IEC 61010-2-101

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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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 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;

2) requirements for any external switch or circuit-breaker (see 6.11.2.1) 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.

Conformity is checked by inspection of the documentation.

5.4.4 Equipment operation

Replacement:

Replace the first paragraph text by the following:

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 so 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 ~~in case of a malfunction~~ 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)~~, the need to use protective gloves or other protective means~~;

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) ~~a statement in the instructions that, if the equipment is used in a manner not specified by the manufacturer, the protection provided by the equipment may be impaired.~~
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)

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 be necessary as a safeguard when equipment and their accessories are maintained, repaired, or transferred. Preferably manufacturers ~~should~~ 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 subclauses:

5.4.4.101 Instructions for use, self-test IVD medical equipment

Instructions for use of self-test IVD medical equipment ~~are given in annex BB~~ shall comply with ISO 18113-5.

~~*Conformity is checked by inspection of the documentation.*~~

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~~. These instructions shall include requirements for minimizing biohazards~~, 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 ~~which~~. Essential information shall be repeated on the outside of the ~~packaging of the equipment (see 5.1)~~ 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.

7 Protection against mechanical HAZARDS

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

7.3.1 General

Replacement:

Replace the second sentence as follows:

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 as follows:

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 item b) 3) text by the following:

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 item to 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 by the following:

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 subclause:

7.3.101 SAMPLE ZONE

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

aa) PROTECTIVE BARRIER or

bb) all following measures 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 visible and close to the area.

8 ~~Mechanical resistance to shock and impact~~ Resistance to mechanical stresses

This clause of part 1 is applicable except as follows:

~~*Addition:*~~

~~*Additional subclause:*~~

8.1 General

Replacement:

Replace the text of item 3) by the following:

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 subclause:

8.101 Transport and storage

When ~~packed~~ 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

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

~~**11.3 Spillage**~~

~~*Replacement:*~~

~~If in NORMAL USE liquid is likely to be spilled into the equipment, the equipment shall be designed so that no HAZARD will occur, as a result of the wetting of insulation or of internal uninsulated parts which are HAZARDOUS LIVE, or as a result of the contact of potentially aggressive substances (such as corrosive, toxic or flammable liquids) with parts of the equipment.~~

~~*Conformity is checked by inspection. In case of doubt, 0,2 l of water is poured steadily from a height of 0,1 m over a period of 15 s onto each point in turn at the area where the OPERATOR has to pour in or handle liquids, and where the liquid might gain access to electrical parts.*~~

~~*Immediately after this treatment, the equipment shall pass the voltage tests of 6.8 (without humidity preconditioning) and ACCESSIBLE parts shall not exceed the limits of 6.3.1.*~~

~~*Where appropriate, conformity is also checked by an examination of the compatibility of potentially aggressive substances with contacted parts of the equipment.*~~

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:

~~*Modification:*~~

~~*Modify the title of the clause as follows:*~~

~~**13 Protection against liberated gases and substances, explosion and implosion**~~

~~**13.1 Poisonous and injurious gases**~~

~~*Modification:*~~

~~*Modify the title as follows:*~~

~~**13.1 Poisonous and injurious gases and substances**~~

~~*Replacement:*~~

~~*Replace the first paragraph by the following two new paragraphs:*~~

~~Equipment shall not liberate dangerous amounts of poisonous or injurious gases or substances in NORMAL CONDITION or in SINGLE FAULT CONDITION.~~

~~If potentially hazardous substances are used in the equipment, the OPERATOR shall not be wetted nor be able to inhale quantities likely to be hazardous. The areas of the equipment containing such substances shall be equipped with protective covers or similar means of protection.~~

Addition:

Add the following 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 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 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 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 e.g. IEC 62061 (SIL) or ISO 13849 (PL) or other solutions providing equivalent functional safety.

16 ~~Measuring circuits~~ HAZARDS resulting from application

This clause of Part 1 is applicable except as follows:

16.2 Ergonomic aspects

Replacement:

Replace the note by the following note:

NOTE RISK assessment procedures for ergonomics can be found in IEC 62366, 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 standard.

