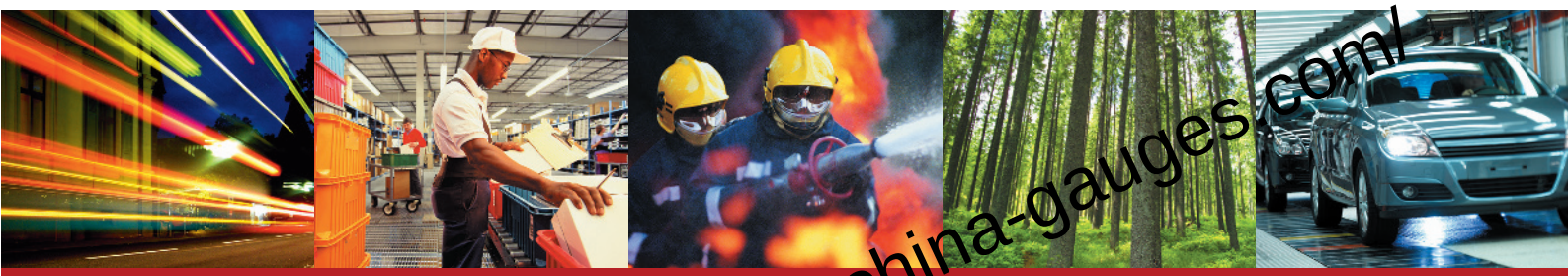
BS EN 61326-2-6:2013



BSI Standards Publication

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

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

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National foreword

This British Standard is the UK implementation of EN 61326-2-6:2013. It is identical to IEC 61326-2-6:2012. It supersedes BS EN 61326-2-6:2006, which will be withdrawn on 4 February 2016.

The UK participation in its preparation was entrusted by Technical Committee GEL/65, Measurement and control, to Subcommittee GEL/65/1, System considerations.

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

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Amd. No.	Date	Text affected

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 61326-2-6

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Supersedes EN 61326-2-6:2006

English version

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

(IEC 61326-2-6:2012)

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)
(CEI 61326-2-6:2012)

Elektrische Mess-, Steuer-, Regel- und Laborgeräte - EMV-Anforderungen - Teil 2-6: Besondere Anforderungen - Medizinische In-vitro-Diagnosegeräte (IVD)
(IEC 61326-2-6:2012)

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European Committee for Electrotechnical Standardization
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Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 65A/631/FDIS, future edition 2 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 61326-2-6:2013.

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) 2013-11-04
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2016-02-04

This document supersedes EN 61326-2-6:2006.

EN 61326-2-6:2013 includes the following significant technical change with respect to EN 61326-2-6:2006:

- update of the document with respect to EN 61326-1:2013.

EN 61326-2-6:2013 is to be used in conjunction with EN 61326-1:2013 and follows the same numbering of clauses, subclauses, tables and figures.

When a particular subclause of EN 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 EN 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 EN 61326-1;

– unless notes are in a new subclause or involve notes in EN 61326-1, they are numbered starting from 101 including those in a replaced clause or subclause;

– additional annexes are lettered AA, BB, etc.

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

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For the relationship with EU Directive(s) see informative Annex ZZ, which is an integral part of this document.

Endorsement notice

The text of the International Standard IEC 61326-2-6:2012 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

ISO 18113-1:2009 NOTE Harmonized as EN ISO 18113-1:2011 (not modified).

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Addition *to the Annex ZA of EN 61326-1:2013*

Publication	Year	Title	EN/HD	Year
IEC 61326-1	2012	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	EN 61326-1	2013
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	2012

Annex ZZ
(informative)

Coverage of Essential Requirements of EU Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers only the essential requirements in B.3.3 (only with regard to electromagnetic disturbances) and B.6.2 as given in Annex I of EU Directive 98/79/EC.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

NOTE: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

CONTENTS

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 medical equipment, taking into account the particularities and specific aspects of this electrical equipment and their electromagnetic environment.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. 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 61326-1:2012 applies, except as follows:

Addition:

IEC 61326-1:2012, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

ISO 14971:2007, *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.

Addition:

3.101
***in vitro* diagnostic 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 1 to entry: Such instruments or apparatus are intended for use in the collection, preparation, and examination of specimens taken from the human body.

3.102
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 measurand.

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

4 General

Clause 4 of IEC 61326-1:2012 applies, except as follows:

Addition:

4.101 Electromagnetic environment of IVD medical equipment

Similar to conventional medical electrical equipment, in-vitro diagnostic medical equipment is used in a wide variety of electromagnetic environments. IVD devices shall function properly and safely in home environments, as well as in typical healthcare environments (hospitals, clinics, doctor's offices). This means that the device shall have a minimum level of immunity appropriate for these areas.

Devices intended for use in other environments, such as in ambulances, aircraft, cars or helicopters, can require a higher level of immunity to ensure the safe and effective performance of the device.

5 EMC test plan

5.1 General

Subclause 5.1 of IEC 61326-1:2012 applies.

5.2 Configuration of EUT during testing

Subclause 5.2 of IEC 61326-1:2012 applies.

5.3 Operation conditions of EUT during testing

Subclause 5.3 of IEC 61326-1:2012 applies, except as follows:

Addition:

5.3.101 Operational conditions

The device shall be set to conditions specified by the manufacturer.

