

INTERNATIONAL STANDARD



GROUP SAFETY PUBLICATION

**Safety requirements for electrical equipment for measurement, control and laboratory use –
Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes**

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**Safety requirements for electrical equipment for measurement, control and laboratory use –
Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

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International Standard IEC 61010-2-081 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

It has the status of a group safety publication in accordance with IEC Guide 104.

This second edition cancels and replaces the first edition published in 2001 and its Amendment 1 (2003). It constitutes a technical revision and includes the following significant changes from the first edition, as well as numerous other changes:

- excluded IEC 61010-2-101 (IVD Equipment) from scope. This separates IEC 61010-2-081 and IEC 61010-2-101 equipment;
- added biological risks symbol to Table 1 in Clause 5;
- added requirement for statement on hazardous substances and gases in Instructions for Use to Clause 5;
- Added marking requirement for flow direction to Clause 5;
- added requirement for OPERATOR maintenance instructions 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.

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

FDIS	Report on voting
66/544/FDIS	66/559/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 2-081 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010).

This Part 2-081 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Safety requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*.

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 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

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 automatic and semi-automatic laboratory equipment for analysis and other purposes.

Automatic and semi-automatic laboratory equipment consists of instruments or systems for measuring or modifying one or more characteristics or parameters of samples, performing the complete process or parts of the process without manual intervention. Equipment forming part of such a system is within the scope of this standard.

Examples of equipment within the scope of this standard include:

- analytical equipment;
- automatic sampler (pipettor, aliquoter);
- equipment for sample replication and amplification.

NOTE 1 In the case of analytical equipment the complete process usually includes the following steps:

- taking a specific quantity of the sample;
- preparing the sample by chemical, thermal, mechanical or other means;
- measurement;
- display, transmission or printing of the results of measurement.

NOTE 2 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) IEC 61010-2-101 (IVD Equipment)

1.2 Object

1.2.1 Aspects included in scope

~~Replacement:~~

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

~~The purpose of this standard is to ensure that the design and 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 specified (see 7.2.101 and annex AA).~~

Addition:

Add the following items:

- aa) biohazards;
- bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following item and note:

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

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:~~

~~IEC 60068-2-75:1997, Environmental testing – Part 2-75: Test – Test Eh: Hammer tests~~

3 Terms and definitions

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

~~3.1 Equipment and states of equipment~~

~~Additions:~~

~~Additional 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 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.~~

4 Tests

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

4.4.2 Application of fault conditions

~~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 international 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

~~Additions:~~

~~Add the following symbol to Table 1:~~

Number	Symbol	Publication	Description
101	 <p>Background colour – yellow optional;</p> <p>Symbol colour – optional;</p> <p>Outline / outline colour – black optional;</p>	ISO 7000-0659 (2004-01)	Biohazard Biological risks

~~5.1.5 TERMINALS, connections and operating devices~~

Additions:

Add the following new note 3:

~~NOTE 3—All connectors, controls and indicators necessary for use by the OPERATOR should be marked.~~

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);
- c) **flow direction of the gas and liquid, if applicable.**

Conformity is checked by inspection.

5.2 Warning markings

Replacement:

Replace the ~~fifth first~~ paragraph by the following ~~five~~ 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.~~

~~Protective covers shall be marked to warn the OPERATOR not to open or remove them except as permitted by 7.2.101 or 7.2.102.~~

~~Any part of the equipment that contains 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), 5.1.5.101, 6.1.2 b), ~~6.5.1.2 g), 6.6.2, 7.2 c), 7.2.101 f), 7.2.102 e), 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~~ **removable only with a TOOL or by appreciable force** 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 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 optionally be used).~~

5.4.1 General

Deletion:

Delete 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 the title and text by the following:

5.4.3 Equipment transportation, installation and assembly instructions

Documentation for the RESPONSIBLE BODY shall include the following as applicable:

- a) instructions for transportation after delivery to the RESPONSIBLE BODY;
- b) floor loading requirements;
- c) individual weights of principal heavy sub-assemblies;
- 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) instructions for 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 switches, circuit breakers (see 6.11.2.1) or overcurrent protection devices (see 9.5). A recommendation that a switch or circuit breaker be near the equipment shall also be included 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:

~~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 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;~~

