IEC 61010-2-101

Edition 3.0 2018-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE DE SÉCURITÉ

Safety requirements for electrical equipment for measurement, control and laboratory use –
Part 2-101: Particular 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)

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INTERNATIONAL
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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

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).

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.

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 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 it is specifically intended by the 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.

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*

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:

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 Union's responsible authority.

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 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.

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 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.

5.3 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.

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;

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 6.11.3.1) 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 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 7.3.101);

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*