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
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

FOREWORD

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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 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.

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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, considerations ~~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.

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.

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.

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:*~~

~~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;

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);

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:

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.

~~**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.

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:

Over-temperature protection devices in self-test IVD medical equipment shall not be self-resetting.

15 Protection by interlocks

This clause of Part 1 is applicable except as follows:

15.1 General

Addition:

Add the following new text after the first sentence:

As an alternative method, for interlock systems containing electric/electronic or programmable components (E/E/P components) the reliability and design requirements can be determined by applying for example IEC 62061 (SIL) or ISO 13849 (all parts) (PL) or other solutions providing equivalent functional safety.

16 HAZARDS resulting from application

This clause of Part 1 is applicable except as follows:

16.2 Ergonomic aspects

Replacement:

Replace the note with the following new note:

NOTE RISK assessment procedures for ergonomics can be found in IEC 62366-1, IEC TR 62366-2, EN 894-2, EN 894-3, ISO 9241, SEMI S8 and other documents. Not all of the requirements in these documents will be applicable to equipment within the scope of this document.

17 RISK assessment

This clause of Part 1 is ~~replaced~~ applicable except as follows:

Replacement:

Replace the text with the following new text:

RISK assessment shall be carried out and documented using the requirements of ISO 14971 for HAZARDS not addressed in this document and Part 1.

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

Annexes

The annexes of Part 1 are applicable except as follows:

Annex L
(informative)

Index of defined terms

Addition:

Add the following new defined terms to the list:

Bibliography

The Bibliography of Part 1 is applicable, except as follows:

Deletion:

Delete the following reference:

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

Addition:

Add the following new references:

IEC 62061, *Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems*

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

IEC TR 62366-2, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*

ISO 13849 (all parts), *Safety of machinery – Safety-related parts of control systems*

ISO 15223-1, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

ASTM D4169, *Standard practice for performance testing for shipping containers*

Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, Washington

EN 980:2008, *Graphical symbols for use in the labelling of medical devices*

World Health Organization, *Laboratory Biosafety Manual*

Publications of the International Safe Transport Association (ISTA)

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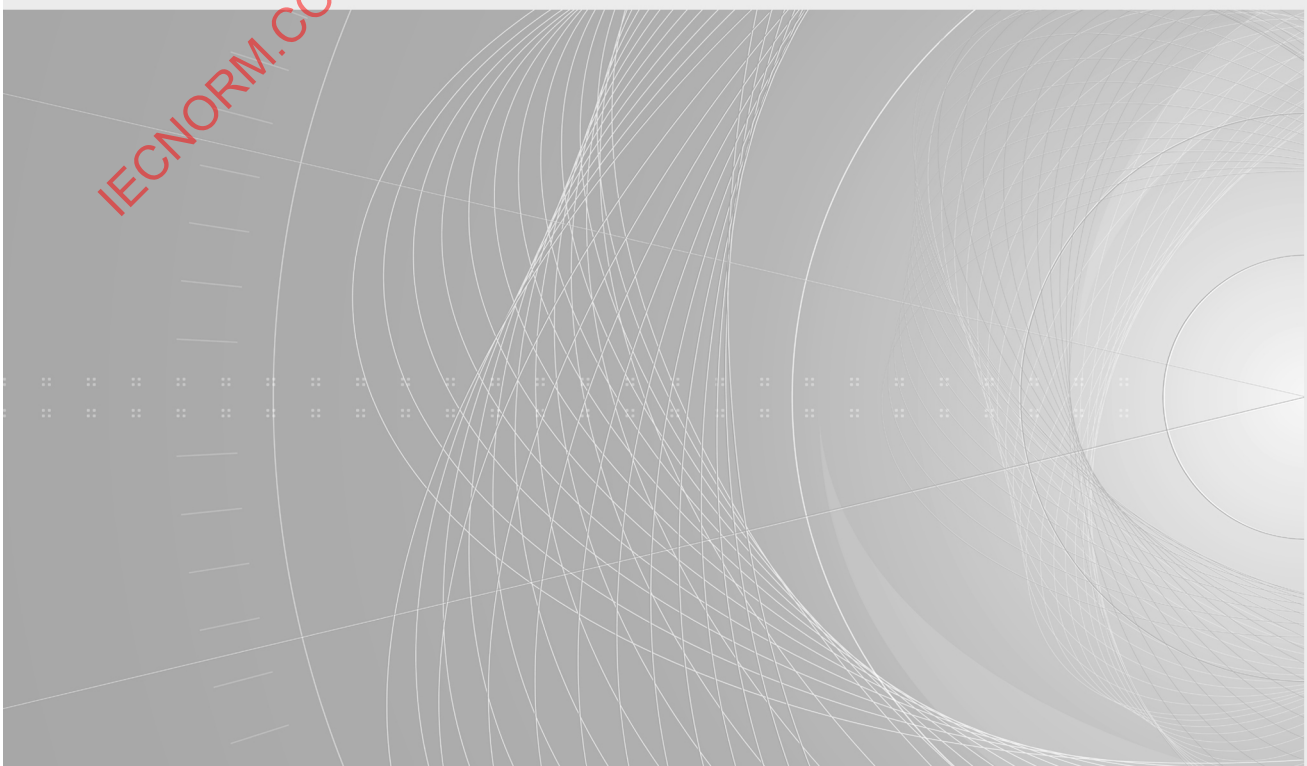
NORME INTERNATIONALE

