SLOVENSKI STANDARD
SIST EN 61010-2-101:2023/A11:2023

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Varnostne zahteve za električno opremo za meritve, nadzor in laboratorijsko uporabo - 2-101. del: Posebne zahteve za diagnostično in vitro (IVD) medicinsko opremo - Dopolnilo A11

Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Safety requirements for in vitro diagnostic (IVD) medical equipment

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte - Teil 2 -101: Besondere Anforderungen an In-vitro-Diagnostik (IVD) Medizingeräte

Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 2-101 : Exigences particulières pour le matériel médical de diagnostic in vitro (DIV)

Ta slovenski standard je istoveten z: **EN IEC 61010-2-101:2022/A11:2022**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
19.080	Električno in elektronsko preskušanje	Electrical and electronic testing
71.040.10	Kemijski laboratoriji. Laboratorijska oprema	Chemical laboratories. Laboratory equipment

SIST EN 61010-2-101:2023/A11:2023 **en,fr,de**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 61010-2-101:2022/A11

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ICS 11.040.55; 19.080

English Version

Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Safety requirements for in vitro diagnostic (IVD) medical equipment

Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 2-101: Exigences particulières pour le matériel médical de diagnostic in vitro (DIV)

Sicherheitsbestimmungen für elektrische Mess-, Steuer-, Regel- und Laborgeräte - Teil 2-101: Besondere Anforderungen an In-vitro-Diagnostik (IVD) Medizingeräte

This amendment A11 modifies the European Standard EN IEC 61010-2-101:2022; it was approved by CENELEC on 2022-09-26. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

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Ref. No. EN IEC 61010-2-101:2022/A11:2022 E

European foreword

This document (EN IEC 61010-2-101:2022/A11:2022) has been prepared by CLC/TC 66X "Safety of measuring, control, and laboratory equipment".

The following dates are fixed:

• latest date by which this document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2023-09-26
• latest date by which the national standards conflicting with this document have to be withdrawn	(dow)	2025-09-26

This document amends EN IEC 61010-2-101:2022.

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

This document is read in conjunction with EN 61010-1:2010 + A1:2019 as modified by EN IEC 61010-2-101:2022 which results in the complete text of EN IEC 61010-2-101:2022. This A11 describes how that text is modified.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

1 Modifications to 1.1.1, "Equipment included in scope"

Replace the title as follows:

"**1.1.1 General**"

Replace the second paragraph with the following:

"This part of IEC 61010 provides particular safety requirements to equipment intended for in vitro diagnostic (IVD) medical purposes, including self-test IVD medical purposes. It is intended to be used in conjunction with the manufacturer's RISK management but not to replace it.

NOTE 1 A good design practice of an equipment starts from the beginning with a RISK management process according to ISO 14971, which provides requirement and guidance for a comprehensive RISK management process and identifies HAZARDS and risks related with the equipment."

Replace the note with the following:

"

NOTE 2 A system, as specified by its manufacturer, is a combination of items of equipment, at least one of these is inter-connected to another item. In the following text the term equipment is used for single equipment and systems.

It is possible that all or part of the equipment falls within the scope of one or more other Part 2 standards of IEC 61010 as well as within the scope of this document. In that case, the requirements of those other Part 2 standards will also apply."

2 Modifications to 1.1.2, "Equipment excluded from scope"

Replace the title as follows:

"**1.1.2 Exclusions from the scope**"

3 Modifications to 1.2.1, "Aspects included in scope"

Replace the first paragraph with the following:

"The purpose of the requirements of this document is to ensure that HAZARDS to the OPERATOR, the SERVICE PERSONNEL and the surrounding area are reduced to a tolerable level."

Add the following item to the list:

"cc) any other energy sources (see Clause 201)"

4 Modifications to 1.2.2, "Aspects excluded from scope"

Delete item b).

