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Edition 2.0 2015-01
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 61010-2-101:2015-01 RLV(en)

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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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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

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

International Standard IEC 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 standard has been prepared in close collaboration with Working Group CENELEC BTTF 88.1.

This second edition cancels and replaces the first edition published in 2002. It constitutes a technical revision and includes the following significant changes from the first edition, as well as numerous other changes:

- excluded IEC 61010-2-081 (general laboratory equipment) from the scope. This separates IEC 61010-2-081 and IEC 61010-2-101 equipment;
- updated Biohazard and Lot symbols in Table 1 in Clause 5;
- added requirement for within expiration consumables and authorized representative details in Instructions for Use to Clause 5;
- added requirement for gas or liquid markings and ratings to Clause 5;
- added requirement to include OPERATOR instructions to deal with consumable or sample spills, jams or breakage inside equipment, disposal of hazardous waste, personal protection, RISK reduction procedures relating to flammable liquids, burns from surfaces, and loading and unloading of sample and reagents in Instructions for Use to Clause 5;
- added requirement for manufacturer to provide instructions on equipment transport, storage and removal from use to Clause 5;
- added normative reference ISO 18113-5 for instructions for use of self-test IVD medical equipment in Clause 5;
- added requirement for OPERATOR maintenance instructions to Clause 7;
- added requirements for sample zones and loading zones to Clause 7;
- excluded equipment whose size and weight make unintentional movement unlikely from drop test in Clause 8;
- added requirement for biohazard marking to Clause 13;
- added requirement for interlock systems containing electric/electronic or programmable components to Clause 15;
- added informative reference to Usability standard IEC 62366 to Clause 16;
- replaced Clause 17 with requirements of ISO 14971 for RISK assessment.
- Annex BB Instructions for use for self-testing IVD Medical Equipment deleted and a reference given to ISO 18113-5 in Clause 5.

The text of this standard is based on the following documents:

FDIS	Report on voting
66/545/FDIS	66/560/RVD

Full information on the voting for the approval of this standard can be found in the report on voting indicated in the above table.

This publication 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).

This Part 2-101 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Safety 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.

The committee has decided that the contents of this publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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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 by the following:

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 IEC 61010 as well as within the scope of this standard, ~~it will also need to meet the requirements of~~ considerations have to be given to those other part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following item:

aa) ~~Products for general laboratory use are not IVD medical devices unless such products, in view of their characteristics,~~ Equipment in the scope of IEC 61010-2-081 unless they are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

1.2 Object

1.2.1 Aspects included in scope

~~*Replacement:*~~

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

~~The purpose of the requirements of this standard is to ensure that the design and the methods of construction used provide a high degree of protection at a TOLERABLE RISK for the OPERATOR and the surrounding area, using RISK management where appropriate (see annex AA).~~

Addition:

Add two items:

~~h~~ aa) biohazards;

~~i~~ bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following item and note:

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

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

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following references:

ISO 14971~~:2000~~, *Medical devices – Application of risk management to medical devices*

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

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 terms and definitions:

~~**3.101**~~
~~**HARM**~~
~~physical injury or damage to the health of people, or damage to property or the environment~~

~~[ISO/IEC Guide 51:1999, definition 3.3]~~

~~**3.102**~~
~~**RISK**~~
~~combination of the probability of occurrence of HARM and the severity of that HARM~~

~~[ISO/IEC Guide 51:1999, definition 3.2]~~

~~**3.103**~~
~~**TOLERABLE RISK**~~
~~RISK which is accepted in a given context based on the current values of society~~

~~[ISO/IEC Guide 51:1999, definition 3.7]~~

~~NOTE 1 TOLERABLE RISK is the result of a balance between the ideal of absolute safety, the demands to be met by a product, process or service, and factors such as benefit to the user, suitability of purpose, cost effectiveness, RISK evaluation, conventions of the society concerned, and the state of the art.~~

~~NOTE 2 The term "acceptable risk" is used in ISO 14971 in the same sense as TOLERABLE RISK.~~

~~**3.104**~~
~~**REASONABLY FORESEEABLE MISUSE**~~
~~use of a product, process or service in a way not intended by the supplier, but which may result from readily predictable human behaviour~~

~~[ISO/IEC Guide 51:1999, definition 3.14]~~

~~**3.105**~~
~~**PERMANENTLY AFFIXED**~~
~~removable only with a TOOL or by appreciable force and able to withstand the effects of temperature, rubbing, common solvents, reagents and vapours encountered during normal use~~

~~**3.106**~~
~~**MARKING**~~
~~inscription, in writing or as a graphical symbol, PERMANENTLY AFFIXED to a product~~

3.1.101
SAMPLE ZONE
area where OPERATOR access is typically unintended; 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 note:

NOTE 1 This is not the European Community responsible authority.

4 Tests

This clause of Part 1 is applicable ~~except as follows~~.

~~**4.4.1 General**~~

~~*Replacement:*~~

~~*Replace item a) of the first paragraph by:*~~

~~a) Equipment and circuit diagrams shall be examined to determine the fault conditions which could arise in NORMAL USE and REASONABLY FORESEEABLE MISUSE, and which could cause a HAZARD.~~

~~*Deletion:*~~

~~*Delete the first dash.*~~

~~*Addition:*~~

~~*Additional subclause:*~~

~~**4.4.2.101 Incorrect voltage selection**~~

~~Multivoltage equipment that can be set by the OPERATOR to different supply voltages shall be set to each voltage in turn and then connected to all other RATED supply voltages in turn.~~

5 Marking and documentation

This clause of Part 1 is applicable except as follows:

5.1.1 General

Replacement:

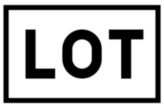
Replace the third paragraph by the following:

Letter symbols for quantities and units shall be in accordance with IEC 60027. 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~~, except for symbol 101 (see table 1)~~. Graphic symbols shall be explained in the documentation.

Table 1 – Symbols

Addition:

Add the following symbols to Table 1:

Number	Symbol	Publication	Description
101	 Background colour – ~~yellow~~ optional; Symbol colour – optional; Outline / outline colour – ~~black~~ optional;	ISO 7000- 0659 (2004-01)	~~Biohazard~~ Biological RISKS
102		~~EN 980, subclause 4~~ ISO 7000- 2492 (2004-01)	Batch code

5.1.2 Identification

Replacement:

Replace the text by the following:

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;

~~c) where this is required by regulation, the name and address of the authorized representative of the manufacturer;~~

~~NOTE For example, in the EU this is the natural or legal person as established within the EC.~~

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 manufacturer and part identification, and where appropriate the batch code, etc.
   ~~iv) any expiry date of consumable parts, expressed as the year, the month and (where relevant) the day, in that order.~~
3) instructions for use shall require 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.

5.1.5 TERMINALS, connections and operating devices

Addition:

Add the following 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 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 ~~fifth~~ first paragraph by the following ~~four paragraphs~~:

~~Equipment that can be potentially infectious due to the samples or reagents used shall be prominently marked with symbol 101 of Table 1.~~

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

~~Containers or bags for biohazardous waste material which can be removed from the equipment during NORMAL USE shall be marked with symbol 101 of Table 1.'~~

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)~~, 6.5.1.2 g), 6.6.2, 7.2 c)~~, 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 by the following paragraph:

Markings required by 5.1.2 to 5.2 ~~shall be PERMANENTLY AFFIXED and~~ 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 ~~first~~ second paragraph the following paragraph:

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 ~~each~~ the most frequently used and/or aggressive solvent or reagent to which the equipment is likely to be exposed in* NORMAL USE

~~(or with~~ A representative sample of groups of solvents or reagents likely to have a similar effect can optional be used~~)~~.

5.4.1 General

Deletion:

Delete the note 2 in the second paragraph.

~~Addition:~~

~~Add a new third paragraph as follows:~~

~~Information shall be given about any RISKS not reduced to a TOLERABLE RISK level by the protective measures specified in this standard. If there is a need for training or for the use of additional protective devices or personal protective equipment to reduce RISKS to a TOLERABLE RISK level, these shall be specified.~~

5.4.3 Equipment installation

Replacement:

Replace subclause 5.4.3 by the following:

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 ~~weights~~ mass of ~~principal~~ heavy ~~subassemblies~~ 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;