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 ELECTROTECHNICAL COMMISSION

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

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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.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
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5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
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8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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*

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 can be necessary as a safeguard when equipment and 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:

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.

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) PROTECTIVE BARRIER; or

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:

3) 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.

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:

Over-temperature protection devices in self-test IVD medical equipment shall not be self-resetting.

15 Protection by interlocks

This clause of Part 1 is applicable except as follows:

15.1 General

Addition:

Add the following new text after the first sentence:

As an alternative method, for interlock systems containing electric/electronic or programmable components (E/E/P components) the reliability and design requirements can be determined by

applying for example IEC 62061 (SIL) or ISO 13849 (all parts) (PL) or other solutions providing equivalent functional safety.

16 HAZARDS resulting from application

This clause of Part 1 is applicable except as follows:

16.2 Ergonomic aspects

Replacement:

Replace the note with the following new note:

NOTE RISK assessment procedures for ergonomics can be found in IEC 62366-1, IEC TR 62366-2, EN 894-2, EN 894-3, ISO 9241, SEMI S8 and other documents. Not all of the requirements in these documents will be applicable to equipment within the scope of this document.

17 RISK assessment

This clause of Part 1 is applicable except as follows:

Replacement:

Replace the text with the following new text:

RISK assessment shall be carried out and documented using the requirements of ISO 14971 for HAZARDS not addressed in this document and Part 1.

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

Annexes

The annexes of Part 1 are applicable except as follows:

Annex L
(informative)

Index of defined terms

Addition:

Add the following new defined terms to the list:

Bibliography

The Bibliography of Part 1 is applicable, except as follows:

Deletion:

Delete the following reference:

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

Addition:

Add the following new references:

IEC 62061, *Safety of machinery – Functional safety of safety-related electrical, electronic and programmable electronic control systems*

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

IEC TR 62366-2, *Medical devices – Part 2: Guidance on the application of usability engineering to medical devices*

ISO 13849 (all parts), *Safety of machinery – Safety-related parts of control systems*

ISO 15223-1, *Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*

ASTM D4169, *Standard practice for performance testing for shipping containers*

Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, Washington

EN 980:2008, *Graphical symbols for use in the labelling of medical devices*

World Health Organization, *Laboratory Biosafety Manual*

Publications of the International Safe Transport Association (ISTA)

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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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)

