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Edition 3.0 2018-10

REDLINE VERSION

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

FOREWORD

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This Redline version provides you with a quick and easy way to compare all the changes between this standard and its previous edition. A vertical bar appears in the margin wherever a change has been made. Additions are in green text, deletions are in strikethrough red text.

International Standard IEC 61010-2-101 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

It has the status of a group safety publication, as specified in IEC Guide 104.

This document has been prepared in close collaboration with Working Group CENELEC BTTF 88.1.

This third edition cancels and replaces the second edition published in 2015. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) adaptation of changes introduced by Amendment 1 of IEC 61010-1;

b) added tolerance for stability of AC voltage test equipment to Clause 6.

The text of this International Standard is based on the following documents:

CDV	Report on voting
66/644/CDV	66/669/RVC

Full information on the voting for the approval of this International Standard can be found in the report on voting indicated in the above table.

This document has been drafted in accordance with the ISO/IEC Directives, Part 2.

A list of all parts of the IEC 61010 series, under the general title: *Safety requirements for electrical equipment for measurement, control, and laboratory use*, may be found on the IEC website.

This Part 2-101 is intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010) and its Amendment 1 (2016).

This Part 2-101 supplements or modifies the corresponding clauses in IEC 61010-1 so as to convert that publication into the IEC standard: *Particular requirements for in vitro diagnostic (IVD) medical equipment.*

Where a particular subclause of Part 1 is not mentioned in this Part 2, that subclause applies as far as is reasonable. Where this part states “addition”, “modification”, “replacement”, or “deletion” the relevant requirement, test specification or note in Part 1 should be adapted accordingly.

In this standard:

1) the following print types are used:
   - requirements: in roman type;
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   - *conformity and test: in italic type;*
   - terms used throughout this standard which have been defined in clause 3: SMALL ROMAN CAPITALS;
2) subclauses, figures, tables and notes which are additional to those in part 1 are numbered starting from 101. Additional annexes are lettered starting from AA and additional list items are lettered from aa).

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

Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

1 Scope and object

This clause of Part 1 is applicable except as follows:

1.1.1 Equipment included in scope

Replacement:

Replace the text, except the first paragraph, with the following new text:

This part of IEC 61010 applies to equipment intended for in vitro diagnostic (IVD) medical purposes, including self-test IVD medical purposes.

IVD medical equipment, whether used alone or in combination, is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue samples, derived from the human body, solely or principally for the purpose of providing information concerning one or more of the following:

- a physiological or pathological state; or
- a congenital abnormality;
- the determination of safety and compatibility with potential recipients;
- the monitoring of therapeutic measures.

Self-test IVD medical equipment is intended by the manufacturer for use by lay persons in a home environment.

NOTE If all or part of the equipment falls within the scope of one or more other Part 2 standards of the IEC 61010 series as well as within the scope of this document, considerations ~~have to be~~ is given to those other Part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following new item:

aa) equipment within the scope of IEC 61010-2-081 unless ~~they are~~ it is specifically intended by the~~ir~~ manufacturer to be used for in vitro diagnostic examination.

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following two new items:

aa) biohazards;

bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following new item and note:

aa) the handling or manipulation outside the equipment of material under analysis.

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

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new references to the list:

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

ISO 18113-5, *In vitro diagnostic medical devices – Information supplied by the manufacturer (labelling) – Part 5: In vitro diagnostic instruments for self-testing*

~~*ISO 13857, Safety of machinery – Safety distances to prevent hazard zones being reached by upper and lower limbs*~~

IEC 61010-2-101

Edition 3.0 2018-10

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE DE SÉCURITÉ

Safety requirements for electrical equipment for measurement, control and laboratory use –
Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

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

IEC 61010-2-101:2018-10(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

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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.

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Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

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This clause of Part 1 is applicable except as follows:

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Replacement:

Replace the text, except the first paragraph, with the following new text:

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- a physiological or pathological state; or
- a congenital abnormality;
- the determination of safety and compatibility with potential recipients;
- the monitoring of therapeutic measures.

Self-test IVD medical equipment is intended by the manufacturer for use by lay persons in a home environment.

NOTE If all or part of the equipment falls within the scope of one or more other Part 2 standards of the IEC 61010 series as well as within the scope of this document, consideration is given to those other Part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following new item:

aa) equipment within the scope of IEC 61010-2-081 unless it is specifically intended by the manufacturer to be used for in vitro diagnostic examination.

1.2 Object

1.2.1 Aspects included in scope

Addition:

Add the following two new items:

aa) biohazards;

bb) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add the following new item and note:

aa) the handling or manipulation outside the equipment of material under analysis.

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

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COMMISSION ÉLECTROTECHNIQUE INTERNATIONALE

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

Partie 2-101: Exigences particulières pour le matériel médical de diagnostic in vitro (DIV)

AVANT-PROPOS

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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.

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

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

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

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

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

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

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

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cette Norme internationale.

Ce document a été rédigé selon les Directives ISO/IEC, Partie 2.

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

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

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

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

Dans la présente norme:

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

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

Partie 2-101: Exigences particulières pour le matériel médical de diagnostic in vitro (DIV)

1 Domaine d'application et objet

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

1.1.1 Appareils inclus dans le domaine d'application

Remplacement:

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

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

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

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

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

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

1.1.2 Appareils exclus du domaine d'application

Addition:

Ajouter le nouveau point suivant:

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

1.2 Objet

1.2.1 Aspects inclus dans le domaine d'application

Addition:

Ajouter les deux nouveaux points suivants:

aa) dangers biologiques;

bb) produits chimiques dangereux.

1.2.2 Aspects exclus du domaine d'application

Addition:

Ajouter le nouveau point suivant et la nouvelle note suivante:

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

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

2 Références normatives

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

Addition:

Ajouter les nouvelles références suivantes à la liste:

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

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