IEC 61326-2-6

Edition 3.0 2020-10
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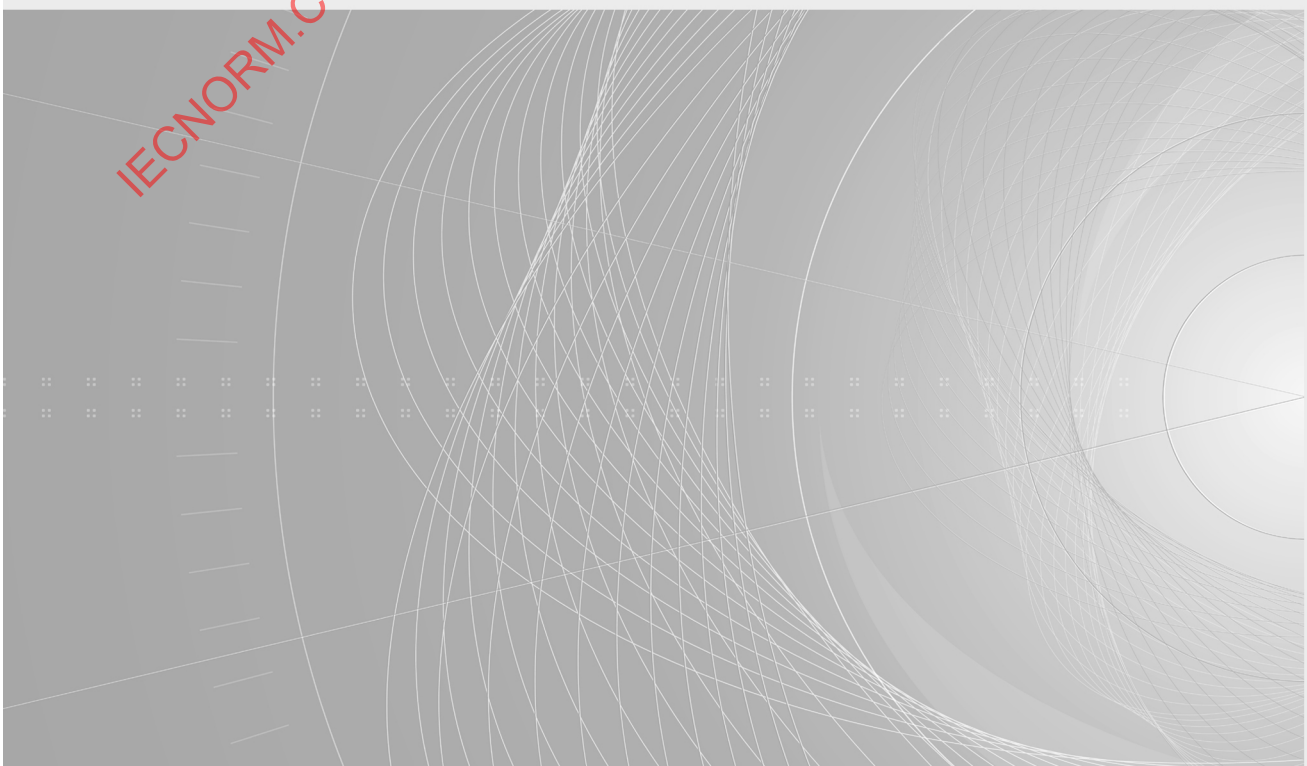
Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment



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

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IEC Central Office
3, rue de Varembé
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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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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ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE – EMC REQUIREMENTS –

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

FOREWORD

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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.

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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.

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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

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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

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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.

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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.

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~~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).~~

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~~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.

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

PORT	Phenomenon	Basic standard	Test value	Perform-ance 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.

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In addition, if, after this document is released, additional frequencies (new bands) become official, they shall be tested or the risk management process should be performed.

While communication might not be possible when IVD MEDICAL EQUIPMENT that includes radio equipment is tested in its passband, the IVD MEDICAL EQUIPMENT shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.

