healthcare facility environments where operators with medical training are 228
- continually available when PATIENTS are present 229

230

- 8 -

231	EXAMPLES	In a car bus	train	hoat	or nlane	. in a wheelchair or walking c	utdoore
201		III a cai, bu	o, trann,	Duai,	oi piane,	, ili a wileciciiali ol walkilig c	utuoois.

232

233 Note 1 to entry: Other places where a PATIENT is present include the outdoor environment, while working and in 234 vehicles.

235

- 3.104 236
- analyte 237
- component represented in the name of a measurable quantity 238
- 239 EXAMPLE In "the type of quantity "mass of protein in 24-hour urine", "protein" is the analyte. In "amount of substance
- 240 of glucose in plasma", "glucose" is the analyte. In both cases, the long phrase represents the measurand.
- 241 [source]: ISO 18113-1:2022, 3.1.4]
- 3.105 242
- basic safety 243
- freedom from unacceptable risk directly caused by physical hazards when IVD MEE is used. 244

245

- 3.106 246
- 247 essential performance
- 248 performance of a diagnostic function, other than that related to BASIC SAFETY, where loss or
- 249 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; 250 251 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 252 degradation would result in unacceptable risk. 253

254

3.107

255 manufacturer 256

natural or legal person with responsibility for the design, manufacture, packaging, assembling, 257 adapting, or labelling of IVD MEE, regardless of whether these operations are performed by 258 that person or on his behalf by another person(s) 259

260 261

3.108 patient eh.ai/catalog/standards/sist/47c1e993-6bb5-4c89-be2b-c46bb4c1ed05/osist-pren-iec-61326-2-6-2023

262

- living being (person or animal) undergoing a medical, surgical or dental procedure 263
- 264 Note 1 to entry: a PATIENT can be an operator

265 3.109

Normal condition 266

condition in which all means for protection against hazards are intact 267

268

- 3.110 269
- Single fault condition 270
- 271 condition of IVD MEE in which one means reducing a risk is defective or one fault is present

272

- 273 Note to entry 1 The context of risk is inclusive of hazards related to BASIC SAFETY and diagnostic function 274 degradation or loss related to ESSENTIAL PERFORMANCE.
- 275 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 276 277 to electromagnetic disturbances. Refer to 6.201 for guidance.

278 279

- 3.2 Abbreviations
- 280 Subclause 3.2 of IEC 61326-1:2020 applies.

-9-

IEC CDV 61326-2-6 © IEC:2023

4. General

- Clause 4 of IEC 61326-1:2020 applies, except as follows:
- 283 Modify final paragraph of Clause to:
- The MANUFACTURER shall perform type testing where TYPE TEST is required.

285

286

291

292

293

294

295

296

297

298

281

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.
- 290 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.
- 299 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.

310

311

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.