17 RISK assessment

This clause of Part 1 is replaced as follows:

Replacement:

RISK assessment shall be carried out and documented using the requirements of ISO 14971 for HAZARDS not addressed in this standard 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:

~~*Additions:*~~

Annex ~~H~~ L
(informative)

Index of defined terms

Addition:

Add the following defined terms to the list:

Additions:

Add the following two new annexes AA and BB as follows:

Annex AA
(normative)

RISK management

RISK analysis and RISK evaluation shall be carried out as specified in ISO 14971, followed by RISK reduction if necessary to achieve an acceptable level of RISK.

NOTE 1 ISO 14971 specifically includes IVD medical equipment in its scope and has an informative annex on IVD medical equipment.

Conformity is checked by evaluation of the RISK management document.

A satisfactory level of safety is achieved by RISK reduction so as to achieve at least a TOLERABLE RISK. RISK assessment is carried out, and documented, so as to achieve at least a TOLERABLE RISK by an iterative process covering the following.

a) RISK analysis

RISK analysis is the process to identify HAZARDS and to estimate the RISKS based on the use of available information.

b) RISK evaluation

Each RISK analysis is based on a plan to work out the estimated severity and probability of a RISK level and to judge the acceptability of the resulting RISK level. Acceptability of RISK levels is judged as follows (see Figure AA.1):

1) Broadly acceptable region

In some cases, the RISK is so low, that it is negligible in comparison with other RISKS and in view of the benefit of using the IVD medical device. In such cases the RISK is acceptable and RISK control need not be actively pursued. This level fulfils the requirement for TOLERABLE RISK.

2) RISK as low as reasonably practicable region (ALARP)

This level does not automatically fulfil the requirement for TOLERABLE RISK. ALARP as a result in a RISK analysis always needs a justification of why the RISK cannot be reduced further in a practicable way.

3) Intolerable region

This level contains RISKS that are not TOLERABLE RISKS.

c) RISK reduction

If the initial RISK is not acceptable, counter measures are identified and put into force. The process of RISK analysis and RISK evaluation is then repeated, including checking that counter measures have not introduced new RISKS.

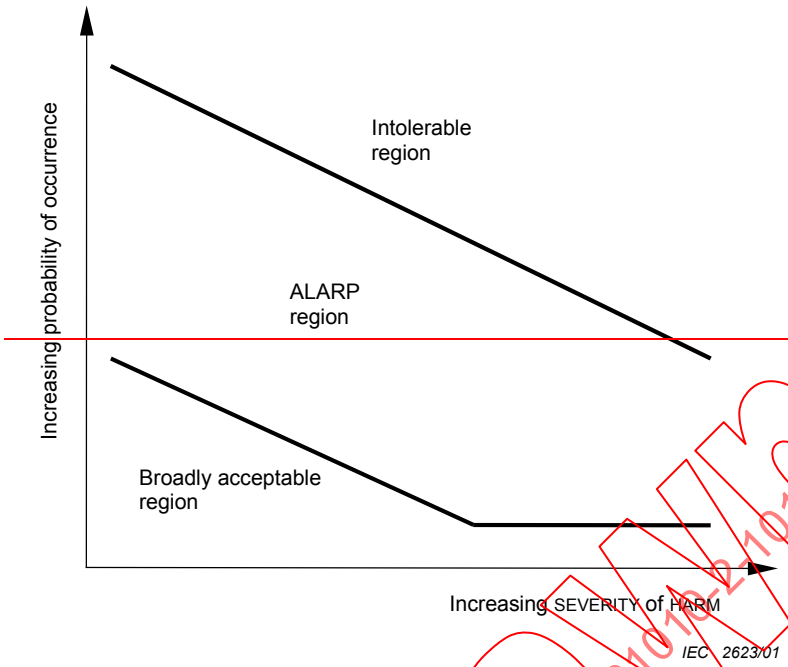

Figure AA.1 — RISK acceptability

Annex BB
(normative)

Instructions for use for self-test IVD medical equipment

Instructions for use shall at least include, as a permanent part, those items of BB.1 to BB.3 that are applicable to the equipment.

BB.1 Warning instructions

BB.1.1 Position and structure

General warning instructions shall be at or near the beginning of the instructions before those for operation and maintenance. Other specific warning instructions may be inserted at the position in the instructions where a particular HAZARD could arise. Warning instructions shall stand out clearly from other instructions (examples include the use of different coloured paper, red type, bold type, larger type).

BB.1.2 Content

BB.1.2.1 General

Warning instructions shall include all the relevant items in BB.1.2.2, using the wording that follows, or using wording which will be equally clear and unambiguous to a lay person.

NOTE 1 The words 'the equipment' can be replaced by the actual name of the equipment, and the word 'manufacturer' by the actual name of the manufacturer or the supplier.

NOTE 2 Simple illustrations are recommended to explain and support the warning instructions.

NOTE 3 Numbering of the warnings is optional.

BB.1.2.2 List of warning instructions

The order of the following list takes account of the importance of the warning and of the sequence in which the user is likely to be exposed to the HAZARDS involved. If either the relative importance or the sequence of exposure is different for the equipment concerned, this order can be changed. Other necessary warnings should be added, in positions based on the same considerations.

IMPORTANT SAFETY INSTRUCTIONS

DANGER – Misuse of electrical equipment can cause electrocution, burns, fire and other HAZARDS.

Basic safety precautions should always be taken, including all those listed below.

Close supervision is necessary when equipment is used by, on, or near children, handicapped persons or invalids.

READ THIS BEFORE USING THE EQUIPMENT

1) Check that the voltage setting matches the supply voltage.

2) Connection to MAINS supply:

   a) For plug-connected equipment only: Where protective earthing is required, plug the equipment into a supply outlet which has an earth connection;

   b) For PERMANENTLY CONNECTED EQUIPMENT only: Do not use the equipment until it has been installed by a qualified electrician or authorized service engineer.

   NOTE 1 This statement may need to be altered to take account of national regulations.

   NOTE 2 For PERMANENTLY CONNECTED EQUIPMENT, replace 'unplug' in warnings 3, 4 and 5 by 'switch off the MAINS supply switch'.

3) Unplug* the equipment immediately after use.

4) Unplug* the equipment before filling with liquid.

5) Do not place the equipment in liquid, nor put it where it could fall into liquid. If the equipment becomes wet, unplug it before touching it.

6) Do not leave the equipment unattended while it is plugged* in.

7) Use the equipment only for the purpose described in the instructions for use.

8) Do not use accessories which are not supplied or recommended by the manufacturer.

9) Do not use the equipment if it is not working properly, or if it has suffered any damage.

   NOTE Examples of typical defects include:

   a) damage to the flexible supply cord or its plug;

   b) damage caused by dropping the equipment;

   c) damage caused by dropping the equipment into water or splashing water onto it.

10) Do not let the equipment or its flexible cord come into contact with surfaces which are too hot to touch.

11) Do not block air openings nor place equipment on a soft surface which might block them, and keep air openings free from lint, hair, fluff, etc.

12) Do not place anything on top of the equipment.

13) Unless specifically instructed to do so by the instructions for use, do not drop or put anything into any opening in the equipment, or into any hose or coupling.

14) Do not use the equipment where aerosol sprays are being used, or where oxygen is being administered.

15) Do not use the equipment out of doors.

KEEP THESE INSTRUCTIONS

BB.2 Instructions for actions before first use

Instructions for actions to be taken once only, before first use in any particular place, shall immediately follow the warning instructions and shall include at least the following, if applicable:

a) assembly instructions;

b) instructions for any necessary protective earthing;

c) for plug-connected equipment, MAINS supply requirements;

d) for PERMANENTLY CONNECTED EQUIPMENT:

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

2) requirements for any external switches or circuit breakers (see 6.12.2.1) or overcurrent protection devices (see 9.6). A recommendation shall also be included that the switch or circuit breaker be near the equipment;

e) for battery equipment, type of battery and method of fixing;

f) instructions for connections to accessories or other equipment;

g) for multi-voltage equipment, instructions on how to set the voltage selector to the correct value, and how to check the setting;

h) instructions for location and mounting including:

1) details of any space around the equipment which needs to be kept clear for access during maintenance or servicing;

2) an instruction not to position the equipment so that it is difficult to operate the disconnecting device;

i) requirements for non-electrical supplies, such as water or gas;

j) requirements for drainage, including instructions for preventing back-syphonage;

k) requirements for venting or exhaust systems;

l) instructions for functional checking and calibration.