Table 103 – Immunity test requirements for equipment intended to be used in a HOME HEALTHCARE ENVIRONMENT

PORT	Phenomenon	Basic standard	Test value	Perform-ance criterion
ENCLOSURE.1	Electromagnetic field [a]	IEC 61000-4-3	9 V/m (710 MHz, 745 MHz, 780 MHz) 28 V/m (1 720 MHz, 1 845 MHz, 1 970 MHz) 28 V/m (2 450 MHz) 9 V/m (5 240 MHz, 5 500 MHz, 5 785 MHz) With a pulse modulation of 217 Hz. The carrier shall be modulated using a 50 % duty cycle square wave signal.	B
ENCLOSURE.2	Electromagnetic field [a]	IEC 61000-4-3	27 V/m (385 MHz) 28 V/m (810 MHz, 870 MHz, 930 MHz) With a pulse modulation of 18 Hz. The carrier shall be modulated using a 50 % duty cycle square wave signal.	B
ENCLOSURE.3	Electromagnetic field [a]	IEC 61000-4-3	28 V/m (430 MHz to 470 MHz) FM [b] ± 5 kHz deviation, 1 kHz sine	B

[a] If necessary to achieve the immunity test level, the distance between the transmitting antenna and the equipment may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[b] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case sensitive equipment.

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6.3 Random aspects

Subclause 6.3 of IEC 61326-1:~~2012~~2020 applies.

6.4 Performance criteria

Subclause 6.4 of IEC 61326-1:~~2012~~2020 applies except as follows.

Addition of the following text after the existing text in 6.4.1:

Performance criteria shall be determined to take into account the EUT operating modes that can affect data and results, sample processing, and the user interface. Applicable immunity test criteria shall be applied for each EUT operating mode and its acceptable performance criterion.

Any change in performance that is within the performance criteria, A, B, or C listed in Table 101, Table 102 or Table 103 shall be justified by an assessment of the residual risk.

Refer to ISO 14971 for guidelines for evaluation of residual risk acceptability.

Performance criteria which are less stringent than those specified in Table 101, Table 102 or Table 103 shall be justified and reported in the test report, user documentation, and risk management of the product.

In addition to the performance criteria A, B and C of 61326-1:2020 the EUT is not allowed to report unacceptable results or fail in its ESSENTIAL PERFORMANCE or BASIC SAFETY. The test plan shall list the acceptable BASIC SAFETY and ESSENTIAL PERFORMANCE parameters.

7 Emission requirements

Clause 7 of IEC 61326-1:~~2012~~2020 applies.

8 Test results and test report

Clause 8 of IEC 61326-1:~~2012~~2020 applies.

9 Instructions for use

Clause 9 of IEC 61326-1:~~2012 is replaced~~ 2020 applies, except as follows:

Addition:

9.101 General requirements for the IVD MEDICAL EQUIPMENT instruction for use

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

NOTE 3 The calculation formula to determine the separation distance between an IVD MEDICAL EQUIPMENT and a mobile phone is given by $d = 6/E \sqrt{P}$, where d is the minimum separation distance in metres, P is the maximum power in watts, and E is the immunity test level in V/m.

9.102 ~~Instructions for IVD medical equipment for self-testing~~ Additional requirements for the instruction for use for equipment to be used in a HOME HEALTHCARE ENVIRONMENT

The instructions 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."

c) "This equipment is designed for use in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference."

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9.103 ~~Instructions for IVD medical equipment for professional use~~ Additional requirements for the instruction for use for equipment to be used in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT

The instructions for use shall include the following information and ~~preventing~~ preventive warning:

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

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."~~ This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

c) "This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference."

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

e) 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 withproper operation."

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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~~2020 does not apply.

NOTE PORTABLE TEST AND MEASUREMENT EQUIPMENT is covered by Table 101 or Table 102.

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Annex B
(informative)

Guide for analysis and assessment for electromagnetic compatibility

Annex B of IEC 61326-1:2020 does not apply.

NOTE The idea of the risk assessment is already implemented in Subclause 6.2.

