IEC 61010-2-101

Edition 3.0 2018-10
REDLINE VERSION

INTERNATIONAL STANDARD

colour inside

GROUP SAFETY PUBLICATION

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

IEC 61010-2-101:2018-10 RLV(en)

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INTERNATIONAL
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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

FOREWORD

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International Standard IEC 61010-2-101 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

It has the status of a group safety publication, as specified in IEC Guide 104.

This document has been prepared in close collaboration with Working Group CENELEC BTTF 88.1.

This third edition cancels and replaces the second edition published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) adaptation of changes introduced by Amendment 1 of IEC 61010-1;

b) added tolerance for stability of AC voltage test equipment to Clause 6.

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

CDV	Report on voting
66/644/CDV	66/669/RVC

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.

A list of all parts of the IEC 61010 series, under the general title: *Safety requirements for electrical equipment for measurement, control, and laboratory use*, may be found on the IEC website.

This Part 2-101 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010) and its Amendment 1 (2016).

This Part 2-101 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Particular requirements for in vitro diagnostic (IVD) medical equipment.*

Where a particular subclause of Part 1 is not mentioned in this Part 2, that subclause applies as far as is reasonable. Where this part states “addition”, “modification”, “replacement”, or “deletion” the relevant requirement, test specification or note in Part 1 should be adapted accordingly.

In this standard:

1) the following print types are used:
   - requirements: in roman type;
   - NOTES: in smaller roman type;
   - *conformity and test: in italic type;*
   - terms used throughout this standard which have been defined in clause 3: SMALL ROMAN CAPITALS;
2) subclauses, figures, tables and notes which are additional to those in part 1 are numbered starting from 101. Additional annexes are lettered starting from AA and additional list items are lettered from aa).

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- reconfirmed,
- withdrawn,
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SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL AND LABORATORY USE –

Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

1 Scope and object

This clause of Part 1 is applicable except as follows:

1.1.1 Equipment included in scope

Replacement:

Replace the text, except the first paragraph, with the following new text:

This part of IEC 61010 applies to equipment intended for in vitro diagnostic (IVD) medical purposes, including self-test IVD medical purposes.

IVD medical equipment, whether used alone or in combination, is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue samples, derived from the human body, solely or principally for the purpose of providing information concerning one or more of the following:

- a physiological or pathological state; or
- a congenital abnormality;
- the determination of safety and compatibility with potential recipients;
- the monitoring of therapeutic measures.

Self-test IVD medical equipment is intended by the manufacturer for use by lay persons in a home environment.

NOTE If all or part of the equipment falls within the scope of one or more other Part 2 standards of the IEC 61010 series as well as within the scope of this document, consideration~~s have to be~~ is given to those other Part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following new item:

aa) equipment within the scope of IEC 61010-2-081 unless ~~they are~~ it is specifically intended by the~~ir~~ manufacturer to be used for in vitro diagnostic examination.

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following two new items:

aa) biohazards;

bb) hazardous chemical substances.

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1.2.2 Aspects excluded from scope

Addition:

Add the following new item and note:

aa) the handling or manipulation outside the equipment of material under analysis.

NOTE Requirements covering these subjects are the responsibility of committees preparing the relevant standards.

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new references to the list:

ISO 14971, *Medical devices – Application of risk management to medical devices*

ISO 18113-5, *In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 5: In vitro diagnostic instruments for self-testing*

~~ISO 13857, *Safety of machinery – Safety distances to prevent hazard zones being reached by upper and lower limbs*~~

3 Terms and definitions

This clause of Part 1 is applicable except as follows:

3.1 Equipment and states of equipment

Addition:

Add the following new terms~~ and definitions~~:

3.1.101
SAMPLE ZONE
area where OPERATOR access is typically unintended

Note 1 to entry: The inside of this zone presents mechanical HAZARDS and a more likely probability of biohazardous human skin puncture.

3.1.102
LOADING ZONE
area of automated equipment where an OPERATOR handles sample or reagent material

3.5.12 RESPONSIBLE BODY

Addition:

Add the following new note:

Note 1 to entry: This is not the European~~ Community~~ Union's responsible authority.

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4 Tests

This clause of Part 1 is applicable.

5 Marking and documentation

This clause of Part 1 is applicable except as follows:

5.1.1 General

Replacement:

Replace the third paragraph with the following new text:

Letter symbols for quantities and units shall be in accordance with IEC 60027 (all parts). Internationally recognized symbols, including those of Table 1, shall be used as far as possible. If other additional symbols are required, it shall not be possible to confuse them with the internationally recognized symbols. There are no colour requirements for symbols. Graphic symbols shall be explained in the documentation.