BB.3 Operating instructions

Operating instructions shall immediately follow the instructions for first use and shall at least include the following where applicable:

a) details of operating controls and their use in all operating modes;

b) an explanation of symbols used on the equipment;

c) limits for intermittent operation;

d) details of accessories and detachable parts (including batteries and fuses replaceable by the user) which are approved for use with the equipment, stating those which must be obtained only from the manufacturer or authorized supplier;

e) details of the type and quantity of all consumable materials (including water) to be used with the equipment, stating those which must be obtained only from the manufacturer or authorized supplier, and giving instructions for storage;

f) if NORMAL USE involves the handling of hazardous substances or potentially infectious substances, instructions on their correct use and the need for any training or personal protection equipment;

g) if there could be contact with the skin when handling infectious substances (such as reagents or human samples), the need to use suitable protective gloves or other personal protective means;

~~h) if the equipment could emit hazardous aerosol vapours in NORMAL USE, instructions for protection of mouth, nose or eyes;~~

~~i) if potentially hazardous visible or invisible radiation could be emitted, instructions for protective devices;~~

~~j) instructions for actions to be taken in case of a malfunction, including fault diagnosis, and specifying the limits of actions to be taken by the user;~~

~~k) instructions for care and storage of the equipment when not in use, with particular reference to preventing damage to the flexible cord;~~

~~l) instructions for preventative maintenance and inspection to be carried out by the user, and details of any maintenance or inspection which must be carried out only by an authorized service engineer;~~

~~m) instructions for cleaning and decontamination, and materials recommended;~~

~~n) instructions for the disposal of waste.~~

Bibliography

Addition:

Add the following references:

~~IEC 60073:1996, *Basic and safety principles for man-machine interface, marking and identification – Coding principles for induction devices and actuators*~~

~~ISO/IEC Guide 51:1999, *Safety aspects – Guidelines for their inclusions in standards*~~

~~ISO 7000:1989, *Graphical symbols for use on equipment – Index and synopsis*~~

EN 980:~~1996~~ 2008, *Graphical symbols for use in the labelling of medical devices*

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*

Laboratory Biosafety Manual, World Health Organization – ~~1984~~

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

Publications of the International Safe Transport Association (ISTA).

IEC 61010-2-101

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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

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –
Partie 2-101: Exigences particulières pour les appareils médicaux de diagnostic in vitro (DIV)

IEC 61010-2-101:2015-01(en-fr)

CONTENTS

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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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.

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, considerations have to be given to those other part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following item:

aa) 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

Addition:

Add two items:

aa) biohazards;

bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following 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 relevant standards.

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following references:

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) – 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:

3.1.101
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:

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. 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 – optional; Symbol colour – optional; Outline / outline colour – optional;	ISO 7000- 0659 (2004-01)	Biological RISKS
102		ISO 7000- 2492 (2004-01)	Batch code

5.1.2 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;

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.

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 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 by the following paragraph:

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 the following paragraph after the second 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 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 optional be used.

5.4.1 General

Deletion:

Delete the note 2 in the second paragraph.

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 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 6.11.2.1) 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.

Conformity is checked by inspection of the documentation.

5.4.4 Equipment operation

Replacement:

Replace the first paragraph text by the following:

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 so 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)

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 be necessary as a safeguard when equipment and their 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 subclauses:

5.4.4.101 Instructions for use, 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.

7 Protection against mechanical HAZARDS

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

7.3.1 General

Replacement:

Replace the second sentence as follows:

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 as follows:

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 item b) 3) text by the following:

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 item to 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 by the following:

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 subclause:

7.3.101 SAMPLE ZONE

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

aa) PROTECTIVE BARRIER or

bb) all following measures 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 visible 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) by the following:

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 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

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 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 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 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 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 e.g. IEC 62061 (SIL) or ISO 13849 (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 by the following note:

NOTE RISK assessment procedures for ergonomics can be found in IEC 62366, 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 standard.