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

5.4 Specification of functional performance

Subclause 5.4 of IEC 61326-1:2012 applies.

5.5 Test description

Subclause 5.5 of IEC 61326-1:2012 applies.

6 Immunity requirements

6.1 Conditions during the tests

Subclause 6.1 of IEC 61326-1:2012 is replaced as follows.

6.1 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.

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.

6.2 Immunity test requirements

Subclause 6.2 of IEC 61326-1:2012 and its title are replaced as follows.

6.2 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 a risk analysis and assessment according to ISO 14971 for guidance in assessing risk associated with direct hazards as well as ISO 14971:2007, 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 are 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.

Risks associated with the use of IVD medical equipment are similar to risks associated with non-life-supporting medical equipment. Therefore the immunity test requirements given in following Table 101 are similar to the requirements for non-life-supporting medical equipment.

Table 101 – Immunity requirements for IVD medical equipment

Port	Phenomenon	EMC Basic Standard	Test value
Enclosure	Electrostatic discharge (ESD)	IEC 61000-4-2	2 kV and 4 kV contact discharge 2 kV, 4 kV and 8 kV air discharge
	Electromagnetic field	IEC 61000-4-3	3 V/m (80 MHz to 1 GHz) 3 V/m (1,4 GHz to 2 GHz) 1 V/m (2,0 GHz to 2,7 GHz)
	Power frequency magnetic field[a]	IEC 61000-4-8	3 A/m, (50 Hz, 60 Hz)
AC power (including protective earth)	Voltage dip[d]	IEC 61000-4-11	0 % during 1 cycle 40 % during 5/6 cycles [d] 70 % during 25/30 cycles [d]
	Short interruptions[d]	IEC 61000-4-11	Less than 5 % during 250/300 cycles
	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)
	Surge	IEC 61000-4-5	1 kV[e] / 2 kV[f]
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)
DC power [b,c] (including protective earth)	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)
	Surge	IEC 61000-4-5	1 kV[e] / 2 kV[f]
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)
I/O signal/control[b]	Burst	IEC 61000-4-4	0,5 kV (5/50 ns, 5 kHz)
	Surge	IEC 61000-4-5	None
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)
I/O signal/control connected directly to mains supply	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)
	Surge	IEC 61000-4-5	None
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)

[a] Test applied to only potentially magnetically sensitive equipment. CRT display interference is allowed above 1 A/m.

[b] Only in case of lines > 3 m.

[c] DC connections between parts of equipment/system which are not connected to a DC distribution network are treated as I/O signal/control ports.

[d] For example: “5/6 cycles" means "5 cycles for 50 Hz test" or "6 cycles for 60 Hz test”

[e] Line to line.

[f] Line to earth (ground).

Performance criteria shall be determined in relation to the electromagnetic phenomena by taking into account EUT operating modes that can affect data results and EUT operating modes that can affect sample processing and user interface. Applicable immunity phenomena from Table 101 shall be applied for each EUT operating mode.

The EUT may show performance criteria A, B or C as a result of the application of the test, but shall not impair the performance characteristics necessary to maintain the residual risk within acceptable limits. Refer to ISO 14971 for guidelines for evaluation of residual risk acceptability.

The performance criteria shall be reported in the test report.

6.3 Random aspects

Subclause 6.3 of IEC 61326-1:2012 applies.

6.4 Performance criteria

Subclause 6.4 of IEC 61326-1:2012 applies.

7 Emission requirements

Clause 7 of IEC 61326-1:2012 applies.

8 Test results and test report

Clause 8 of IEC 61326-1:2012 applies.

9 Instructions for use

Clause 9 of IEC 61326-1:2012 is replaced as follows.

9.1 Requirements for the IVD medical equipment instruction for use

The following information shall be in the instructions for use that accompany the IVD equipment.

NOTE 1 It is the manufacturer's responsibility to provide equipment electromagnetic compatibility information to the customer or user.

NOTE 2 It is the user's responsibility to ensure that a compatible electromagnetic environment for the equipment can be maintained in order that the device will perform as intended.

9.2 Instructions for IVD medical equipment for self-testing

The instruction for use shall include the necessary preventive warnings with regard to EMC, expressed e.g. by the following wording:

a) "Use of this instrument in a dry environment, especially if synthetic materials are present (synthetic clothing, carpets etc.) may cause damaging electrostatic discharges that may cause erroneous results."

b) "Do not use this instrument in close proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation."

9.3 Instructions for IVD medical equipment for professional use

The instruction for use shall include the following information and preventing warning:

a) A statement that the IVD medical equipment complies with the emission and immunity requirements described in this part of the IEC 61326 series.

b) If emission compliance is Class A, state the warning: "This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference."

c) An advisory that the electromagnetic environment should be evaluated prior to operation of the device.

d) In addition, the instruction for use shall include the following preventive warnings with regard to EMC, e.g. "Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

Annex A
(normative)

Immunity test requirements for portable test and measurement equipment powered by battery or from the circuit being measured

Annex A of IEC 61326-1:2012 does not apply.

Bibliography

ISO 18113-1:2009, *In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 1: Terms, definitions and general requirements*

AAMI TIR 18:1997, *Guidance on electromagnetic compatibility of medical devices for clinical/ biomedical engineers – Part 1: Radiated radio-frequency electromagnetic energy*

ANSI C63.18:1997: *American National Standard – Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters*

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BSI Group Headquarters

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