



UL 61010-2-040 (IEC
61010-2-040:2015)

STANDARD FOR SAFETY

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

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UL Standard for 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, UL 61010-2-040 (IEC 61010-2-040:2015)

Second Edition, Dated January 15, 2016

Summary of Topics

Adoption of IEC 61010-2-040, 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 (second edition issued July 2015) as a new IEC-based UL standard, UL 61010-2-040 (IEC 61010-2-040:2015), with no National Differences.

Although this is the first-time publication of this Standard by UL, it is being published as the Second edition in order to align UL's edition number with that of the IEC Standard. As a result, one or more UL edition numbers have been skipped to match that of the IEC edition number.

The new requirements are substantially in accordance with Proposal(s) on this subject dated November 13, 2015.

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ANSI/UL 61010-2-040-2016

UL 61010-2-040 (IEC 61010-2-040:2015)

**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**

Second Edition

January 15, 2016

This ANSI/UL Standard for Safety consists of the Second Edition.

The most recent designation of ANSI/UL 61010-2-040 (IEC 61010-2-040:2015) as an American National Standard (ANSI) occurred on January 15, 2016. ANSI approval for this IEC standard does not include the Cover Page, Transmittal Pages, Title Page, Preface or the IEC Foreword.

Comments or proposals for revisions on any part of the Standard may be submitted to UL at any time. Proposals should be submitted via a Proposal Request in UL's On-Line Collaborative Standards Development System (CSDS) at <http://csds.ul.com>.

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Annexes

Annex G (informative) Leakage and rupture from fluids under pressure

Annex L (informative) Index of defined terms

Bibliography

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Preface (UL)

This UL Standard is based on IEC Publication 61010-2-040: second edition 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. IEC publication 61010-2-040 is copyrighted by the IEC.

Efforts have been made to synchronize the UL edition number with that of the corresponding IEC standard with which this standard is harmonized. As a result, one or more UL edition numbers have been skipped to match that of the IEC edition number.

This UL Standard 61010-2-040 Standard for Safety for 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, is to be used in conjunction with the third edition of UL 61010-1. The requirements for laboratory equipment for the heating of materials are contained in this Part 2 Standard and UL 61010-2-040.

Requirements of this Part 2 Standard, where stated, amend the requirements of UL 61010-1.

Where a particular subclause of UL 61010-1 is not mentioned in UL 61010-2-040, the UL 61010-1 subclause applies.

The text, figures and tables of IEC Publication 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, IEC 61010-2-040, copyright July, 2015 are used in this Standard with the consent of the IEC and the American National Standards Institute (ANSI). The IEC copyrighted material has been reproduced with permission from ANSI. ANSI should be contacted regarding the reproduction of any portion of the IEC material. The IEC Foreword and Introduction are not a part of the requirements of this Standard but are included for information purposes only. Copies of IEC Publication 61010-2-040 may be purchased from ANSI, 11 West 42nd Street, New York, New York, 10036, (212) 642-4900.

Note – Although the intended primary application of this Standard is stated in its Scope, it is important to note that it remains the responsibility of the users of the Standard to judge its suitability for their particular purpose.

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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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6) All users should ensure that they have the latest edition of this publication.

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9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

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 test: *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.

DV.1 DE Add the following paragraph to the Foreword:

The numbering system in the standard uses a space instead of a comma to indicate thousands and uses a comma instead of a period to indicate a decimal point. For example, 1 000 means 1,000 and 1,01 means 1.01.

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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.

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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:

Addition:

Add the following terms and definitions:

3.5.2 HAZARDS

Addition:

Add the following new note:

Note 1 to entry: In the context of this standard, the term HAZARD relates only to potential sources of harm to the OPERATOR and surroundings (see 1.2.1), and does not include potential sources of harm related to the efficacy of the process.

3.5.11 OPERATOR

Addition:

Add the following note:

Note 1 to entry: An OPERATOR includes persons installing, operating, adjusting, maintaining, cleaning, repairing or moving equipment.

Addition:

Add the following new terms and definitions:

3.2.101 CHAMBER part of the equipment which receives the LOAD

3.2.102 LOAD equipment or materials put into a CHAMBER to be processed through an OPERATING CYCLE

3.2.103 STERILIZER equipment designed to achieve sterilization which comprises a series of actions or operations needed to achieve the specified requirements for sterility

3.2.104 PRESSURE VESSEL assembly comprising the CHAMBER, the jacket (if fitted), doors, and all other components in permanent open connection with the CHAMBER

Note 1 to entry: The PRESSURE VESSEL does not include parts from which it can be isolated, such as steam generators, pipework, and fittings.

3.2.105 OPERATING CYCLE complete set of stages of the process that is carried out, in a specified sequence

Note 1 to entry: Loading and unloading are not part of the OPERATING CYCLE.

3.2.106 WASHER-DISINFECTOR equipment intended to clean and disinfect medical devices and other articles used in the context for example of medical, dental, pharmaceutical and veterinary practice

4 Tests

This clause of Part 1 is applicable except as follows:

4.3.2.4 Covers and removable parts

Addition:

Add the following new second paragraph:

Covers including panels and control box enclosures which do not require the use of a TOOL for removal need not be removed if they have interlocks which meet the requirements of Clause 15, and which automatically de-activate all parts which would otherwise present a HAZARD when the cover is opened.

4.3.2.12 Duty cycle

Addition:

Add the following new second paragraph:

Equipment which can be operated continuously shall also be tested without any interval between consecutive OPERATING CYCLES.

Addition:

Add the following new subclause:

4.3.2.101 Non-electrical supplies and services

These shall be set to the least favourable RATED settings.

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