AVANT-PROPOS

1) La Commission Electrotechnique Internationale (IEC) est une organisation mondiale de normalisation composée de l'ensemble des comités électrotechniques nationaux (Comités nationaux de l'IEC). L'IEC a pour objet de favoriser la coopération internationale pour toutes les questions de normalisation dans les domaines de l'électricité et de l'électronique. A cet effet, l'IEC – entre autres activités – publie des Normes internationales, des Spécifications techniques, des Rapports techniques, des Spécifications accessibles au public (PAS) et des Guides (ci-après dénommés "Publication(s) de l'IEC"). Leur élaboration est confiée à des comités d'études, aux travaux desquels tout Comité national intéressé par le sujet traité peut participer. Les organisations internationales, gouvernementales et non gouvernementales, en liaison avec l'IEC, participent également aux travaux. L'IEC collabore étroitement avec l'Organisation Internationale de Normalisation (ISO), selon des conditions fixées par accord entre les deux organisations.
2) Les décisions ou accords officiels de l'IEC concernant les questions techniques représentent, dans la mesure du possible, un accord international sur les sujets étudiés, étant donné que les Comités nationaux de l'IEC intéressés sont représentés dans chaque comité d'études.
3) Les Publications de l'IEC se présentent sous la forme de recommandations internationales et sont agréées comme telles par les Comités nationaux de l'IEC. Tous les efforts raisonnables sont entrepris afin que l'IEC s'assure de l'exactitude du contenu technique de ses publications; l'IEC ne peut pas être tenue responsable de l'éventuelle mauvaise utilisation ou interprétation qui en est faite par un quelconque utilisateur final.
4) Dans le but d'encourager l'uniformité internationale, les Comités nationaux de l'IEC s'engagent, dans toute la mesure possible, à appliquer de façon transparente les Publications de l'IEC dans leurs publications nationales et régionales. Toutes divergences entre toutes Publications de l'IEC et toutes publications nationales ou régionales correspondantes doivent être indiquées en termes clairs dans ces dernières.
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6) Tous les utilisateurs doivent s'assurer qu'ils sont en possession de la dernière édition de cette publication.
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8) L'attention est attirée sur les références normatives citées dans cette publication. L'utilisation de publications référencées est obligatoire pour une application correcte de la présente publication.
9) L'attention est attirée sur le fait que certains des éléments de la présente Publication de l'IEC peuvent faire l'objet de droits de brevet. L'IEC ne saurait être tenue pour responsable de ne pas avoir identifié de tels droits de brevets et de ne pas avoir signalé leur existence.

La Norme internationale IEC 61010-2-101 a été établie par le comité d'études 66 de l'IEC: Sécurité des appareils de mesure, de commande et de laboratoire.

Elle a le statut d'une publication groupée de sécurité conformément au Guide IEC 104.

Ce document a été élaboré en étroite collaboration avec le groupe de travail CENELEC BTTF 88.1.

Cette troisième édition annule et remplace la deuxième édition parue en 2015. Cette édition constitue une révision technique.

Cette édition inclut les modifications techniques majeures suivantes par rapport à l'édition précédente:

a) adaptation des modifications introduites par l'Amendement 1 de l'IEC 61010-1;
b) ajout à l'Article 6 de la tolérance pour la stabilité du matériel d'essai en tension alternative.

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

CDV	Rapport de vote
66/644/CDV	66/669/RVC

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.

Une liste de toutes les parties de la série IEC 61010, sous le titre général: *Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire*, peut être consultée sur le site web de l'IEC.

Cette Partie 2-101 est destinée à être utilisée conjointement avec l'IEC 61010-1. Elle a été établie sur la base de la troisième édition (2010) et de son Amendement 1 (2016).

La présente Partie 2-101 complète ou modifie les articles correspondants de l'IEC 61010-1 de façon à transformer cette publication en norme IEC: *Exigences particulières pour le matériel médical de diagnostic in vitro (DIV).*

Lorsqu'un paragraphe particulier de la Partie 1 n'est pas mentionné dans la présente Partie 2, ce paragraphe s'applique pour autant que cela soit raisonnable. Lorsque cette partie indique «addition», «modification», «remplacement» ou «suppression», il convient en conséquence d'adapter l'exigence, la modalité d'essai ou la note correspondante de la Partie 1.