5.1.2 Identification

Replacement:

Replace the text with the following new text:

Equipment shall, as a minimum, be marked with the following information:

a) manufacturer's name or trade mark, and the address. The address shall include at least the city and country;

NOTE 1 National regulation may require more details on the address than required in a).

b) model number, name, or other means of identifying the equipment.

The following additional information shall be marked on the equipment or packaging or in the instructions for use:

1) the serial number, for example SN XXXX or alternatively the batch code, preceded by 'LOT', using symbol 102 of Table 1;
2) the following information:
   i) a clear indication that the equipment is IVD medical equipment;
   ii) if applicable, a clear indication that the equipment is self-test IVD medical equipment;
   iii) if a potential RISK is posed, the identification of detachable components by the manufacturer and the part identification, and where appropriate the batch code, etc.;
3) instructions for use ~~shall require~~ requiring that the OPERATOR only use consumables that are within their expiration date. Where this is required by regulation, the name and address of the authorized representative of the manufacturer.

NOTE 2 For example, in the European Union this is the natural or legal person as established within the European Community.

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Table 1 – Symbols

Addition:

Add the following new symbols to Table 1:

Number	Symbol	Publication	Description
101	Background colour – optional; Symbol colour – optional; Outline / outline colour – optional;	ISO 7000- 0659 (2004-01)	Biological RISKS
102		ISO 7000- 2492 (2004-01)	Batch code

5.1.5 TERMINALS, connections and operating devices

Addition:

Add the following new subclause:

5.1.5.101 Gas and liquid connections

If necessary for safety, the equipment shall be clearly marked near ~~to~~ the connector on the equipment with:

a) a means of identifying the gas or liquid to be used. Where no internationally recognized symbol (including chemical formulae) exists, the equipment shall be marked with symbol 14 of Table 1;

b) the maximum permitted pressure, or alternatively symbol 14 of Table 1 (see 5.4.3).

Conformity is checked by inspection.

Addition:

Add the following new subclause:

5.1.101 Transport and storage

Packaging of equipment shall be labelled to indicate any special conditions for transport or storage (see 5.4.102).

Conformity is checked by inspection.

~~**5.2 Warning markings**~~

~~*Replacement:*~~

~~*Replace the first paragraph by the following:*~~

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~~Warning Markings specified in 5.1.5.1, 5.1.5.2 c), 5.1.5.2 d), 5.1.5.101, 6.1.2 b), 7.3.2 b) 3), 7.4, 10.1, 13.2.2 and 13.101 shall meet the following requirements:~~

5.3 Durability of markings

Replacement:

Replace the first paragraph with the following new text:

Markings required by 5.1.2 to 5.2 shall remain clear and legible under conditions of NORMAL USE, and resist the effects of temperature and rubbing, and of solvent and reagents likely to be encountered in NORMAL USE, including cleaning and decontaminating agents specified by the manufacturer.

Addition:

Add, after the second paragraph, the following new text:

If a solvent or reagent specified for use with the equipment could affect the durability of a particular marking, that marking is also rubbed for 30 s with the most frequently used and/or aggressive solvent or reagent to which the equipment is likely to be exposed in NORMAL USE.

A representative sample of groups of solvents or reagents likely to have a similar effect can optionally be used.

5.4.1 General

Deletion:

Delete Note 2 ~~in the second paragraph~~.

5.4.3 Equipment installation

Replacement:

Replace the title and text with the following new title and text:

5.4.3 Equipment transportation, installation and assembly instructions

Documentation for the RESPONSIBLE BODY shall include the following, if applicable:

a) instructions for transportation after delivery to the RESPONSIBLE BODY;

b) floor loading requirements;

NOTE Mass and dimensions are sufficient information for floor loading.

c) individual mass of heavy units;

d) location and mounting instructions, including the space required for ventilation, and for safe and efficient OPERATOR maintenance;

e) assembly instructions;

f) instructions for protective earthing;

g) the sound data required by 12.5.1;

h) instructions relating to the handling, containment and exhaust of hazardous substances, including any requirements for preventing back-syphonage;

i) any drainage systems required where a HAZARD could occur from the discharge of biological and chemical substances and hot fluids;

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j) details of protective measures relating to hazardous radiation (see Clause 12);

k) connections to the supply;

l) for PERMANENTLY CONNECTED EQUIPMENT only:

1) MAINS supply requirements and details of connections, including the RATED temperature of the cable required at maximum RATED ambient temperature;

2) requirements for any external switch or circuit-breaker (see 6.11.~~2~~3.1) and external overcurrent protection devices (see 9.6.1) and a recommendation that the switch or circuit-breaker be near the equipment if this is necessary for safety;

m) requirements ~~for special services (for example air, cooling liquid) including pressure limits~~ and safety characteristics for special external services, for example: maximum and minimum temperature, pressure, or flow of air or cooling liquid.

Conformity is checked by inspection of the documentation.

5.4.4 Equipment operation

Replacement:

Replace the first paragraph with the following new text:

Instructions for use shall include, if applicable:

a) details of operating controls and their use in all operating modes, with any sequence of operation;

NOTE 1 IEC 60073 gives guidance on colours and symbols of operating controls.

b) an instruction not to position the equipment in such a way that it is difficult to operate the disconnecting device (see 6.11);

c) instructions for interconnections to accessories and other equipment, including details of suitable accessories, detachable parts and any special consumable materials;

d) limits for intermittent operation;

e) an explanation of symbols used on the equipment and, where HAZARDS are involved, the reason for using a symbol in each particular case;

f) instructions for any actions to be taken by an OPERATOR to deal with a HAZARD resulting from equipment spills, lock-ups, container breakage and similar malfunctions;

g) instructions and recommendations for cleaning and decontamination, with materials recommended (see 11.2);

h) instructions for the disposal of hazardous waste;

i) if NORMAL USE involves the handling of hazardous chemical substances, instructions on correct use and any need for training or personal protection measures;

j) appropriate instruction to use personal protective equipment (e.g. gloves, gowns) where there could be contact with the skin when handling potentially infectious substances or surfaces (such as human samples or reagents);

k) appropriate instructions and requirements for protection of the mouth, nose or eyes shall be given where the equipment could emit hazardous aerosol vapours in NORMAL USE;

l) appropriate instructions and requirements for protective devices, such as protective glasses shall be given where potentially hazardous visible or invisible radiation could be emitted;

m) detailed instructions about RISK reduction procedures relating to flammable liquids (see 9.5 c));

n) details of methods of reducing the RISKS of burns from surfaces permitted to exceed the temperature limits of 10.1;

o) appropriate warnings to reduce RISK during loading and unloading of samples and reagents (see 7.3.~~102~~101);

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p) instructions for the RESPONSIBLE BODY to ensure that all retaining hardware (e.g. screws, fasteners) are in place on removable PROTECTIVE BARRIERS, and the removable PROTECTIVE BARRIERS are in place on the instrument during normal operation;

q) a statement that, if a TOOL is required to remove a fixed PROTECTIVE BARRIER and/or ENCLOSURE guarding a SAMPLE ZONE, access to that tool should be controlled by the RESPONSIBLE BODY;

r) a statement listing the tools to be controlled by the RESPONSIBLE BODY.

NOTE 2 Information on decontaminants, their use, dilution and potential application is contained in the *Laboratory Biosafety Manual,* published by the World Health Organization and the *Biosafety in Microbiological and Biomedical Laboratories*, published by Centers for Disease Control and Prevention and National Institutes of Health, Washington. There are also national guidelines that cover these areas.

NOTE 3 Cleaning and decontamination ~~may~~ can be necessary as a safeguard when equipment and ~~their~~ its accessories are maintained, repaired or transferred. Preferably manufacturers provide a format for the RESPONSIBLE BODY to certify to those maintaining, repairing or transferring equipment that such a treatment has been carried out.

Conformity is checked by inspection of the documentation.

Addition:

Add the following new subclauses:

5.4.4.101 Instructions for use of self-test IVD medical equipment

Instructions for use of self-test IVD medical equipment shall comply with ISO 18113-5.

5.4.101 Removal of equipment from use for repair or disposal

Instructions shall be provided for the RESPONSIBLE BODY for eliminating or reducing HAZARDS involved in removal from use, transportation or disposal, or appropriate contact information shall be provided in the documentation.

NOTE Regional or international requirements can apply.

Conformity is checked by inspection of the documentation.

5.4.102 Transport and storage

The manufacturer shall specify the conditions for transport and storage of the equipment. The documentation shall contain a specification of the permissible environmental conditions for transport and storage. Essential information shall be repeated on the outside of the package using appropriate symbols (see 5.1.101).

When the manufacturer assumes responsibility for delivery and installation the above is not required in the documentation.

Compliance is checked by inspection.

6 Protection against electric shock

This clause of part 1 is applicable except as follows:

6.8.3.1 The AC voltage test

Replacement:

Replace the first sentence with the following new sentence:

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The voltage tester shall be capable of maintaining the test voltage throughout the test within ± 5 % of the specified value.

7 Protection against mechanical HAZARDS

This clause of part 1 is applicable, except as follows:

7.3.1 General

Replacement:

Replace the second sentence with the following new sentence:

The conditions specified in 7.3.4, 7.3.5, and 7.3.101 are considered to represent a tolerable level.

