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 sterilisers 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(en-fr)

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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.

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 smaller 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,
- 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 gases 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 the manufacturer to be used:

1) in the diagnosis, treatment, or monitoring of a 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 13.2.101 and 13.2.102);

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