17 RISK assessment

This clause of Part 1 is replaced as follows:

Replacement:

RISK assessment shall be carried out and documented using the requirements of ISO 14971 for HAZARDS not addressed in this standard 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 defined terms to the list:

Bibliography

Addition:

Add the following references:

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

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*

Laboratory Biosafety Manual, World Health Organization

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

Publications of the International Safe Transport Association (ISTA).

SOMMAIRE

COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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RÈGLES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –

Partie 2-101: Exigences particulières pour les appareils médicaux 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.
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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.

Cette norme a le statut de publication groupée de sécurité, conformément au Guide 104 de l'IEC.

La préparation de cette norme a été réalisée en étroite collaboration avec le groupe de travail CENELEC BTTF 88.1.

Cette deuxième édition annule et remplace la première édition parue en 2002. Cette édition constitue une révision technique et inclut les modifications techniques majeures suivantes par rapport à la première édition, ainsi que de nombreuses autres modifications:

- exclusion de l'IEC 61010-2-081 (appareils d'usage général de laboratoire) du domaine d'application, ce qui distingue les appareils de l'IEC 61010-2-081 et ceux de l'IEC 61010-2-101;
- mise à jour des symboles Danger biologique et Lot dans le Tableau 1 à l'Article 5;
- ajout d'une exigence relative aux consommables possédant une date d'expiration et aux informations concernant le représentant autorisé dans les Instructions d'utilisation à l'Article 5;
- ajout d'une exigence relative aux marquages et caractéristiques assignées des gaz et liquides à l'Article 5;
- ajout d'une exigence incluant des instructions à l'OPERATEUR permettant de couvrir les déversements, bourrages ou bris de consommables ou de prélèvements à l'intérieur des appareils, l'élimination des déchets dangereux, la protection individuelle, les procédures de réduction de RISQUE applicables aux liquides inflammables, brûlures causées par des surfaces, ainsi que le chargement et le déchargement de prélèvements et de réactifs dans les Instructions d'utilisation à l'Article 5;
- ajout d'une exigence imposant au fabricant de fournir des instructions relatives au transport, au stockage et au retrait d'utilisation des appareils à l'Article 5;
- ajout de la référence normative ISO 18113-5 relative aux instructions d'utilisation des appareils médicaux d'autodiagnostic DIV à l'Article 5;
- ajout d'exigences relatives aux instructions d'entretien par l'OPERATEUR à l'Article 7;
- ajout d'exigences relatives aux zones de prélèvement et aux zones de chargement à l'Article 7;
- exclusion des appareils dont la taille et le poids rendent improbable un mouvement involontaire de l'essai de chute à l'Article 8;
- ajout d'une exigence relative au marquage des dangers biologiques à l'Article 13;
- ajout d'une exigence relative aux systèmes de verrouillage incluant des composants électriques/électroniques ou programmables à l'Article 15;
- ajout d'une référence informative à la Norme d'aptitude à l'utilisation IEC 62366 à l'Article 16;
- remplacement de l'Article 17 par les exigences de l'ISO 14971 concernant l'évaluation du RISQUE.
- suppression des instructions d'utilisation de l'Annexe BB relatives aux appareils médicaux d'autodiagnostic DIV et ajout d'une référence à l'ISO 18113-5 à l'Article 5.

Le texte de cette norme est issu des documents suivants:

FDIS	Rapport de vote
66/545/FDIS	66/560/RVD

Toute information sur le vote ayant abouti à l'approbation de cette norme se trouve dans le rapport de vote indiqué dans le tableau ci-dessus.

Cette publication a été rédigée selon les Directives ISO/IEC, Partie 2.

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

La présente Partie 2-101 doit être utilisée conjointement avec l'IEC 61010-1. Elle a été établie sur la base de la troisième édition (2010).