Dans la présente norme:

1) les caractères d'imprimerie suivants sont utilisés:
   – exigences: caractères romains;
   – NOTES: petits caractères romains;
   – *conformité et essais: caractères italiques;*
   – termes définis à l'Article 3 et utilisés dans toute cette norme: PETITES CAPITALES EN CARACTÈRES ROMAINS;
2) les paragraphes, figures, tableaux et notes qui viennent en supplément de ceux de la Partie 1 sont numérotés à partir de 101. Les annexes complémentaires sont désignées à partir de AA et les listes de termes additionnels à partir de aa).

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

- reconduit,
- supprimé,
- remplacé par une édition révisée, ou
- amendé.

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)

1 Domaine d'application et objet

L'article de la Partie 1 est applicable à l'exception de ce qui suit:

1.1.1 Appareils inclus dans le domaine d'application

Remplacement:

Remplacer le texte, excepté le premier alinéa, par le nouveau texte suivant:

La présente partie de l'IEC 61010 s'applique aux appareils destinés aux applications médicales de diagnostic in vitro (DIV), y compris aux appareils médicaux d'autotest DIV.

Le matériel médical DIV, utilisé seul ou en combinaison avec d'autres appareils, est destiné par le fabricant à l'examen in vitro de prélèvements, y compris les prélèvements de sang et de tissus d'origine humaine, dans le but unique ou principal de fournir des informations sur un ou plusieurs des éléments suivants:

- état physiologique ou pathologique; ou
- anomalie congénitale;
- détermination de la sécurité et de la compatibilité de receveurs potentiels;
- contrôle et suivi des mesures thérapeutiques.

Le matériel médical d'autotest DIV est conçu par le fabricant pour être utilisé par un non-initié dans un environnement domestique.

NOTE Si une ou toutes les parties de l'appareil relèvent du domaine d'application d'une ou de plusieurs autres Parties 2 de la série IEC 61010, ainsi que du domaine d'application du présent document, ces autres Parties 2 sont prises en compte.

1.1.2 Appareils exclus du domaine d'application

Addition:

Ajouter le nouveau point suivant:

aa) les appareils relevant du domaine d'application de l'IEC 61010-2-081, sauf s'ils sont spécifiquement destinés par le fabricant à être utilisés à des fins de diagnostic in vitro.

1.2 Objet

1.2.1 Aspects inclus dans le domaine d'application

Addition:

Ajouter les deux nouveaux points suivants:

aa) dangers biologiques;

bb) produits chimiques dangereux.

1.2.2 Aspects exclus du domaine d'application

Addition:

Ajouter le nouveau point suivant et la nouvelle note suivante:

aa) la manutention ou la manipulation de substances analysées en dehors de l'appareil.

NOTE Les exigences applicables à ces sujets relèvent de la responsabilité des comités préparant les normes appropriées.

2 Références normatives

L'article de la Partie 1 est applicable à l'exception de ce qui suit:

Addition:

Ajouter les nouvelles références suivantes à la liste:

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

ISO 18113-5, *Dispositifs médicaux de diagnostic in vitro – Informations fournies par le fabricant (étiquetage) – Partie 5: Instruments de diagnostic in vitro pour auto-test*

3 Termes et définitions

L'article de la Partie 1 est applicable à l'exception de ce qui suit:

3.1 Appareils et états des appareils

Addition:

Ajouter les nouveaux termes suivants:

3.1.101
ZONE DE PRÉLÈVEMENT
zone dans laquelle l'accès de l'OPÉRATEUR est généralement involontaire

Note 1 à l'article: L'intérieur de cette zone présente des DANGERS mécaniques et une probabilité supérieure de piqûre biologiquement dangereuse de la peau humaine.

3.1.102
ZONE DE CHARGEMENT
zone d'appareillage automatisé dans laquelle un OPÉRATEUR manipule des prélèvements ou des réactifs

3.5.12 AUTORITÉ RESPONSABLE

Addition:

Ajouter la nouvelle note suivante:

Note 1 à l'article: Il ne s'agit pas de l'autorité responsable de l'Union européenne.

4 Essais

L'article de la Partie 1 est applicable.

5 Marquage et documentation

L'article de la Partie 1 est applicable à l'exception de ce qui suit:

5.1.1 Généralités

Remplacement:

Remplacer le troisième alinéa par le nouveau texte suivant:

Les symboles littéraux pour les grandeurs et les unités doivent être conformes à l'IEC 60027 (toutes les parties). Les symboles internationaux reconnus, y compris ceux du Tableau 1, doivent être utilisés dans toute la mesure du possible. Si d'autres symboles complémentaires sont exigés, il ne doit pas être possible de les confondre avec les symboles internationaux reconnus. Aucune exigence n'est spécifiée en ce qui concerne les couleurs des symboles. Les symboles graphiques doivent être expliqués dans la documentation.

5.1.2 Identification

Remplacement:

Remplacer le texte existant par le nouveau texte suivant:

Les appareils doivent être marqués, au minimum, avec les informations suivantes:

c) le nom du fabricant ou la marque de fabrique et l'adresse. L'adresse doit comprendre au moins la ville et le pays;

NOTE 1 La réglementation nationale peut exiger des informations plus détaillées concernant l'adresse que celles exigées en a).

d) le numéro, le nom du modèle ou tout autre moyen pour identifier l'appareil.

Les informations complémentaires suivantes doivent être marquées sur les appareils, sur l'emballage ou dans la notice d'utilisation:

1) le numéro de série, par exemple SN XXXX, ou bien le code du lot, précédé du mot «LOT», en utilisant le symbole 102 du Tableau 1;
2) les informations suivantes:
   i) une indication claire selon laquelle l'appareil est un matériel médical DIV;
   ii) si applicable, une indication claire selon laquelle l'appareil est un matériel médical d'autotest DIV;
   iii) en cas de RISQUE potentiel, l'identification des composants amovibles par le fabricant et l'identification des différentes pièces et, le cas échéant, le code du lot, etc.;
3) la notice d'utilisation exigeant que l'OPÉRATEUR utilise exclusivement des consommables n'ayant pas dépassé leur date d'expiration. Lorsque la réglementation l'exige, le nom et l'adresse du représentant autorisé du fabricant.

NOTE 2 Par exemple, dans l'Union européenne, la personne physique ou légale établie dans la Communauté européenne.

Tableau 1 – Symboles

Addition:

Ajouter les nouveaux symboles suivants au Tableau 1*:*

Numéro	Symbole	Publication	Description
101	 Couleur du fond – facultatif; Couleur du symbole – facultatif; Contour / couleur du contour – facultatif;	ISO 7000 0659 (200401)	RISQUES biologiques
102		ISO 7000 2492 (200401)	Code de lot

5.1.5 BORNES, connexions et dispositifs de manœuvre

Addition:

Ajouter le nouveau paragraphe suivant:

5.1.5.101 Raccordements des gaz et liquides

Si la sécurité le nécessite, l'appareil doit porter un marquage clair à proximité du raccord sur l'appareil, comportant:

a) un moyen d'identification du gaz ou du liquide à utiliser. En l'absence de symbole reconnu au niveau international (y compris les formules chimiques), l'appareil doit être marqué par le symbole 14 du Tableau 1;

b) la pression maximale autorisée ou, en variante, le symbole 14 du Tableau 1 (voir 5.4.3).

La conformité est vérifiée par examen.

Addition:

Ajouter le nouveau paragraphe suivant:

5.1.101 Transport et stockage

Les inscriptions portées sur l'emballage des appareils doivent préciser toutes les indications particulières concernant les conditions de transport et de stockage (voir 5.4.102).

La conformité est vérifiée par examen.

5.3 Durabilité du marquage

Remplacement:

Remplacer le premier alinéa par le nouveau texte suivant: