



IEC 61010-2-081

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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**

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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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	
Annex AA (normative) Risk management	
Annex BB (normative) Impact spring hammer (see 8.2)	
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.
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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 61010-2-081 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:

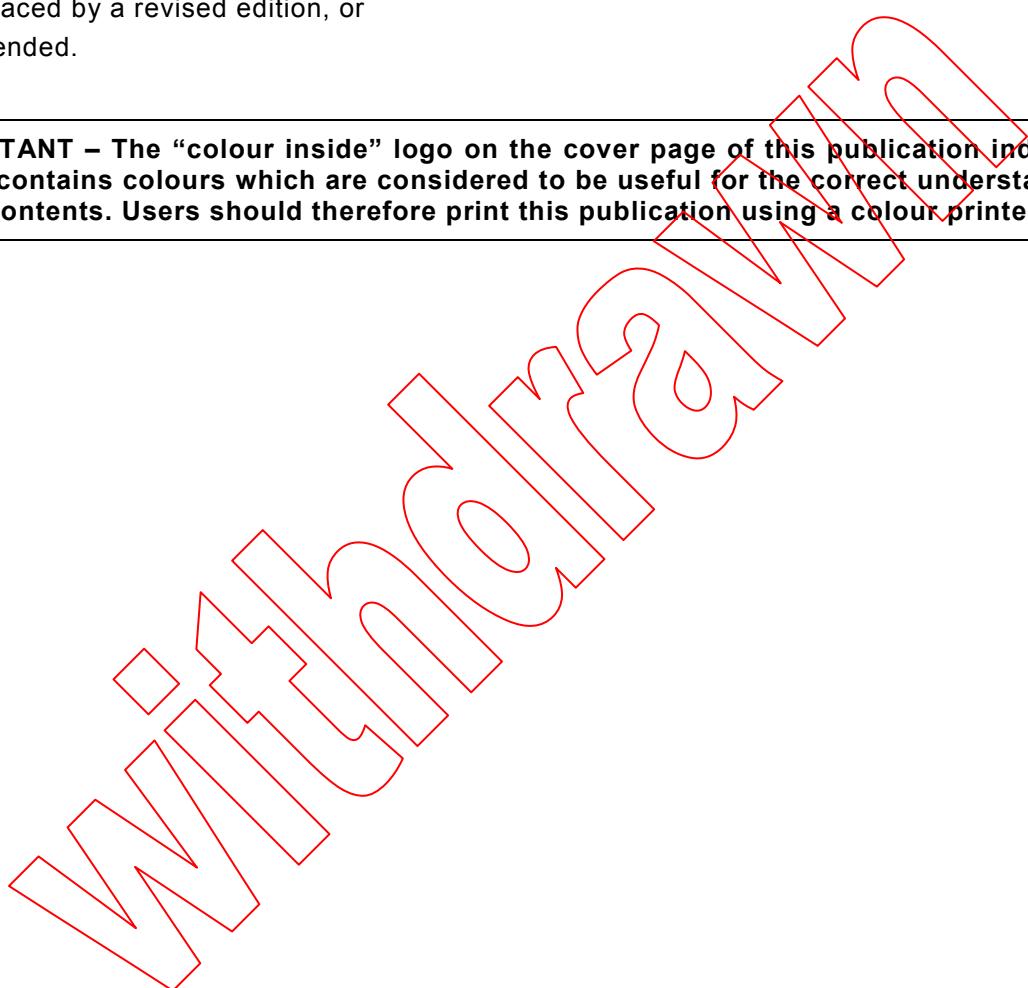
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 - requirements: in roman type;
 - NOTES: in smaller roman type;
 - *conformity and test: in italic type;*

- 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,
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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 Eh: Hammer tests~~

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE 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**

CONTENTS

FOREWORD.....	3
1 Scope and object.....	6
2 Normative references.....	7
3 Terms and definitions	7
4 Tests.....	7
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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 HAZARDS resulting from application.....	11
17 RISK assessment	11
Annexes	11
Bibliography	11
Table 1 – Symbols	7

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Withdrawn

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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.

Withdrawn

SOMMAIRE

AVANT-PROPOS	13
1 Domaine d'application et objet	16
2 Références normatives	17
3 Termes et définitions	17
4 Essais	17
5 Marquage et documentation	17
6 Protection contre les chocs électriques	19
7 Protection contre les DANGERS mécaniques	19
8 Résistance aux contraintes mécaniques	19
9 Protection contre la propagation du feu	20
10 Limites de température de l'appareil et résistance à la chaleur	20
11 Protection contre les dangers provenant des fluides	20
12 Protection contre les radiations, y compris les sources laser, et contre la pression acoustique et ultrasonique	20
13 Protection contre les émissions de gaz et de substances et contre les explosions et les implosions	20
14 Composants et sous-ensembles	20
15 Protection par systèmes de verrouillage	20
16 DANGERS résultant de l'application	21
17 Evaluation du RISQUE	21
Annexes	21
Bibliographie	21
Tableau 1 – Symboles	17

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,
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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'OPÉRATEUR 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 mesure, 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 CARACTÈRES 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

- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

withdrawn

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

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 de laboratoire, automatiques et semi-automatiques, destinés à l'analyse et autres usages.

Les appareils de laboratoire automatiques et semi-automatiques comprennent les instruments ou systèmes utilisés pour mesurer ou modifier un ou plusieurs paramètres ou caractéristiques d'échantillons, réalisant tout ou partie du processus sans intervention manuelle. Les équipements faisant partie d'un tel système sont couverts par le domaine d'application de la présente norme.

Exemples d'équipements entrant dans le domaine d'application de la présente norme:

- équipement réalisant des analyses;
- échantilleur automatique (pipeteur, aliquoteur);
- équipement réalisant la réplication ou l'amplification d'échantillon.

NOTE 1 En ce qui concerne les équipements réalisant des analyses, le processus complet comprend habituellement les phases suivantes:

- prélèvement d'une quantité déterminée de l'échantillon;
- préparation de l'échantillon par des moyens chimiques, thermiques, mécaniques ou autres;
- mesurage;
- affichage, transmission ou impression des résultats de mesurage.

NOTE 2 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, ces autres Parties 2 doivent également être prises en considération.

1.1.2 Aspects exclus du domaine d'application

Addition:

Ajouter le point suivant:

- aa) IEC 61010-2-101 (appareils DIV)

1.2 Objet

1.2.1 Aspects inclus dans le domaine d'application

Addition:

Ajouter les points suivants:

- 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 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.