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REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

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

IEC 61326-2-6:2020-10 RLV(en)

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FOREWORD

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This redline version of the official IEC Standard allows the user to identify the changes made to the previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

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 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 61326-1:2020.

The text of this International Standard is based on the following documents:

FDIS	Report on voting
65A/979/FDIS	65A/990/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.

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.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

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 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:~~2012~~2020 applies, except as follows:

Addition:

IEC 61326-1:~~2012~~2020, *Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 1: General requirements*

ISO 14971:~~2007~~2019, *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.

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 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 without direct or wired patient connection with the device.

Note 2 to entry: IVD: In vitro diagnostic.

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 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. However, 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 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 3 to entry: It is assumed that IVD MEDICAL EQUIPMENT is not directly connected to the public mains network.

Note 4 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. IVD MEDICAL EQUIPMENT that might be used in ambulances, or any ground vehicle or aircraft can require a higher level of immunity than the PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT.

3.103
home healthcare environment
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 or while operating under battery power, IVD MEDICAL EQUIPMENT is usually connected to the public mains network.

Note 2 to entry: The characteristics of this environment justify higher immunity test levels for basic safety and ESSENTIAL PERFORMANCE. Locations include the home, and any public place such as shops and libraries, offices, transport stations and airports, etc. Examples of electromagnetic sources that might be used near IVD MEDICAL EQUIPMENT in these environments or otherwise expose the IVD MEDICAL 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 ~~measurand~~ measured property.

[SOURCE: ISO 18113-1:2009, 3.3, modified – property has been added after measurand]

3.105
basic safety
freedom from unacceptable risk to the operator directly caused by physical hazards when IVD MEDICAL EQUIPMENT is used under normal condition and single fault condition

3.106
essential performance
performance of a clinical function, other than that related to BASIC SAFETY, where loss or degradation beyond the limits specified in the user documentation results in an unacceptable risk

Note 1 to entry: ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable risk.

3.2 Abbreviations

Subclause 3.2 of IEC 61326-1:2020 applies.

4 General

Clause 4 of IEC 61326-1:~~2012~~2020 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~~2020 applies.

5.2 Configuration of EUT during testing

Subclause 5.2 of IEC 61326-1:~~2012~~2020 applies.

5.3 Operation conditions of EUT during testing

Subclause 5.3 of IEC 61326-1:~~2012~~2020 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.~~

The device shall be set to conditions specified in the user documentation in accordance with the intended use.

For each mode of operation, the power option (e.g. battery, AC or DC supply) which represents the most severe condition shall be specified in accordance with the product risk analysis.

5.4 Specification of FUNCTIONAL PERFORMANCE

Subclause 5.4 of IEC 61326-1:~~2012~~2020 applies.

5.5 Test description

Subclause 5.5 of IEC 61326-1:~~2012~~2020 applies.

6 Immunity requirements

6.1 Conditions during the tests

Subclause 6.1 of IEC 61326-1:~~2012~~2020 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 document, as applicable.

~~The tests shall be conducted in accordance with the basic standards.~~ The tests shall be carried out one at a time in accordance with the basic standards. 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:~~2012~~2020 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~~ MEDICAL 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.~~

The manufacturer shall perform risk management according to ISO 14971 for guidance in assessing risk associated with direct hazards.

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.

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.

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

In addition, depending on the outcome of the risk assessment of the electromagnetic environment, consideration shall be given to include the immunity test requirements of Table 102 and Table 103.

The risk assessment shall include point-of-care testing equipment or other equipment used close to patients, who might have home use electronics such as mobile phones even in the professional environment.

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	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	IEC 61000-4-8	3 A/m (50 Hz, 60 Hz)	A
AC power (including protective earth)	Burst	IEC 61000-4-4	± 1 kV (5 kHz or 100 kHz)	B
	Surge	IEC 61000-4-5	± 0,5 kV line-to-line ± 1 kV line-to-ground	B B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
	Voltage dip	IEC 61000-4-11	0 % during 0,5 cycles 0 % during 1 cycle 70 % during 25/30 cycles [a]	B B C
	Short interruptions	IEC 61000-4-11	0 % during 250/300 cycles [a]	C
DC power [b, c] (including protective earth)	Burst	IEC 61000-4-4	± 1 kV (5 kHz or 100 kHz)	B
	Surge	IEC 61000-4-5	± 0,5 kV line-to-line ± 1 kV line-to-ground	B B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
I/O signal/control [c] (including functional earth)	Burst [b]	IEC 61000-4-4	± 0,5 kV (5 kHz or 100 kHz)	B
	Surge [e]	IEC 61000-4-5	± 1 kV line-to-ground	B
	Conducted RF [b]	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
I/O signal/control [c] connected directly to mains supply	Burst [b]	IEC 61000-4-4	± 1 kV (5 kHz or 100 kHz)	B
	Surge [d]	IEC 61000-4-5	± 0,5 kV line-to-line ± 1 kV line-to-ground	B B
	Conducted RF [b]	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A

[a] For example, “25/30 cycles" means "25 cycles for 50 Hz test" or "30 cycles for 60 Hz test”.

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

[c] DC POWER PORTS intended to be connected to a low voltage DC supply (≤ 60 V), where secondary circuits (isolated from the AC mains supply) are not subject to transient overvoltages (i.e. reliably-grounded, capacitive-filtered DC secondary circuits) shall be regarded as I/O signal/control PORTS.

[d] Only in the case of LONG-DISTANCE LINES.

For equipment intended to be used in a HOME HEALTHCARE ENVIRONMENT, the immunity requirements of Table 102 and Table 103 shall be applied.

Table 102 – Immunity test requirements for equipment intended to be used in a HOME HEALTHCARE ENVIRONMENT

PORT	Phenomenon	Basic standard	Test value	Performance criterion
ENCLOSURE	Electrostatic discharge	IEC 61000-4-2	±6 kV contact ±2 kV, ±4 kV, ±8 kV air	B B
	Electrostatic discharge	IEC 61000-4-2	±8 kV contact ±15 kV air	C C
	Electromagnetic field	IEC 61000-4-3	10 V/m (80 MHz to 1 GHz) 3 V/m (1 GHz to 6 GHz)	A A
	Magnetic field	IEC 61000-4-8	30 A/m (50 Hz, 60 Hz)	A
AC power	Voltage dip	IEC 61000-4-11	0 % during 0,5 cycles 0 % during 1 cycle 70 % during 25/30 cycles [a]	B B C
	Short interruptions	IEC 61000-4-11	0 % during 250/300 cycles [a]	C
	Burst	IEC 61000-4-4	± 2 kV (5 kHz or 100 kHz)	B
	Surge [e]	IEC 61000-4-5	± 0,5 kV, ± 1 kV line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV line-to-ground	B B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
			6 V in ISM and amateur radio bands in the frequency range 150 kHz to 80 MHz [b] 80 % AM at 1 kHz	A
DC power and/or I/O signal/control [c, d] including protective earth	Burst	IEC 61000-4-4	± 2 kV (5 kHz or 100 kHz)	B
	Surge [e]	IEC 61000-4-5	± 0,5, ± 1 kV Line to line ± 0,5 kV, ±1 kV, ±2 kV Line to ground	B B
	Conducted RF	IEC 61000-4-6	3 V (150 kHz to 80 MHz)	A
			6 V in ISM and amateur radio bands in the frequency range 150 kHz to 80 MHz [e] 80 % AM at 1 kHz	A

[a] For example “25/30 cycles" means "25 cycles for 50 Hz test" or "30 cycles for 60 Hz test”.

[b] The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[c] Only in the case of lines > 3 m.

[d] DC connections between parts of equipment/system which are not connected to a DC DISTRIBUTION NETWORK are treated as I/O signal/control PORTS (USB charging and communication combined). Using for example USB connection only as a power source, it falls under DC power.

[e] Only in the case of LONG-DISTANCE LINES.

The frequencies and services listed in Table 103 are representative examples that are based on RF communications equipment in use at the time of publication of this document. The test specification does not attempt to cover every frequency and service used in every country. The risk management process should take the country specific communications services into account. Testing should be performed at the additional frequencies identified that are not represented in Table 103.