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

~~h) instructions for the disposal of waste;~~

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

~~j) if there could be contact with the skin when handling potentially infectious substances (such as human samples or reagents), the need to use protective gloves;~~

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

~~l) if potentially hazardous visible or invisible radiation could be emitted, instructions and requirements for protective devices, such as protective glasses;~~

~~m) instructions relating to access to moving parts (see 7.2.101 and 7.2.102).~~

~~There shall be 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.~~

~~NOTE 2 Manufacturers should be aware of the internationally recognized Laboratory Biosafety Manual, published by the World Health Organization. This gives information on decontaminants, their use, dilutions, and potential applications. There are also national guidelines that cover these areas.~~

~~NOTE 3 Cleaning and decontamination may be necessary as a safeguard when equipment and its accessories are maintained, repaired, or transferred. Manufacturers should provide a format for RESPONSIBLE BODIES 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.~~

Replace the text in item h) by the following item h) and note:

~~h) a statement listing any potentially poisonous or injurious gases or substances that can be liberated from the equipment, and possible quantities;~~

~~NOTE Manufacturers can find valuable details in the internationally recognized Laboratory Biosafety Manual, published by the World Health Organization. This gives information on decontaminants, their use, dilutions and potential applications. There are also national guidelines that cover these areas.~~

Addition:

Add the following subclauses:

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, if any, or appropriate contact information shall be provided in the instructions.~~

NOTE Regional or international requirements can apply.

Conformity is checked by inspection of the documentation.

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:

~~7.2 Moving parts~~

~~Deletion~~

~~Delete paragraphs two and three.~~

~~Addition:~~

~~Additional subclauses:~~

~~7.2.101 Accessibility during NORMAL USE~~

~~As an exception, if moving parts are unavoidably exposed in NORMAL USE, RISK management (see annex AA) shall be carried out to establish whether the moving parts could cause injury to the OPERATOR. Any RISKS shall be minimized as far as practicable by protective measures, in the following order of priority:~~

- ~~a) protective devices (interlock systems or other means, removable only with a TOOL);~~
- ~~b) protective covers;~~
- ~~c) mechanical BARRIERS;~~
- ~~d) sufficient distance between safe areas and moving parts;~~
- ~~e) warning signals (audible or visible);~~
- ~~f) warning markings (see 5.2).~~

~~Measures b) to d) shall be combined with warnings regarding hazardous areas (see 5.4.1).~~

~~If moving parts are unavoidably exposed during NORMAL USE, the instructions shall specify that procedures which could result in injury are carried out only by OPERATORS who have been warned of the potential HAZARDS and have received adequate training in carrying out the procedures in the safest possible manner.~~

~~Conformity is checked by inspection and as specified in annex AA.~~

7.2.102 Accessibility outside NORMAL USE

If an OPERATOR carrying out routine maintenance outside NORMAL USE has, for unavoidable technical reasons, to perform a procedure, such as adjustment which requires access to hazardous moving parts, access is permitted provided that all of the following precautions have been taken:

- a) access to moving parts protected by devices specified in 7.2.101 a) is not possible without the use of a TOOL;
- b) the instructions for the RESPONSIBLE BODY include a statement that OPERATORS must be trained before being allowed to perform the hazardous procedure;
- c) there are warning markings (see 5.2) on any covers or parts which have to be removed to obtain access and the warning prohibits access by untrained OPERATORS. As an alternative, symbol 14 of Table 1 shall be placed on the covers or parts and the warnings included in the documentation.

Conformity is checked by inspection and as specified in annex AA.

7.3.2 Exceptions

Replacement:

Replace the text in item b) 3) 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.

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

8 Mechanical Resistance to shock and impact Resistance to mechanical stresses

This clause of Part 1 is applicable except as follows:

8.1.2 Dynamic test

Replacement:

- **Impact hammer test**

Bases, covers, etc., intended to be removed and replaced by the OPERATOR have their fixing screws tightened with the torque applied in NORMAL USE. The equipment is then held firmly against a rigid support and tested with the impact spring hammer specified in Annex BB. The hammer nose is pressed perpendicularly against the surface of all external parts which are accessible in NORMAL USE and which would be likely to cause a hazard if broken.

Three blows with an energy of 0,5 J are applied to each part.