Replace item c) with the following:

"c) EMC requirements, except when related to safety (see the IEC 61326 series);"

5 Modifications to Clause 2, "Normative references"

Add the following references:

"

EN IEC 61326-2-6:2021, *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment*

EN 61326-3-1, *Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 3-1: Immunity requirements for safety-related systems and for equipment intended to perform safety-related functions (functional safety) - General industrial applications*

EN IEC 62061:2021, *Safety of machinery - Functional safety of safety-related control systems*

EN 62366-1, *Medical devices - Part 1: Application of usability engineering to medical devices*

EN ISO 13849-1:2015, *Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design (ISO 13849-1:2015)*

EN ISO 13850, *Safety of machinery - Emergency stop function - Principles for design (ISO 13850)*

"

6 Modifications to Clause 3.2, “Parts and accessories”

Add the following new term and definition.

"

3.2.201
CONTROL SYSTEM
all the parts of the equipment forming a system to provide, for example, operational control, monitoring, interlocking, communications, protection or safety-related control functions

NOTE 1 to entry: These parts include electrical, electronic and programmable electronic parts and devices as well as the mechanical parts.

NOTE 2 to entry: Safety-related control functions can be performed by a CONTROL SYSTEM that is either integral to or independent of those parts of a CONTROL SYSTEM that performs non-safety-related functions.

“

7 Modifications to Clause 3.5, “Safety terms”

Add the following new term and definition.

"

3.5.201
SERVICE PERSONNEL
person who is installing, changing or repairing the equipment, with the appropriate technical training, experience and awareness of HAZARDS and of measures to minimize danger to himself/herself, other persons or to the equipment.

"

8 Modifications to Table 1 in 5.1.3, “Mains supply”

Add the following item to Table 1:

201		ISO 7010 – W010 (modified)	Caution, RISK of frostbite

9 Modification to Clause 5.1, “Marking”

Add the following new subclause:

"**5.1.201 Limited lifetime**

If equipment has a limited lifetime, it shall be marked on the equipment. The information can be given in time, date, or cycles, whatever is appropriate for the equipment."

10 Modification to Clause 5.4.3 “Equipment transportation, installation and assembly instructions”

Add the following item and note to the list:

"zz) Minimum hardware, software, and other related requirements to operate the equipment as intended and to connect it to a network to ensure safe operation.

NOTE Guidance can be found in IEC 80001-1."

11 Modifications to Clause 7, "Protection against mechanical HAZARDS"

In 7.1 “General”:

Add the following items to the list:

“

aaa) being trapped inside the equipment (see 7.201).

bbb) slipping, tripping or falling (see 7.202).

ccc) hand transmitted vibrations (see 7.203)

”

Replace the conformity statement with the following text:

“Conformity is checked as specified in 7.2 to 7.7 and 7.201 to 7.203."

In 7.5.1 “General”*:*

Replace the first paragraph with the following text:

“Equipment or parts having a mass of 18 kg or more shall be provided with a means for lifting and carrying, instructions shall be given in the documentation to ensure safe transport, storage, installation, and disposal (also see 8.101).”

Add the following new subclauses

“

7.201 Prevention of being trapped in the equipment

If RISK assessment shows that the OPERATOR or professional SERVICE PERSONNEL can be exposed to a HAZARD of being trapped inside the equipment during NORMAL USE or during professional service, the design shall ensure that

— this situation is eliminated (inherent safety) or

— the trapped person is able to free herself/himself or

— the trapped person can set an alarm to get help from another person.

In addition, the instructions for use shall have a respective safety instruction.

Conformity is checked by inspection of the design and the instructions for use.

7.202 Prevention of slipping, tripping or falling

Surfaces belonging to the equipment on which OPERATOR or SERVICE PERSONNEL need to stand or step to carry out their duties shall be equipped with a non-slip surface compatible with normal work footwear. Where such surfaces are elevated by more than 0,3 m from the room floor or are narrower than 0,3 m (that is to say, they don’t allow the whole foot to rest flat on the surface without twisting) handholds or handrails shall be provided. Any steps built into the equipment shall provide for adequate engagement of the foot on the step. A minimum of 0,15 m is considered adequate. The safe use of the handholds or handrails shall be explained in the instructions for use.