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Bibliography

The Bibliography of IEC 61326-1:2020 applies, except as follows:

Addition:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

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~~2010, *Guidance on electromagnetic compatibility of medical devices ~~for clinical/ biomedical engineers – Part 1: Radiated radio-frequency electromagnetic energy~~ in healthcare facilities*

ANSI C63.18:~~1997~~2014, *American National Standard – Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to ~~Specific~~ Radiated Radio-Frequency (RF) Emissions from RF Transmitters*

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IEC 61326-2-6

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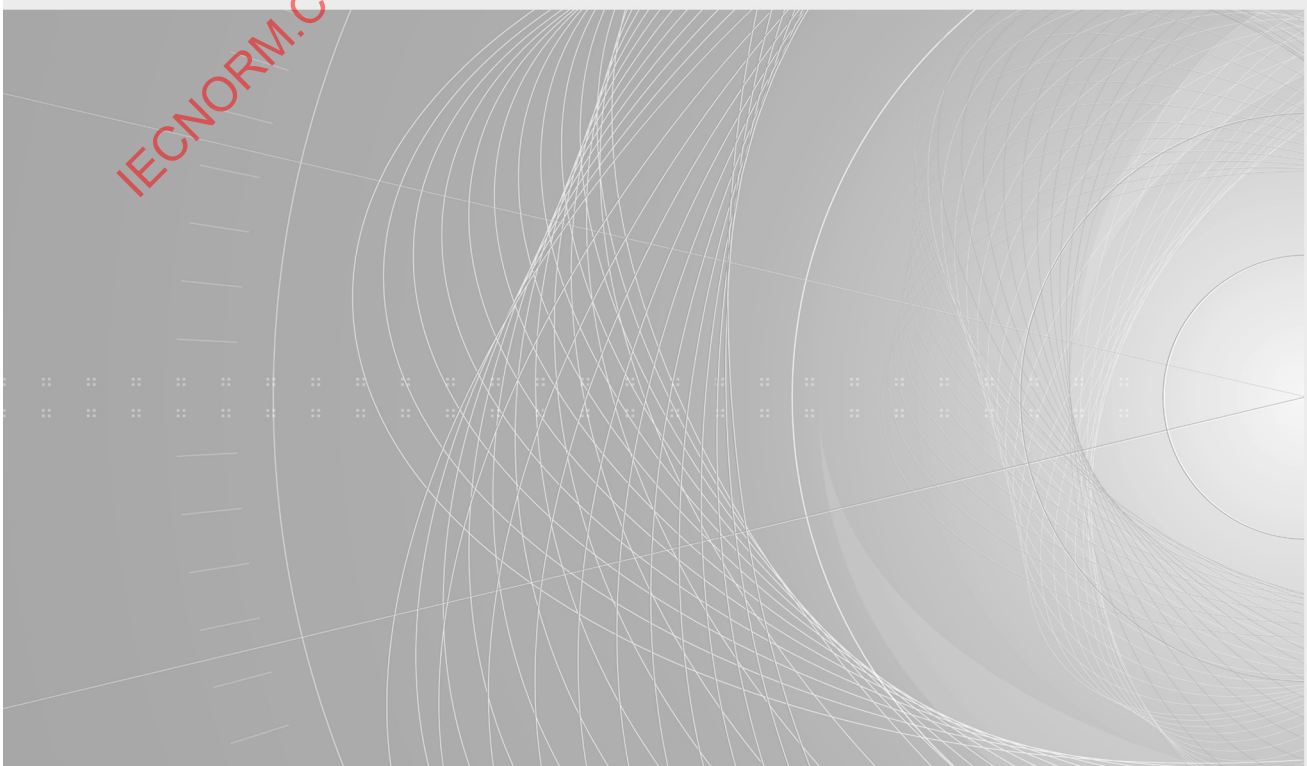
Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

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)



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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 – In vitro diagnostic (IVD) medical 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.
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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.

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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 61326-1:2020 applies, except as follows:

Addition:

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

ISO 14971:2019, *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

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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 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

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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 61326-1:2020 applies.

5 EMC test plan

5.1 General

Subclause 5.1 of IEC 61326-1:2020 applies.

