IEC 61010-2-040

Edition 3.0 2020-05

INTERNATIONAL STANDARD

colour inside

REDLINE VERSION

Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

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 2-040: Particular requirements for STERILIZERS and WASHER-DISINFECTORS used to treat medical materials

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 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 61010-2-040 has been prepared by IEC technical committee 66: Safety of measuring, control and laboratory equipment.

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) it is established on the basis of the third edition (2010) of IEC 61010-1 and its Amendment 1 (2016);
b) added tolerance for stability of a.c. voltage test equipment to 6.8.3.1;
c) the status of a Group Safety Publication has been removed (this does not change the technical requirements in the document).

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

CDV	Report on voting
66/699/CDV	66/716/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.

The reader's attention is drawn to the fact that Annex G lists all of the "in-some-country" clauses on differing practices of a less permanent nature relating to the subject of this standard.

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

This Part 2-040 is to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010) of IEC 61010-1 and its Amendment 1 (2016), hereinafter referred to as Part 1.

This Part 2-040 supplements or modifies the corresponding clauses in Part 1 so as to convert that publication into the IEC standard: *Particular requirements for STERILIZERS and WASHER-DISINFECTORS used to treat medical materials*.

Where a particular subclause of Part 1 is not mentioned in this Part 2-040, that subclause applies as far as is reasonable. Where this Part 2-040 states "addition", "modification", "replacement", or "deletion", the relevant requirement, test specification or note in Part 1 shall be adapted accordingly.

In this standard:

1) the following print types are used:
   - requirements: in roman type;
   - NOTES: in small roman type;
   - conformity and tests: *in italic type*;
   - terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS.

2) subclauses, figures, and tables 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).

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

- reconfirmed,
- withdrawn,
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- amended.

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

Part 2-040: Particular requirements for STERILIZERS and WASHER-DISINFECTORS used to treat medical materials

1 Scope and object

This clause of Part 1 is applicable except as follows:

1.1.1 Equipment included in scope

Replacement:

Replace the existing text with the following:

This part of IEC 61010 specifies safety requirements for electrical equipment intended for sterilization, washing, and disinfection of medical materials in the medical, veterinary, pharmaceutical and laboratory fields, when used under the environmental conditions of 1.4.

Examples of such equipment include the following:

a) STERILIZERS and disinfectors using steam and/or hot water as the sterilant;

b) STERILIZERS and disinfectors using toxic gas, toxic aerosol or toxic vapour as the sterilant;

c) STERILIZERS and disinfectors using hot air or hot inert gas as the sterilant; and

d) WASHER-DISINFECTORS.

1.1.2 Equipment excluded from scope

Addition:

Add the following note to item f):

NOTE IEC 60601-1:2005, 3.63, defines "medical electrical equipment" as follows (notes to entry are omitted):

Electrical equipment, having an applied part or transferring energy to or from the patient or detecting such energy transfer to or from the patient and which is:

a) provided with not more than one connection to a particular supply MAINS; and

b) intended by its manufacturer to be used:

1) in the diagnosis, treatment, or monitoring of a patient; ~~and that makes physical or electrical contact with the patient or transfers energy to or from the patient or detects such energy transfer to or from the patient~~ or

2) for compensation or alleviation of disease, injury or disability.

Addition:

Add the following new second paragraph after the lettered list:

This document does not apply to the following types of equipment:

aa) equipment for use in hazardous atmospheres (see IEC 60079); however this document does apply to an atmosphere created inside equipment by a flammable sterilizing agent (see ~~13.0~~ 13.2.101 and 13.2.102);

bb) laboratory equipment for the heating of materials for purposes other than sterilization or disinfection (see IEC 61010-2-010);

cc) laundry equipment (see IEC 60335-2-4, IEC 60335-2-7, IEC 60335-2-11, and ISO 10472 (all parts)), unless designed for disinfecting medical materials;

dd) dishwashers (see IEC 60335-2-5 and IEC 60335-2-58).

1.2.1 Aspects included in scope

Replacement:

Replace item g) with the following new text:

g) liberated gases (including the non-intentional escape of toxic gas), pathogenic substances, explosion and implosion (see Clause 13).

1.2.2 Aspects excluded from scope

Addition:

Add the following two new items:

aa) special requirements for protection against chemical and high-risk micro-biological HAZARDS associated with the LOAD;

bb) general requirements for the design of calorifiers, shell boilers and PRESSURE VESSELS.

NOTE National and other regulations or codes apply for the safety of calorifiers, shell boilers and PRESSURE VESSELS (see 14.101).

2 Normative references

This clause of Part 1 is applicable except as follows:

Addition:

Add the following new references:

IEC 61770, *Electric appliances connected to the water mains – Avoidance of backsiphonage and failure of hose-sets*

~~IEC 62471, *Photobiological safety of lamps and lamp systems*~~

~~IEC TR 62471-2, *Photobiological safety of lamps and lamp systems – Part 2: Guidance on manufacturing requirements relating to non-laser optical radiation safety*~~

ISO 3585, *Borosilicate glass 3.3 – Properties*

ISO 4126-1, *Safety devices for protection against excessive pressure – Part 1: Safety valves*

ISO 4126-2, *Safety devices for protection against excessive pressure – Part 2: Bursting disc safety devices*

IEC 61010-2-040

Edition 3.0 2020-05

INTERNATIONAL STANDARD

NORME INTERNATIONALE

Safety requirements for electrical equipment for measurement, control, and laboratory use –
Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

Exigences de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –
Partie 2-040: Exigences particulières pour sterilisateurs et laveurs desinfecteurs utilisés pour traiter le matériel médical



IEC 61010-2-040:2020-05(en-fr)

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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 2-040: Exigences particulières pour STERILISATEURS et LAVEURS DESINFECTEURS utilisés pour traiter le matériel médical

AVANT-PROPOS

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La Norme internationale IEC 61010-2-040 a été établie par le comité d'études 66 de l'IEC: Sécurité des appareils de mesure, de commande et de laboratoire.

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) elle est établie sur la base de la troisième édition (2010) de l'IEC 61010-1 et son Amendement 1 (2016);
b) tolérance ajoutée pour la stabilité des matériels d'essai sous tension alternative spécifiés en 6.8.3.1;

c) le statut de publication groupée de sécurité a été supprimé (ce qui ne modifie pas les exigences techniques du document).

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

CDV	Rapport de vote
66/699/CDV	66/716/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.

L'attention du lecteur est attirée sur le fait que l'Annexe G énumère tous les articles traitant des différences à caractère moins permanent inhérentes à certains pays, concernant le sujet de la présente norme.

Une liste de toutes les parties de la série IEC 61010, publiées 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.

La présente Partie 2-040 doit être utilisée conjointement avec l'IEC 61010-1. Elle a été établie sur la base de la troisième édition (2010) de l'IEC 61010-1 et son Amendement 1 (2016), désignée ci-après comme la Partie 1.

La présente Partie 2-040 complète ou modifie les articles correspondants de la Partie 1 de façon à transformer cette publication en norme IEC: *Exigences particulières pour les STÉRILISATEURS et LAVEURS DESINFECTEURS utilisés pour traiter le matériel médical*.

Lorsqu'un paragraphe particulier de la Partie 1 n'est pas mentionné dans cette Partie 2-040, ce paragraphe s'applique pour autant que cela soit raisonnable. Lorsque la présente Partie 2-040 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 utilisés:
   - exigences: caractères romains;
   - NOTES: petits caractères romains;
   - conformité et essais: *caractères italiques;*
   - termes définis à l'Article 3 et utilisés dans cette norme: PETITES CAPITALES EN CARACTERES ROMAINS.
- les paragraphes, figures et tableaux qui sont ajoutés à ceux de la Partie 1 sont numérotés à partir de 101; les annexes complémentaires sont nommées à partir de AA et les listes de termes complémentaires à partir de aa).

Le comité a décidé que le contenu de ce document 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 au document recherché. À cette date, le document sera

- reconduit,
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- remplacé par une édition révisée, ou
- amendé.

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

Partie 2-040: Exigences particulières pour STERILISATEURS et LAVEURS DESINFECTEURS utilisés pour traiter le matériel médical

1 Domaine d'application et objet

Cet article de la Partie 1 s'applique, avec les exceptions suivantes:

1.1.1 Appareils inclus dans le domaine d'application

Remplacement:

Remplacer le texte par le nouveau texte suivant:

La présente partie de l'IEC 61010 définit les exigences de sécurité pour les appareils électriques destinés à la stérilisation, au lavage et à la désinfection du matériel médical dans les domaines médicaux, vétérinaires, pharmaceutiques et de laboratoire, lorsqu'ils sont utilisés dans les conditions d'environnement de 1.4.

Exemples de ce type d'appareils:

a) les STERILISATEURS et désinfecteurs utilisant la vapeur et/ou l'eau chaude comme agent stérilisant;

b) les STERILISATEURS et désinfecteurs utilisant le gaz toxique, l'aérosol toxique, ou la vapeur toxique comme agent stérilisant;

c) les STERILISATEURS et désinfecteurs utilisant de l'air chaud ou du gaz inerte chaud comme agent stérilisant; et

d) les LAVEURS DESINFECTEURS.

1.1.2 Appareils exclus du domaine d'application

Addition:

Ajouter la note suivante au point f):

NOTE L'IEC 60601-1:2005, 3.63, définit les appareils électromédicaux comme suit (sans les notes à l'article):

appareil électrique qui possède une partie appliquée ou qui transfère de l'énergie vers le patient ou à partir de celui-ci ou qui détecte un tel transfert d'énergie vers le patient ou à partir de celui-ci et qui est:

a) équipé au plus d'un moyen de raccordement à un RESEAU d'alimentation donné; et

b) destiné par son fabricant à être utilisé:

1) pour le diagnostic, le traitement ou la surveillance d'un patient ou

2) pour la compensation ou l'atténuation d'une maladie, d'une blessure ou d'une incapacité

Addition:

Ajouter le nouveau second alinéa suivant après la liste:

Le présent document ne s'applique pas aux types d'appareils suivants:

aa) appareils destinés à être utilisés dans des atmosphères dangereuses (voir l'IEC 60079), mais il s'applique toutefois à une atmosphère créée à l'intérieur de l'appareil par un agent stérilisant inflammable (voir 13.2.101 et 13.2.102);

bb) équipements de laboratoire pour le chauffage des matériaux pour d'autres usages que la stérilisation ou la désinfection (voir l'IEC 61010-2-010);

cc) équipement de blanchisserie (voir l'IEC 60335-2-4, l'IEC 60335-2-7, l'IEC 60335-2-11, et l'ISO 10472 (toutes les parties)), sauf s'il est conçu pour la désinfection des matériels médicaux;

dd) lave-vaisselle (voir l'IEC 60335-2-5 et l'IEC 60335-2-58).

1.2.1 Aspects inclus dans le domaine d'application

Remplacement:

Remplacer le point g) par le nouveau texte suivant:

g) les émissions de gaz (y compris l'échappement involontaire de gaz toxiques), les substances pathogènes, les explosions et les implosions (voir l'Article 13).

1.2.2 Aspects exclus du domaine d'application

Addition:

Ajouter les deux nouveaux points suivants:

aa) les exigences particulières pour la protection contre les DANGERS chimiques et microbiologiques à haut risque associés à la CHARGE;

bb) les exigences générales pour la conception des calorifères, chaudières à tubes de fumée et RESERVOIRS SOUS PRESSION.

NOTE Les règlements ou codes nationaux et autres règlements ou codes s'appliquent pour la sécurité des calorifères, chaudières à tubes de fumée et RESERVOIRS SOUS PRESSION (voir 14.101).

2 Références normatives

Cet article de la Partie 1 s'applique, avec l'exception suivante:

Addition:

Ajouter les nouvelles références suivantes:

IEC 61770, *Appareils électriques raccordés au réseau d'alimentation en eau – Exigences pour éviter le retour d'eau par siphonnage et la défaillance des ensembles de raccordement*

ISO 3585, *Verre borosilicaté 3.3 – Propriétés*

ISO 4126-1, *Dispositifs de sécurité pour protection contre les pressions excessives – Partie 1: Soupapes de sûreté*

ISO 4126-2, *Dispositifs de sécurité pour protection contre les pressions excessives – Partie 2: Dispositifs de sûreté à disque de rupture*