~~NOTE—A revised impact test is under consideration.~~

~~8.2.1 Equipment other than HAND-HELD EQUIPMENT and direct plug-in equipment~~

~~8.1 General~~

~~Replacement:~~

~~Replace the text of *e item 3*) by the following:~~

~~€3) *no test is required* 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.~~

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.~~

~~In areas where an automatic dosing process is performed, the above test is also carried out using a volume of water equal to 5 times the maximum amount of liquid which is likely to be spilled during NORMAL USE by the equipment itself.~~

~~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 liberated, 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 biohazardous due to the use of biohazardous substances shall be prominently marked with symbol 101 of Table 1, or the appropriate international symbol, or (if none is available) symbol 14 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.

Any part of the equipment that contains biohazardous waste material which can be removed from the equipment during NORMAL USE or a biohazardous drain connection shall be marked with an appropriate biohazard symbol.

14 Components and subassemblies

This clause of Part 1 is applicable.

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 ~~Test and measurement equipment~~ HAZARDS resulting from application

This clause of Part 1 is applicable.

17 Risk assessment

This clause of Part 1 is applicable.

Annexes

The annexes of Part 1 are applicable **except as follows**.

Additions:

Annex H

Index of defined terms

Additional defined terms:

HARM	3.101
RISK	3.102
TOLERABLE RISK	3.103

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

~~Annex AA (normative)~~

~~Risk management~~

~~To meet the requirements of 7.2.101, a satisfactory level of safety shall be achieved by RISK reduction to achieve at least a TOLERABLE RISK. RISK management shall be carried out, and documented, 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 requires 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 equipment. 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 shall be identified and put into force. The process of RISK analysis and RISK evaluation shall then be repeated, including checking that counter measures have not introduced new RISKS.~~

~~NOTE 1 For IVD medical equipment within the scope of IEC 61010-2-101, the RISK management process specified in that standard applies. For other equipment, guidance on RISK management is given in the following standards: ISO 14971 and ISO 14121.~~

~~NOTE 2 Where ISO 14121 requires conformity with a recommendation of ISO/TR 12100-2, that recommendation is replaced by the relevant requirement of IEC 61010.~~

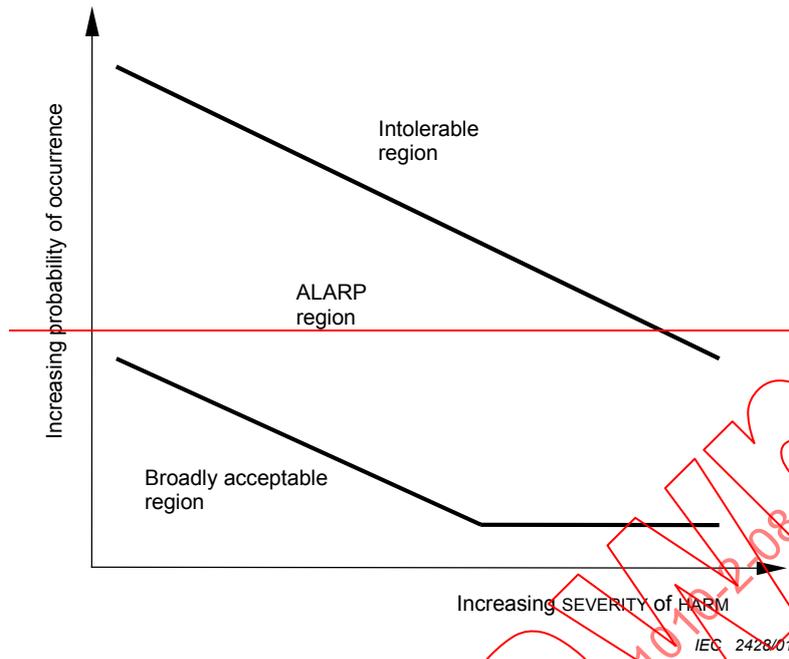


Figure AA.1 — Risk acceptability

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Annex BB (normative)

Impact spring hammer (see 8.2)

IEC 60068-2-75 describes the construction, the application and the calibration of the spring hammer Ehb. The following brief description is not intended to give full details of how to make or calibrate the apparatus.

The test apparatus (see figure below) consists of three main parts: the body, the striking element and the spring-loaded release cone.

The body comprises the housing, the striking element guide, the release mechanism and all parts rigidly fixed thereto.