5.2 Configuration of EUT during testing

Subclause 5.2 of IEC 61326-1:2020 applies.

5.3 Operation conditions of EUT during testing

Subclause 5.3 of IEC 61326-1:2020 applies, except as follows:

Addition:

5.3.101 Operational conditions

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 61326-1:2020 applies.

5.5 Test description

Subclause 5.5 of IEC 61326-1:2020 applies.

6 Immunity requirements

6.1 Conditions during the tests

Subclause 6.1 of IEC 61326-1:2020 is replaced as follows.

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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 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 61326-1:2020 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 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 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 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 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.

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.

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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.

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

PORT	Phenomenon	Basic standard	Test value	Perform-ance 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.

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In addition, if, after this document is released, additional frequencies (new bands) become official, they shall be tested or the risk management process should be performed.

While communication might not be possible when IVD MEDICAL EQUIPMENT that includes radio equipment is tested in its passband, the IVD MEDICAL EQUIPMENT shall still be able to provide its BASIC SAFETY and ESSENTIAL PERFORMANCE.

Table 103 – Immunity test requirements for equipment intended to be used in a HOME HEALTHCARE ENVIRONMENT

PORT	Phenomenon	Basic standard	Test value	Perform-ance criterion
ENCLOSURE.1	Electromagnetic field [a]	IEC 61000-4-3	9 V/m (710 MHz, 745 MHz, 780 MHz) 28 V/m (1 720 MHz, 1 845 MHz, 1 970 MHz) 28 V/m (2 450 MHz) 9 V/m (5 240 MHz, 5 500 MHz, 5 785 MHz) With a pulse modulation of 217 Hz. The carrier shall be modulated using a 50 % duty cycle square wave signal.	B
ENCLOSURE.2	Electromagnetic field [a]	IEC 61000-4-3	27 V/m (385 MHz) 28 V/m (810 MHz, 870 MHz, 930 MHz) With a pulse modulation of 18 Hz. The carrier shall be modulated using a 50 % duty cycle square wave signal.	B
ENCLOSURE.3	Electromagnetic field [a]	IEC 61000-4-3	28 V/m (430 MHz to 470 MHz) FM [b] ± 5 kHz deviation, 1 kHz sine	B

[a] If necessary to achieve the immunity test level, the distance between the transmitting antenna and the equipment may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[b] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case sensitive equipment.

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6.3 Random aspects

Subclause 6.3 of IEC 61326-1:2020 applies.

6.4 Performance criteria

Subclause 6.4 of IEC 61326-1:2020 applies except as follows.

Addition of the following text after the existing text in 6.4.1:

Performance criteria shall be determined to take into account the EUT operating modes that can affect data and results, sample processing, and the user interface. Applicable immunity test criteria shall be applied for each EUT operating mode and its acceptable performance criterion.

Any change in performance that is within the performance criteria, A, B, or C listed in Table 101, Table 102 or Table 103 shall be justified by an assessment of the residual risk.

Refer to ISO 14971 for guidelines for evaluation of residual risk acceptability.

Performance criteria which are less stringent than those specified in Table 101, Table 102 or Table 103 shall be justified and reported in the test report, user documentation, and risk management of the product.

In addition to the performance criteria A, B and C of 61326-1:2020 the EUT is not allowed to report unacceptable results or fail in its ESSENTIAL PERFORMANCE or BASIC SAFETY. The test plan shall list the acceptable BASIC SAFETY and ESSENTIAL PERFORMANCE parameters.

7 Emission requirements

Clause 7 of IEC 61326-1:2020 applies.

8 Test results and test report

Clause 8 of IEC 61326-1:2020 applies.

9 Instructions for use

Clause 9 of IEC 61326-1:2020 applies, except as follows:

Addition:

9.101 General requirements for the IVD MEDICAL EQUIPMENT instruction for use

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

NOTE 3 The calculation formula to determine the separation distance between an IVD MEDICAL EQUIPMENT and a mobile phone is given by $d = 6/E \cdot \sqrt{P}$, where d is the minimum separation distance in metres, P is the maximum power in watts, and E is the immunity test level in V/m.

