

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**

IEC 61010-2-081:2015

<https://standards.iteh.ai/catalog/standards/iec/3190b666-e7ba-4269-b02f-fc7e717a84ca/iec-61010-2-081-2015>



THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2015 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
Fax: +41 22 919 03 00
info@iec.ch
www.iec.ch

About the IEC

The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications

The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigenda or an amendment might have been published.

IEC Catalogue - webstore.iec.ch/catalogue

The stand-alone application for consulting the entire bibliographical information on IEC International Standards, Technical Specifications, Technical Reports and other documents. Available for PC, Mac OS, Android Tablets and iPad.

IEC publications search - www.iec.ch/searchpub

The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,...). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished

Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and also once a month by email.

Electropedia - www.electropedia.org

The world's leading online dictionary of electronic and electrical terms containing more than 30 000 terms and definitions in English and French, with equivalent terms in 15 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary

More than 60 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

IEC Customer Service Centre - webstore.iec.ch/csc

If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: csc@iec.ch.

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**

IEC 61010-2-081:2015

<https://standards.iteh.ai/catalog/standards/iec/3190b666-e7ba-4269-b02f-fc7e717a84ca/iec-61010-2-081-2015>

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

ICS 19.080, 71.040.10

ISBN 978-2-8322-2241-6

Warning! Make sure that you obtained this publication from an authorized distributor.

CONTENTS

FOREWORD	3
1 Scope and object	6
2 Normative references	7
3 Terms and definitions	7
4 Tests	7
5 Marking and documentation	7
6 Protection against electric shock	9
7 Protection against mechanical HAZARDS	9
8 Mechanical resistance to shock and impact Resistance to mechanical stresses	9
9 Protection against the spread of fire	9
10 Equipment temperature limits and resistance to heat	10
11 Protection against hazards from fluids	10
12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	10
13 Protection against liberated gases and substances, explosion and implosion	10
14 Components and subassemblies	10
15 Protection by interlocks	10
16 Test and measurement equipment HAZARDS resulting from application	11
17 Risk assessment	11
Annexes	11
Annex H – Index of defined terms	11
Annex AA (normative) – Risk management	11
Annex BB (normative) – Impact spring hammer (see 8.2)	11
Bibliography	11
Table 1 – Symbols	7

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.
- 2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
- 3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
- 4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
- 5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
- 6) All users should ensure that they have the latest edition of this publication.
- 7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
- 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.

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 61010-2-081 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.

IMPORTANT – The “colour inside” logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this publication using a colour printer.

iTech Standards
(<https://standards.iteh.ai>)
Document Preview

[IEC 61010-2-081:2015](https://standards.iteh.ai/standards/iec/31590666-e7ba-4269-b02f-fc7e717a84ca/iec-61010-2-081-2015)

<https://standards.iteh.ai/standards/iec/31590666-e7ba-4269-b02f-fc7e717a84ca/iec-61010-2-081-2015>

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, ~~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;~~