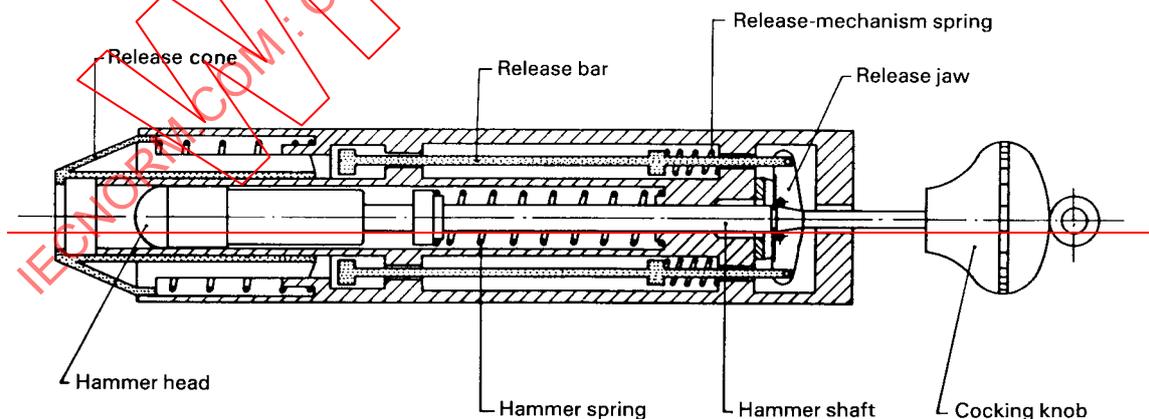
The striking element comprises the hammer head, the hammer shaft and the cocking knob. The hammer head has a hemispherical face of polyamide having a Rockwell hardness of HR 100, with a radius of 10 mm; it is so fixed to the hammer shaft that the distance from its tip to the plane of the front of the cone when the striking element is on the point of release is 20 mm.

The cone has a mass of 60 g and the cone spring is such that it exerts a force of 20 N when the release jaws are on the point of releasing the striking element.

The apparatus is cocked by pulling the cocking knob until the release jaws engage in the hammer shaft.

For an impact energy of $0,5 \text{ J} \pm 0,05 \text{ J}$, the hammer spring is adjusted so that the product of the compression, in millimetres, and the force exerted, in newtons, equals 1 000, the compression being approximately 20 mm.

For other energy levels, adjust as described in IEC 60068-2-75 or according to the instructions supplied with the apparatus.



533/90

Figure BB.1 – Impact spring hammer

Bibliography

Addition:

Add the following reference:

~~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~~

~~ISO/TR 12100-2:1992, Safety of machines – Basic concepts, general principles for design – Part 2: Technical principles and specifications~~

~~ISO 14121:1999, Safety of machinery – Principles of risk assessment~~

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

World Health Organization, *Laboratory biosafety manual*, 1984

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INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPEE DE SÉCURITÉ

Safety requirements for electrical equipment for measurement, control and laboratory use –

Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –

Partie 2-081: Exigences particulières pour les appareils de laboratoire, automatiques et semi-automatiques, destinés à l'analyse et autres usages

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR
MEASUREMENT, CONTROL, AND LABORATORY USE –****Part 2-081: Particular requirements for automatic and
semi-automatic laboratory equipment for analysis and other purposes**

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.
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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 61010-2-081 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

It has the status of a group safety publication in accordance with IEC Guide 104.

This second edition cancels and replaces the first edition published in 2001 and its Amendment 1 (2003). It constitutes a technical revision and includes the following significant changes from the first edition, as well as numerous other changes:

- excluded IEC 61010-2-101 (IVD Equipment) from scope. This separates IEC 61010-2-081 and IEC 61010-2-101 equipment;
- added biological risks symbol to Table 1 in Clause 5;
- added requirement for statement on hazardous substances and gases in Instructions for Use to Clause 5;

- Added marking requirement for flow direction to Clause 5;
- added requirement for OPERATOR maintenance instructions 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.

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

FDIS	Report on voting
66/544/FDIS	66/559/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 2-081 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010).

This Part 2-081 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Safety requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes*.

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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Withdrawn

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

Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

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 automatic and semi-automatic laboratory equipment for analysis and other purposes.

Automatic and semi-automatic laboratory equipment consists of instruments or systems for measuring or modifying one or more characteristics or parameters of samples, performing the complete process or parts of the process without manual intervention. Equipment forming part of such a system is within the scope of this standard.

Examples of equipment within the scope of this standard include:

- analytical equipment;
- automatic sampler (pipettor, aliquoter);
- equipment for sample replication and amplification.

NOTE 1 In the case of analytical equipment the complete process usually includes the following steps:

- taking a specific quantity of the sample;
- preparing the sample by chemical, thermal, mechanical or other means;
- measurement;
- display, transmission or printing of the results of measurement.

NOTE 2 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) IEC 61010-2-101 (IVD Equipment)

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following items:

- aa) biohazards;
- bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following item and note:

- aa) handling or manipulation of material outside the equipment.

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

2 Normative references

This clause of Part 1 is applicable.

3 Terms and definitions

This clause of Part 1 is applicable

4 Tests

This clause of Part 1 is applicable.

5 Marking and documentation

This clause of Part 1 is applicable except as follows:

Table 1 – Symbols

Additions:

Add the following symbol to Table 1:

Number	Symbol	Publication	Description
101	 <p>Background colour – optional; Symbol colour – optional; Outline / outline colour – optional;</p>	ISO 7000-0659 (2004-01)	Biological risks

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);
- c) flow direction of the gas and liquid, if applicable.

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), 5.1.5.101, 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 be removable only with a TOOL or by appreciable force 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 the following paragraph after the second paragraph:

If a solvent or reagent specified for use with the equipment could affect the durability of 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.

5.4.4 Equipment operation

Replacement:

Replace the text in item h) by the following item h) and note:

- h) a statement listing any potentially poisonous or injurious gases or substances that can be liberated from the equipment, and possible quantities;

NOTE Manufacturers can find valuable details in the internationally recognized Laboratory Biosafety Manual, published by the World Health Organization. This gives information on decontaminants, their use, dilutions and potential applications. There are also national guidelines that cover these areas.

Addition:

Add the following subclauses:

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 instructions.

NOTE Regional or international requirements can apply.

Conformity is checked by inspection of the documentation.

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:

7.3.2 Exceptions

Replacement:

Replace the text in item b) 3) 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:

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

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.*

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 biohazardous due to the use of biohazardous substances shall be prominently marked with symbol 101 of Table 1, or the appropriate international symbol, or (if none is available) symbol 14 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.

Any part of the equipment that contains biohazardous waste material which can be removed from the equipment during NORMAL USE or a biohazardous drain connection shall be marked with an appropriate biohazard symbol.

14 Components and subassemblies

This clause of Part 1 is applicable.

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.

17 Risk assessment

This clause of Part 1 is applicable.

Annexes

The annexes of Part 1 are applicable.

Bibliography

Addition:

Add the following reference:

World Health Organization, *Laboratory biosafety manual*

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

**RÈGLES DE SÉCURITÉ POUR APPAREILS ÉLECTRIQUES
DE MESURAGE, DE RÉGULATION ET DE LABORATOIRE –****Partie 2-081: Exigences particulières pour les appareils de laboratoire,
automatiques et semi-automatiques, destinés à l'analyse et autres usages**

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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- 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.
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La Norme internationale IEC 61010-2-081 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.

Cette deuxième édition annule et remplace la première édition parue en 2001 et son amendement 1. 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 61010-2-101 (appareils DIV) du domaine d'application, ce qui distingue les appareils de l'IEC 61010-2-081 et ceux de l'IEC 61010-2-101;
- ajout d'un symbole relatif aux risques biologiques dans le Tableau 1 à l'Article 5;
- ajout d'une exigence relative aux indications sur les substances et gaz dangereux dans les Instructions d'utilisation à l'Article 5;
- ajout d'une exigence relative au marquage du sens de circulation à l'Article 5;
- ajout d'une exigence relative aux instructions d'entretien par l'OPERATEUR 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.

Le texte de cette norme est issu des documents suivants:

FDIS	Rapport de vote
66/544/FDIS	66/559/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 2-081 doit être utilisée conjointement avec l'IEC 61010-1. Elle a été établie sur la base de la troisième édition (2010).

La présente Partie 2-081 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 de laboratoire, automatiques et semi-automatiques, destinés à l'analyse et autres usages*.

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 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.