9.102 Additional requirements for the instruction for use for equipment to be used in a HOME HEALTHCARE ENVIRONMENT

The instructions 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 proximity to sources of strong electromagnetic radiation, as these may interfere with the proper operation."

c) "This equipment is designed for use in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference."

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9.103 Additional requirements for the instruction for use for equipment to be used in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT

The instructions for use shall include the following information and preventive warning:

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

b) If emission compliance is Class A, state the warning: This equipment is not intended for use in residential environments and may not provide adequate protection to radio reception in such environments.

c) “This equipment is designed for use in a PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT. It is likely to perform incorrectly if used in a HOME HEALTHCARE ENVIRONMENT. If it is suspected that performance is affected by electromagnetic interference, correct operation may be restored by increasing the distance between the equipment and the source of the interference.”

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

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

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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 61326-1:2020 does not apply.

NOTE PORTABLE TEST AND MEASUREMENT EQUIPMENT is covered by Table 101 or Table 102.

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Annex B
(informative)

Guide for analysis and assessment for electromagnetic compatibility

Annex B of IEC 61326-1:2020 does not apply.

NOTE The idea of the risk assessment is already implemented in Subclause 6.2.

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Bibliography

The Bibliography of IEC 61326-1:2020 applies, except as follows:

Addition:

IEC 60601-1-2:2014, *Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests*

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

AAMI TIR 18:2010, *Guidance on electromagnetic compatibility of medical devices in healthcare facilities*

ANSI C63.18:2014, *American National Standard – Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Radiated Radio-Frequency (RF) Emissions from RF Transmitters*

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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)

AVANT-PROPOS

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La Norme internationale IEC 61326-2-6 a été établie par le sous-comité 65A: Aspects systèmes, du comité d'études 65 de l'IEC: Mesure, commande et automation dans les processus industriels.

Cette troisième édition annule et remplace la deuxième édition parue en 2012. Cette édition constitue une révision technique.

Cette édition inclut la modification technique majeure suivante par rapport à l'édition précédente:

– mise à jour du document par rapport à l'IEC 61326-1:2020.

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Le texte de cette Norme internationale est issu des documents suivants:

FDIS	Rapport de vote
65A/979/FDIS	65A/990/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2.

Dans le présent document, les caractères d'imprimerie suivants sont utilisés:

– Termes définis à l'Article 3 du présent document et de l'IEC 61326-1:2020 et utilisés dans tout ce document: PETITES MAJUSCULES.

La présente partie de l'IEC 61326 doit être utilisée conjointement avec l'IEC 61326-1:2020 et suit la même numérotation d'articles, de paragraphes, de tableaux et de figures.

Lorsqu'un paragraphe particulier de l'IEC 61326-1 n'est pas mentionné dans présente partie, ce paragraphe s'applique pour autant qu'il est raisonnable. Lorsque la présente norme spécifie "addition", "modification" ou "remplacement", le texte correspondant de l'IEC 61326-1 doit être adapté en conséquence.

NOTE Le système de numérotation suivant est utilisé:

– paragraphes, tableaux et figures: ceux qui sont numérotés à partir de 101 sont complémentaires à ceux de l'IEC 61326-1;

– à l'exception de celles qui sont dans un nouveau paragraphe ou de celles qui concer nent des notes de l'IEC 61326-1, les notes sont numérotées à partir de 101, y compris celles des articles ou paragraphes qui sont modifiés ou remplacés;

– les annexes supplémentaires sont appelées AA, BB, etc.

Une liste de toutes les parties de la série IEC 61326, publiées sous le titre général *Matériel électrique de mesure, de commande et de laboratoire – Exigences relatives à la CEM*, peut être consultée sur le site web de l'IEC.

Le comité a décidé que le contenu de ce document ne sera pas modifié avant la date de stabilité indiquée sur le site web de l'IEC sous "http://webstore.iec.ch" dans les données relatives au document recherché. A cette date, le document sera

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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)

1 Domaine d'application

En complément au domaine d'application de l'IEC 61326-1, la présente partie de l'IEC 61326 spécifie les exigences minimales pour l'immunité et les émissions relatives à la compatibilité électromagnétique des MATERIELS MEDICAUX DE DIAGNOSTIC IN VITRO (IVD – *in vitro diagnostic*), en prenant en compte les particularités et aspects spéc ifiques de ces matériels et de leur environnement électromagnétique.