Replace the conformity statement with the following new conformity statement:

Conformity is checked as specified in 7.3.2, 7.3.3, 7.3.4, 7.3.5, 7.3.101, and Clause 17 as applicable.

7.3.2 Exceptions

Replacement:

Replace the text of item b) 3) text with the following new text:

there are warning markings prohibiting access by untrained OPERATORS. Markings shall be placed within the area requiring maintenance where they can alert the OPERATOR to the HAZARD. As an alternative, symbol 14 of Table 1 can be used, with the warnings included in the documentation;

Addition:

Add the following new item to the list:

b) 4) there are OPERATOR maintenance instructions that specify safe maintenance procedures.

7.3.3 RISK assessment for mechanical HAZARDS to body parts

Replacement:

Replace text with the following new text:

If equipment is specified by the manufacturer for continuous loading of sample and reagent materials, and associated HAZARDS in the SAMPLE ZONE are solely caused by the sample and/or reagent probes, 7.3.101 applies specifically for the SAMPLE ZONE. Subclause 7.3.101 does not apply to self-testing and point of care equipment.

RISKS shall be reduced to a tolerable level by at least the applicable minimum protective measure of Table 12, taking into account the severity, probability of exposure and possibility of avoiding the HAZARD.

Conformity is checked by evaluation of the RISK assessment documentation to ensure that the RISKS have been eliminated or that only TOLERABLE RISKS remain.

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~~**Table 12 – Protective measures against mechanical HAZARDS to body parts**~~

~~*Replacement:*~~

~~*Replace the text of item B by the following text:*~~

~~Moderate measures; emergency switches, PROTECTIVE BARRIERS or covers removable only with a TOOL, distances (see ISO 13857), or separations (see ISO 13854 or EN 349).~~

Addition:

Add the following new subclause:

7.3.101 SAMPLE ZONE

Equipment with a SAMPLE ZONE shall comply with the requirements of one or more of the following:

a~~a~~) PROTECTIVE BARRIER; or

b~~b~~) all of the following measures, which apply:

1) the minimum maintained gap between LOADING ZONE and SAMPLE ZONE is 120 mm;
2) unintentional contact between OPERATOR and sample/reagent pipettor is unlikely;
3) the area between LOADING ZONE and SAMPLE ZONE is marked with symbol 14 and symbol 101 of Table 1 (see 5.4.4 o)), or if not visible by the OPERATOR the marking shall be located in a visible manner and close to the area.

8 Resistance to mechanical stresses

This clause of part 1 is applicable except as follows:

8.1 General

Replacement:

Replace the text of item 3) with the following new text:

1) except for FIXED EQUIPMENT, for equipment with a mass over 100 kg, or for equipment whose size and weight make unintentional movement unlikely and which is not moved in NORMAL USE, the appropriate test of 8.3. The equipment is not operated during the tests.

Addition:

Add the following new subclause:

8.101 Transport and storage

When delivered in the manufacturer's packaging, equipment shall not cause a HAZARD during NORMAL USE after transport or storage in the conditions specified by the manufacturer (see 5.1.101 and 5.4.101).

If the manufacturer assumes responsibility for delivery and installation, the above requirement is met without inspection of test records.

Conformity is checked by inspection of records of transport tests performed by the manufacturer.

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NOTE Guidance on tests is given in ASTM D4169, and in the publications of the International Safe Transport Association (ISTA).

9 Protection against the spread of fire

This clause of Part 1 is applicable.

10 Equipment temperature limits and resistance to heat

This clause of Part 1 is applicable.

11 Protection against HAZARDS from fluids and solid foreign objects

This clause of Part 1 is applicable.

12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure

This clause of Part 1 is applicable.

13 Protection against liberated gases and substances, explosion and implosion

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new subclause:

13.101 Biohazardous substances

Equipment that can be potentially infectious due to the samples or reagents used shall be prominently marked with symbol 101 of Table 1. At minimum, a biohazard symbol shall be near the sampling area and visible in NORMAL USE.

Biohazard symbols shall be near biohazardous areas accessed during OPERATOR maintenance and visible only during this maintenance.

Symbol 101 of Table 1 shall be marked on containers or bags for biohazardous waste material which can be removed from the equipment during NORMAL USE, and near any biohazardous drain connection.

Equipment that can be hazardous due to the use of hazardous substances shall be marked with the appropriate international symbol, or (if none is available) symbol 14 of Table 1.

14 Components and subassemblies

This clause of Part 1 is applicable except as follows:

14.3 Over-temperature protection devices

Addition:

Add the following new paragraph after the second paragraph:

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