Conformity is checked by inspection and by testing that each handhold and handrail withstand a force of 3200N.

Unless the mounting screws (if any) are secured against loosening, one screw is removed before performing these tests. The force is applied uniformly over a 70 ±5 mm width at the center of the handhold, without clamping. The force is steadily increased so that the test value is attained after 10 s and maintained for a period of 1 min.

After the tests the handhold shall not have broken loose from the equipment and there shall not be any permanent distortion, cracking or other evidence of failure which could cause an exposure to a HAZARD.

7.203 Hand-transmitted vibration

Except for vibrations directly required to carry out the NORMAL USE of the equipment, information shall be provided to protect the OPERATOR and other persons if in NORMAL USE the hand-transmitted frequency-weighted RMS acceleration generated by the equipment exceeds the values below:

— 2,5 m/s^2 for a cumulative time of 8 h during a 24 h period; and

— 5,0 m/s^2 for a cumulative time of 2 h during a 24 h period.

NOTE Interpolation or extrapolation is allowed for allowable acceleration in accordance with the following formula: 2,5 x √(8 h / t), in m/s^2, where t is the cumulative time over a 24 h period. (Example for 4 h instead of 8 h: = 2,5 m/s^2 x √(8 h / 4 h) = 3,54 m/s^2).

Conformity is checked by inspection and in case of doubt by measurements at points of equipment in hand contact with the OPERATOR or other persons. Measurements are made in accordance with ISO 5349-1.

"

12 Modifications to Clause 8, "Resistance to mechanical stresses"

Replace the title and the first two paragraphs of 8.101 with the following:

"8.101 Transport, storage and disposal

Equipment shall not cause a HAZARD when delivered in the manufacturer's packaging

1) to the persons involved in the transport, storage, during installation, and disposal of the equipment,

2) to the persons involved in NORMAL USE after transport or storage,

if the equipment is handled in accordance with the instructions specified in the instruction for use and markings on the equipment packaging (see 5.1.101 and 5.4.101).

Provisions for lifting and carrying shall be provided as defined in 7.5.

The above requirement is excluded from the scope if the manufacturer assumes responsibility for delivery, installation, and disposal."

13 Modifications to Clause 10, "Equipment temperature limits and resistance to heat"

Replace the title of Clause 10 as follows:

"10 Equipment temperature limits and resistance to heat and cold"

Replace the title of 10.1 as follows:

"10.1 Surface temperature limits for protection against burns and frostbite"

In 10.1, replace the conformity statement with the following text, table, and new conformity statement:

"

Cold touchable surfaces in NORMAL CONDITION shall not be below the values of Table 201.

Table 201 — Cold surface temperature limits in NORMAL CONDITION

Part	Limit °C
1 Touchable outer surface of enclosure (unintentional contact)	
a) metal, uncoated or anodized	-20
b) metal, coated (paint, non-metallic)	-30
c) plastics, plastic films, labels	-40
d) glass and ceramics	-30
2 Knobs (NORMAL USE contact for short periods up to 4s)	
a) metal	2
b) plastics	-40
c) glass and ceramics	-20
3 Handles (NORMAL USE contact for periods up to 120s)	5
NOTE ISO 13732-3 gives information about the effect of the duration of contact.	

Exception for temperatures lower than the values of Table 201 in NORMAL CONDITION and lower than -40°C in SINGLE FAULT CONDITION are permitted, provided that they are recognizable as such by appearance or function or are marked with symbol 201 (ISO 7010 – W010) of Table 1. Equipment cooled by its environment to temperature values lower than the values in Table 201 in NORMAL CONDITION and -40°C in SINGLE FAULT CONDITION need not to be marked with symbol 201 (ISO 7010 – 1818 W010).

Conformity is checked by measurements as specified in 10.4, and by inspection of barriers to check that they protect against accidentally touching surfaces that are at temperatures above the values of Table 19, or below the values of Table 201, and that they cannot be removed without a TOOL.