2 Références normatives

L'Article 2 de l'IEC 61326-1:2020 s'applique, avec les exceptions suivantes:

Addition:

IEC 61326-1:2020, *Matériel électrique de mesure, de commande et de laboratoire – Exigences relatives à la CEM – Partie 1: Exigences générales*

ISO 14971:2019, *Dispositifs médicaux – Application de la gestion des risques aux dispositifs médicaux*

3 Termes et définitions

Pour les besoins du présent document, les termes et définitions don nés dans l'IEC 61326-1 s'appliquent, avec les exceptions suivantes.

L'ISO et l'IEC tiennent à jour des bases de données terminologiques destinées à être utilisées en normalisation, consultables aux adresses suivantes:

- IEC Electropedia: disponible à l'adresse http://www.electropedia.org/
- ISO Online browsing platform: disponible à l'adresse http://www.iso.org/obp

Addition:

3.101
matériel médical de diagnostic in vitro
instruments et matériels destinés à être utilisés pour le diagnostic de maladies ou d'autre s conditions, comprenant une détermination de l'état de santé, de façon à soigner, atténuer, traiter, ou prévenir la maladie

Note 1 à l'article: De tels instruments ou matériels sont destinés à être utilisés dans la collecte, la préparation et l'examen des spécimens prélevés sur le corps humain sans connexion directe ou câblée du patient avec le dispositif.

3.102
environnement d'installation de soins de santé professionnels
environnement dans lequel des soins de santé professionnels sont administrés

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Note 1 à l'article: Les emplacements comprennent les hôpitaux, les laboratoires de diagnostic, les banqu es du sang, les centres de don du sang, les cabinets de médecin, les unités de soins intensifs, les centres chirurgicaux, les salles d'urgence, les salles de chirurgie, les cliniques, les chambres des patients, les cabinets dentaires, les centres de dialyse de soins spécialisés, les maisons de retraite, les pharmacies avec opérateurs qualifiés, et les infirmeries.

Note 2 à l'article: La plupart des environnements et des emplacements de l'ENVIRONNEMENT D'INSTALLATION DE SOINS DE SANTE PROFESSIONNELS sont réputés avoir un ENVIRONNEMENT ELECTROMAGNETIQUE CONTROLE en ce qui concerne les sources électromagnétiques fixes. Cependant, les dispositifs de communication mobiles sont largement utilisés par les professionnels de soins de santé pour prodiguer des soins efficaces aux patients. Pour cette raison, il est plus difficile de contrôler l'environnement des perturbations électromagnétiques proches. Des exemples de sources électromagnétiques pouvant être utilisées près du MATERIEL MEDICAL IVD sont:

– les appareils d'électrochirurgie à haute fréquence;
– les systèmes d'identification par radio fréquence (RFID);
– les réseaux locaux sans fil (WLAN);
– les radios mobiles portables (par exemple radio TETRA et radio bidirectionnelle);
– les systèmes de radiomessagerie;
– d'autres dispositifs sans fil (y compris les dispositifs du public).

Note 3 à l'article: Par hypothèse, le MATERIEL MEDICAL IVD n'est pas directement relié au réseau d'alimentation public.

Note 4 à l'article: Il convient que le MATERIEL MEDICAL IVD possède un niveau d'immunité adapté afin de garantir une performance sécurisée et efficace du dispositif dans son environnement d'utilisation prévu. Le MATERIEL MEDICAL IVD qui peut utilisé dans les ambulances, dans tout véhicule terrestre ou dans les avions, peut exiger un niveau d'immunité plus élevé que l'ENVIRONNEMENT D'INSTALLATION DE SOINS DE SANTE PROFESSIONNELS typique.