La présente Partie 2-101 complète ou modifie les articles correspondants de l'IEC 61010-1 de façon à la transformer en norme IEC: *Règles de sécurité pour les appareils médicaux de diagnostic in vitro (DIV).*

Lorsqu'un paragraphe particulier de la Partie 1 n'est pas mentionné dans cette Partie 2, ce paragraphe s'applique pour autant qu'il est raisonnable. Lorsque cette partie spécifie «addition», «modification», «remplacement», ou «suppression», l'exigence, la modalité d'essai ou la note correspondante de la Partie 1 doit être adaptée en conséquence.

Dans la présente norme:

1) les caractères d'imprimerie suivants sont employés:
   - exigences: caractères romains;
   - NOTES: petits caractères romains;
   - *conformité et essai: caractères italiques;*
   - termes définis à l'Article 3 et utilisés dans toute cette norme: PETITES CAPITALES EN CARACTERES ROMAINS;
2) les paragraphes, figures, tableaux et notes complémentaires à ceux de la Partie 1 sont numérotés à partir de 101. Les annexes complémentaires sont nommées à partir de AA.

Le comité a décidé que le contenu de cette publication 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 à la publication recherchée. A cette date, la publication sera

- transformée en Norme internationale,
- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

RÈGLES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –

Partie 2-101: Exigences particulières pour les appareils médicaux de diagnostic in vitro (DIV)

1 Domaine d'application et objet

Cet 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 par ce qui suit:

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'autodiagnostic DIV.

Les appareils médicaux de diagnostic in vitro DIV, utilisés seuls ou en combinaison avec d'autres appareils, sont destinés par le fabricant à l'examen in vitro de spécimens, y compris les prélèvements de sang et de tissus d'origine humaine, dans le but unique ou principal de donner 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.

Les appareils médicaux d'autodiagnostic DIV sont conçus par le fabricant pour être utilisés par un non-initié dans un environnement domestique.

NOTE Si l'équipement dans sa totalité ou quelques-uns de ses sous-ensembles relèvent du domaine d'application d'une ou plusieurs autres Parties 2 de la norme IEC 61010 ainsi que du domaine d'application de la présente norme, il est nécessaire de tenir compte de ces autres Parties 2.

1.1.2 Appareils exclus du domaine d'application

Addition:

Ajouter le point suivant:

aa) Les appareils couverts par le domaine d'application de l'IEC 61010-2-081, sauf s'ils sont spécifiquement destinés par leur 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 deux points:

aa) dangers biologiques;

bb) produits chimiques dangereux.

1.2.2 Aspects exclus du domaine d'application

Addition:

Ajouter le point et la note suivants:

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

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

2 Références normatives

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

Addition:

Ajouter les références suivantes:

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) — Instruments de diagnostic in vitro pour auto-tests*

ISO 13857, *Sécurité des machines – Distances de sécurité empêchant les membres supérieurs et inférieurs d'atteindre les zones dangereuses*

3 Termes et définitions

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

3.1 Appareils et états des appareils

Addition:

Ajouter les termes et définitions suivants:

3.1.101
ZONE DE PRELEVEMENT
zone dans laquelle l'accès de l'OPERATEUR est généralement involontaire; 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 OPERATEUR manipule des prélèvements ou des réactifs

3.5.12 AUTORITE RESPONSABLE

Addition:

Ajouter la note suivante:

NOTE 1 à l'article: Il ne s'agit pas de l'autorité responsable de la Communauté Européenne.

4 Essais

Cet article de la Partie 1 est applicable:

5 Marquage et documentation

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

5.1.1 Généralités

Remplacement:

Remplacer le troisième alinéa par ce qui suit:

Les symboles littéraux pour les grandeurs et les unités doivent être conformes à l'IEC 60027. Les symboles internationaux reconnus, y compris ceux du Tableau 1, doivent dans la mesure du possible être utilisés prioritairement. Si d'autres symboles complémentaires sont nécessaires, 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.

Tableau 1 – Symboles

Addition:

Ajouter les 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 (2004-01)	DANGERS biologiques
102		ISO 7000- 2492 (2004-01)	Code de lot

5.1.2 Identification

Remplacement:

Remplacer le texte par ce qui suit:

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

a) 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 nécessiter des informations plus détaillées concernant l'adresse que celles exigées en a).