"

14 Modifications to Clause 12, "Protection against radiation, including laser sources, and against sonic and ultrasonic pressure"

In 12.1 "General":

Replace the first sentence with the following text:

"The equipment shall provide protection against the effects of internally generated ultraviolet, ionizing and microwave radiation, laser sources, sonic and ultrasonic pressure, and electromagnetic radiation.

NOTE Only safety aspects caused by the equipment are covered by this clause. General requirements for electromagnetic compatibility are excluded.

Conformity is checked as specified in 12.2 to 12.6 and 12.201 to 12.202."

In 12.5.1 "Sound level":

Replace the first two paragraphs and note 1 and note 2 with the following text:

"If the equipment can produce noise at a level which could cause harm to the OPERATOR, the manufacturer shall measure the maximum sound pressure level which the equipment can produce in NORMAL USE. The maximum sound pressure level does not apply to alarms and sound sources remote from the equipment.

If all levels are ≤ 70 dB(A) above a reference sound pressure of 20 µPa, this fact shall be stated in the documentation.

For equipment which produces a maximum sound pressure level >70 dB(A) above a reference sound pressure of 20 µPa the maximum sound pressure value shall be stated in the documentation and the following exposure threshold values limits shall not be exceeded.

L_{EX},8h = 80 dB(A) and L_{pC},peak = 135 dB(C) respectively

NOTE The daily noise exposure level (L_{EX},8h) is the time-weighted average of the noise exposure levels on the basis of an eight-hour shift. It comprises all noise events occurring at the workplace. Attention is drawn to the RESPONSIBLE BODY that installation of equipment in a workplace with additional noise sources can create an exposure to HAZARD. The peak sound pressure level (L_{pC},peak) is the maximum value of the instantaneous sound pressure level.

When applying the limit values, the attenuation provided by individual hearing protection worn by the OPERATOR shall not be considered.

Technical measures shall take precedence over organizational measures and shall have priority over the use of personal protective equipment."

Replace the first sentence of the conformity statement with the following text:

"*Conformity is checked by measuring the maximum A-weighted sound pressure level, and if required, the maximum C-weighted sound pressure level at the OPERATOR position and at bystander positions, but not further than 1 m from the equipment surfaces."*

Add the following new subclauses (to Clause 12):

"

12.201 Safety aspect of electromagnetic disturbances

The safety protection shall not be impaired by electromagnetic disturbances.

For equipment intended to be used in professional healthcare facility environment, the immunity requirements of Table 101 of EN IEC 61326-2-6:2021 shall be applied.

For equipment intended to be used in home healthcare environment, the immunity requirements of Tables 102 and 103 of EN IEC 61326-2-6:2021 shall be applied.

Conformity is checked by inspection and the test of Clause 6 of EN IEC 61326-2-6:2021 test documentation.

12.202 Safety aspect of electromagnetic emissions

Equipment that includes components which emits intentionally electromagnetic fields shall be safe for OPERATORS and SERVICE PERSONNEL. The emission requirements of EN IEC 61326-2-6:2021 shall be applied.

NOTE 1 Such components could be wireless communication devices like cell phone, WLAN, RFID, Bluetooth and the like.

NOTE 2 Wireless devices fall under the RE Directive 2014/53/EU and their harmonized standards.

Conformity is checked by inspection and the test of Clause 7 of EN IEC 61326-2-6:2021 test documentation."

15 Modifications to Clause 13, "Protection against liberated gases and substances, explosion and implosion"

Add the following new subclause:

"

13.201 Applications using explosive and poisonous gases, liquids and dusts

A RISK assessment shall be performed in case of inevitable use of explosive and / or poisonous gases, liquids, and dusts, named substances thereafter.

The safe design to prevent an exposure to HAZARD to OPERATOR and / or SERVICE PERSONNEL due to these substances shall be based on the following principles:

1. inherent safety by design to achieve under NORMAL CONDITION and SINGLE FAULT CONDITION; and