3.103
environnement de soins de santé à domicile
environnement autre qu'un ENVIRONNEMENT D'INSTALLATION DE SOINS DE SANTE PROFESSIONNELS ayant un environnement électromagnétique bien plus différent avec des perturbations électromagnétiques pouvant être moins contrôlées et moins bien caractérisées en ce qui concerne l'amplitude et la probabilité d'occurrence

Note 1 à l'article: A l'exception du transport ou lors d'un fonctionnement alimenté par batterie, le MATERIEL MEDICAL IVD est généralement relié au réseau d'alimentation public.

Note 2 à l'article: Les caractéristiques de cet environnement justifient des niveaux d'essai d'immunité plus élevés pour la SECURITE DE BASE et la PERFORMANCE ESSENTIELLE. Les emplacements comprennent le domicile et tout lieu public, tels que les magasins et bibliothèques, les bureaux, les gares de transports et les aéroports, etc. Les exemples de sources électromagnétiques qui peuvent être utilisées près du MATERIEL MEDICAL DE DIAGNOSTIC IN VITRO dans ces environnements, faute de quoi le MATERIEL MEDICAL IVD est exposé à d'intenses perturbations électromagnétiques, sont:

– des petits transformateurs de fréquence réseau (50 Hz et 60 Hz), par exemple dans une horloge radio sur une table de chevet);
– des perturbations du réseau;
– des téléphones portables (souvent plusieurs);
– des stations de radiodiffusion fixes;
– des équipements de transmission télé;
– des équipements radio amateurs;
– des émetteurs radio mobiles (par exemple, de police et de taxi).

3.104
analyte
constituant d'un échantillon avec une propriété mesurable

EXEMPLES Dans l'expression "masse de protéines dans un prélèvement d'urine de 24 h", le terme "protéine" est l'ANALYTE et le terme "masse" la propriété. Dans l'expression "concentration de glucose dans le plasma", le terme "glucose" est l'ANALYTE et le terme "concentration" la propriété. Dans les deux cas, la longue expression désigne la propriété mesurée.

[SOURCE: ISO 18113-1:2009, 3.3, modifiée – "propriété" a été ajouté après "mesurande"]

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3.105
sécurité de base
absence de risque inacceptable pour l'opérateur directement causé par des dangers physiques lorsque le MATERIEL MEDICAL DE DIAGNOSTIC IN VITRO est utilisé dans des conditions normales et dans des conditions de premier défaut

3.106
performance essentielle
performance d'une fonction clinique différente de celle relative à la SECURITE DE BASE, pour laquelle la perte ou la dégradation au-delà des limites spécifiées dans la documentation de l'utilisateur entraîne un risque inacceptable

Note 1 à l'article: Le terme PERFORMANCE ESSENTIELLE est plus facilement compris en examinant si son absence ou sa dégradation donne lieu à un risque inacceptable.

3.2 Abréviations

Le Paragraphe 3.2 de l'IEC 61326-1:2020 s'applique.

4 Généralités

L'Article 4 de l'IEC 61326-1:2020 s'applique.

5 Plan d'essai de CEM

5.1 Généralités

Le Paragraphe 5.1 de l'IEC 61326-1:2020 s'applique.

5.2 Configuration de l'EST lors des essais

Le Paragraphe 5.2 de l'IEC 61326-1:2020 s'applique.

5.3 Conditions de fonctionnement de l'EST lors des essais

Le Paragraphe 5.3 de l'IEC 61326-1:2020 s'applique, avec l'exception suivante:

Addition:

5.3.101 Conditions de fonctionnement

Le dispositif doit être réglé aux conditions spécifiées dans la documentation de l'utilisateur conformément à l'utilisation prévue.

Pour chaque mode de fonctionnement, l'option d'alimentation (par exemple, batterie, alimentation en courant alternatif ou en courant continu) qui représente les conditions les plus sévères doit être spécifiée conformément à l'analyse de risque du produit.

5.4 Spécification des PERFORMANCES FONCTIONNELLES

Le Paragraphe 5.4 de l'IEC 61326-1:2020 s'applique.

5.5 Description de l'essai

Le Paragraphe 5.5 de l'IEC 61326-1:2020 s'applique.

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