BRITISH STANDARD

BS EN
61326-2-6:2006

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

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

The European Standard EN 61326-2-6:2006 has the status of a British Standard

ICS 25.040.40; 33.100

BSI
British Standards

National foreword

This British Standard is the official English language version of EN 61326-2-6:2006. It is identical with IEC 61326-2-6:2005.
BS EN 61326-2-6:2006 partially supersedes BS EN 61326:1998 which will be withdrawn on publication of BS EN 61326-1:2006 and all of the parts of the BS EN 61326-2 series of standards (BS EN 61326-2-1:2006, BS EN 61326-2-2:2006, BS EN 61326-2-3, BS EN 61326-2-4 and BS EN 61326-2-5).

The UK participation in its preparation was entrusted by Technical Committee GEL/65, Measurement and control, to Subcommittee GEL/65/1, Systems considerations, which has the responsibility to:

— aid enquirers to understand the text;

— present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;

— monitor related international and European developments and promulgate them in the UK.

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

Cross-references

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Summary of pages

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English version

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

(IEC 61326-2-6:2005)

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 61326-2-6:2005)

Elektrische Mess-, Steuer-, Regel- und Laborgeräte – EMV-Anforderungen Teil 2-6: Besondere Anforderungen – Medizinische In-vitro-Diagnosegeräte (IVD)
(IEC 61326-2-6:2005)

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Ref. No. EN 61326-2-6:2006 E

Foreword

The text of document 65A/455/FDIS, future edition 1 of IEC 61326-2-6, prepared by SC 65A, System aspects, of IEC TC 65, Industrial-process measurement and control, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61326-2-6 on 2005-12-01.

The EN 61326 series supersedes EN 61326:1997 + corrigendum September 1998 + A1:1998 + A2:2001 + A3:2003.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2006-12-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2009-02-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 98/79/EC. See Annex ZZ.

Annexes ZA and ZZ have been added by CENELEC.

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Endorsement notice

The text of the International Standard IEC 61326-2-6:2005 was approved by CENELEC as a European Standard without any modification.

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 International Standard IEC 61326-1, this part 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 referenced documents are indispensable for the application 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.

IEC 60050-161:1990, *International Electrotechnical Vocabulary (IEV) – Part 161: Electromagnetic compatibility*

IEC 61326-1:2005, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

ISO 14971: 2000, *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 and IEC 60050(161) as well as the following apply.

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. Such instruments or apparatus are intended for use in the collection, preparation, and examination of specimens taken from the human body.

4 General

IEC 61326-1 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, may require a higher level of immunity to ensure the safe and effective performance of the device.

5 EMC test plan

5.1 General

IEC 61326-1 applies.

5.2 Configuration of EUT during testing

5.2.1 General

IEC 61326-1 applies.

5.2.2 Composition of EUT

IEC 61326-1 applies.

5.2.3 Assembly of EUT

IEC 61326-1 applies.

5.2.4 I/O ports

IEC 61326-1 applies.

5.2.5 Auxiliary equipment

IEC 61326-1 applies.

5.2.6 Cabling and earthing (grounding)

IEC 61326-1 applies.

5.3 Operation conditions of EUT during testing

IEC 61326-1 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 performance criteria

IEC 61326-1 applies.

5.5 Test description

IEC 61326-1 applies.

6 Immunity requirements

6.1 Conditions during the tests

IEC 61326-1 applies, except as follows:

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 1.

The tests shall be conducted in accordance with the basic IEC 61000 series of 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 is replaced by the following:

6.2.101 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 may 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 may also cause malfunctions that pose a direct threat to the operator, for example through unexpected mechanical movements.

Refer to ISO 14971 for guidance in assessing risk associated with direct hazards and ISO 14971, 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 1 are similar to the requirements for non-life-supporting medical equipment.

Table 1 – Minimum *in vitro* diagnostic (IVD) medical equipment immunity requirements

Port	Phenomenon	EMC Basic Standard	Test value
Enclosure	Electrostatic discharge (ESD)	IEC 61000-4-2	2, 4, 8 kV air and 2, 4 kV contact
	Radiated E-field	IEC 61000-4-3	3 V/m, 80 MHz to 2,0 GHz, 80 % AM
	Rated power frequency magnetic field[a)]	IEC 61000-4-8	3 A/m, 50 and 60 Hz
AC power	Voltage dips[d)]	IEC 61000-4-11	1 cycle 0 %; 5/6 cycles 40 %; 25/30 cycles 70 %
	Voltage interruptions[d)]	IEC 61000-4-11	5 % during 250/300 cycles
	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)
	Surge	IEC 61000-4-5	2 kV line to ground /1 kV line to line
	Conducted RF	IEC 61000-4-6	3 V, 150 kHz to 80 MHz, 80 % AM
DC power [c)]	Burst	IEC 61000-4-4	1 kV (5/50 ns, 5 kHz)
	Surge	IEC 61000-4-5	2 kV line to ground /1 kV line to line
	Conducted RF	IEC 61000-4-6	3 V, 150 kHz to 80 MHz, 80 % AM
I/O signals [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, 80 % AM
I/O signals connected to mains	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, 80 % AM

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

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

[c)] Not applicable to input ports intended for connection to a battery or a rechargeable battery which should be removed or disconnected from the apparatus for recharging.
Apparatus with a d.c. power input port intended for use with an a.c. - d.c. power adaptor shall be tested on the a.c. power input of the a.c.- d.c. power adaptor specified by the manufacturer or, where none is so specified, using a typical a.c. - d.c. power adaptor. The test is applicable to d.c. power input ports intended to be connected permanently to long distance lines.

[d)] "5/6 cycles" means "5 cycles for 50 Hz test" and "6 cycles for 60 Hz test".

Performance criteria shall be determined in relation to the electromagnetic phenomena by taking into account EUT operating modes that may affect data results and EUT operating modes that may affect sample processing and user interface. Applicable immunity phenomena from Table 1 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 included in the test report.

6.3 Random aspects

IEC 61326-1 applies.

6.4 Performance criteria

IEC 61326-1 applies.

7 Emission requirements

IEC 61326-1 applies.

8 Test results and test report

IEC 61326-1 applies

9 Instructions for use

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

Replacement:

9.101 Requirements for the IVD 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.

9.102 Instructions for *in vitro* diagnostic equipment for self-testing

The instruction for use shall include the following preventive warnings with regard to EMC, e.g.

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

9.103 Instructions for *in vitro* diagnostic equipment for professional use.

The instruction for use shall include the following information.

a) A statement that the IVD 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.

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 may interfere with the proper operation.

Bibliography

AAMI TIR No. 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*

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application 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 Where an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Publication	Year	Title	EN/HD	Year
IEC 60050-161	1990	International Electrotechnical Vocabulary Chapter 161: Electromagnetic compatibility	–	–
IEC 61326-1	2005	Electrical equipment for measurement, control and laboratory use – EMC requirements Part 1: General requirements	EN 61326-1	2006
ISO 14971	2000	Medical devices – Application of risk management to medical devices	EN ISO 14971	2000

Annex ZZ
(informative)

Coverage of Essential Requirements of EC 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 all relevant essential requirements as given in Annex I of the EC Directive 98/79/E.

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

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

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