

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPEE DE SÉCURITÉ

**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**

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



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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**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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International Standard IEC 61010-2-040 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 second edition cancels and replaces the first edition published in 2005. This edition constitutes a technical revision.

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

- a) A new clause (4.3.2.101) has been added for non-electrical supplies and services.
- b) Additional requirements for marking and documentation (Clause 5) have been added.

- c) Additional requirements for protection against mechanical hazards (Clause 7) have been included.
- d) Additional requirements for protection against radiation, including laser sources, and against sonic and ultrasonic pressure (Clause 12) have been included.

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

| | |
|-------------|------------------|
| FDIS | Report on voting |
| 66/570/FDIS | 66/576/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 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 intended to be used in conjunction with IEC 61010-1. It was established on the basis of the third edition (2010). Consideration may be given to future editions of, or amendments to, IEC 61010-1.

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 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 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 publication will remain unchanged until the stability date indicated on the IEC website 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.

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 defines medical electrical equipment as follows:

Electrical equipment, provided with not more than one connection to a particular supply MAINS and intended by its manufacturer to be used 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.

Addition:

Add the following new second paragraph:

This part of IEC 61010 does not apply to the following types of equipment:

- aa) equipment for use in hazardous atmospheres (see IEC 60079) but does apply to an atmosphere created inside equipment by a flammable sterilizing agent (see 13.0);
- bb) laboratory equipment for the heating of materials for other purposes 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), 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 back-siphonage 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*

3 Terms and definitions

This clause of Part 1 is applicable except as follows:

3.5.2

HAZARD

Addition:

Add the following new note: