IEC 61010-2-040

Edition 2.0 2015-07

INTERNATIONAL STANDARD

NORME INTERNATIONALE

GROUP SAFETY PUBLICATION
PUBLICATION GROUPÉE 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

IEC 61010-2-040:2015-07(en-fr)

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

COMMISSION ELECTROTECHNIQUE INTERNATIONALE

ICS 19.080; 71.040.10

ISBN 978-2-8322-2776-3

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials

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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:

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.

4.4.2.5 Motors

Addition:

Add the following new second paragraph:

If it is impracticable to test a motor in place, a separate identical motor can be tested but it shall be tested in conditions that meet or exceed the conditions within the equipment.

4.4.2.13 Interlocks

Addition:

Add the following new second paragraph:

If an interlock provides protection against accidental contact with a hazardous substance, it is tested using a non-hazardous substance.

Addition:

Add the following three new subclauses:

4.4.2.101 Pressure controllers

Pressure controllers, except for overpressure safety devices meeting the requirements of 11.7.4, shall be overridden to supply the service continuously.

4.4.2.102 Failure, or partial failure, of the MAINS supply

The equipment shall be operated at 90 % and 110 % of the RATED voltage for one cycle. The voltage shall then be set to 90 % of the RATED voltage for 5 min. The voltage shall then be reduced gradually at a rate of approximately 10 V per min until the equipment fails to operate normally. The voltage shall then be reset to the RATED voltage with the equipment still switched on.

4.4.2.103 Failure, or partial failure, of other supplies and services

In turn, each non-electrical supply and service shall be interrupted, or partially interrupted, whichever is less favourable.

NOTE Examples include air, steam, feedwater, sterilant gas, detergent, disinfectant, and systems for drainage, exhaust, and ventilation.

5 Marking and documentation

This clause of Part 1 is applicable except as follows:

5.1.2 Identification

Replacement:

Replace the existing text by the following:

The equipment shall be marked with at least the following:

a) the name and address of the manufacturer;

b) any additional markings required by national and local regulations, including the name and address of the manufacturer's authorized representative in the country of intended use;

c) a marking that uniquely identifies the individual unit of manufacture such as a serial number;

d) year and place of manufacture, if different from manufacturer's address;

e) model identification;

f) designated purpose of the equipment.

Conformity is checked by inspection.

Addition:

Add the following two new subclauses:

5.1.101 Overpressure safety device

The device (see 11.7.4) shall be marked with the name of the manufacturer, the model number, and the pressure to which it is set. If a bursting disc is located between the CHAMBER and the overpressure safety device, the disc shall be marked with its specified bursting pressure and associated temperature.

NOTE National, local regulations and other codes may apply.

5.1.102 PRESSURE VESSELS and shell boilers

Attention is drawn to the existence of national and local regulations that can require additional markings.

5.2 Warning markings

Replacement:

Replace the first paragraph by the following new paragraph:

Warning markings specified in 5.1.5.1,5.1.5.2 c), 5.1.5.2 d), 5.1.8, 5.4.4 r), 6.1.2 b), 7.3.2, 7.102 b), 7.102 c), 9.1, 10.1, 13.2.2, and 14.103 shall meet the following requirements.

Warning and Caution symbols shall be at least 10 mm high.

5.4.1 General

Replacement:

Replace the first paragraph by the following new paragraph:

The following documentation necessary for safety purposes, as needed by the OPERATOR or RESPONSIBLE BODY, shall be marked with its date of issue or revision status and provided with the equipment.

Add the following two new items to the first paragraph after item h):

aa) attention is drawn to the existence of national and local regulations that can apply to the documentation,

bb) if NORMAL USE involves the handling of a hazardous substance, documentation shall include information on constituents, correct storage, use and safe disposal.

Delete the second note.

Add a new paragraph before the conformity statement:

Marking, information and language shall:

1) comply with regulations applying in the country of intended use;

NOTE 2 ISO 15223-2 offers guidance for equipment classified as a medical device.

2) include instructions for the disposal of the equipment, its accessories and its packaging;

3) give due consideration to the technical knowledge, education and training of different OPERATOR categories;

4) not contradict information contained in documentation provided to describe the equipment.

5.4.2 Equipment ratings

Addition:

Add the following new item to the first paragraph after item f):

aa) for each non-electrical service, if applicable, the RATED ranges of temperature, pressure and flow-rate.

5.4.3 Equipment installation

Replacement:

Replace items a) to g) by the following:

a) location and mounting instructions;

b) space required for safe and efficient maintenance;

c) individual weights of principal heavy subassemblies;

d) overall weight and floor loading requirements;

e) unpacking and assembly instructions (see also 7.108);

f) mains supply requirements and connections; including the temperature rating of any cable required to meet 5.1.8;

g) for PERMANENTLY CONNECTED EQUIPMENT,

1) supply wiring requirements;

2) requirements for any external switch or circuit-breaker (see 6.11.3.1) and external overcurrent protection devices (see 9.6.1) and a recommendation that the switch or circuit-breaker be near the equipment;

h) ventilation requirements (see 11.101, 13.1.103.1, and 13.1.101);

i) drainage requirements (see 11.101);

j) instructions for protective earthing;

k) instructions relating to sound level (see 12.5.1);

l) requirements for special services, for example air, feed water, cooling liquid;

m) requirements related to hazardous gas atmospheres (see 13.0);

n) instructions to position the equipment so that it is not difficult to operate the disconnecting device;

o) instructions relating to the handling and containment of hazardous substances, including any need for additional equipment that can be required to control emissions (see 13.1);

p) instructions relating to HAZARDS caused by liquids or hot items falling from the equipment (see 9.1);

q) requirements for material used in the installation of the equipment and which can come in contact with sterilant (see 13.1.103.4 and 13.2.101);

r) instructions for ambient illumination (see also 11.102);

NOTE ISO 12100 and EN 1837 give guidance on lighting.

s) instructions relating to heat emission.

Addition:

Add the following new subclause:

5.4.3.101 Special systems

Installation instructions shall include details of the following special systems, if needed to protect against possible HAZARDS:

a) non-recirculating ventilation system for the room in which the equipment is installed (also see 13.1.103.3);

Such a ventilation system shall normally give a minimum of 10 air changes per hour, but for large installations this may need to be increased.

b) for equipment using toxic sterilant, means to protect against HAZARDS arising from failure of the room ventilation system (see 13.1.103.3);

c) a non-recirculating local exhaust system to remove fugitive emissions (see 13.1.101.4);

d) a drainage system (see 13.1.101.3);

e) a venting system for the drain (see 13.1.101.3);

f) a CHAMBER exhaust system (see13.1.101.2);

g) a system used to control escaping biological emissions (see 13.1.104);

h) any other supply, for example sterilant, steam, compressed air, hot or cold water (including instructions on the prevention of back siphonage (see 11.104).

Conformity is checked by inspection

5.4.4 Equipment operation

Replacement:

Replace items a) to j) by the following:

a) identification of operating controls and their use in all operating modes;

b) an instruction not to position the equipment so that it is difficult to operate the disconnecting device;

c) instructions for interconnection to accessories and other equipment, including details of suitable accessories, detachable parts and any special materials;

d) specification of limits for intermittent operation;

e) an explanation of symbols related to safety which are used on the equipment (see 5.2);

f) instructions for cleaning (see 11.2);

g) instructions for making the equipment safe after an incomplete OPERATING CYCLE;

h) instructions for the correct use of the lockable door closure prevention device [see 7.102.b)];

i) instructions to the RESPONSIBLE BODY for safe access to the LOAD in the CHAMBER in the event of a fault (see 13.1.102);

j) instructions for action in case of a malfunction, including fault diagnosis;

NOTE 1 These instructions can include any special methods of interpreting data recorded or noted during the OPERATING CYCLE, to detect failure or trends that can lead to failure, for example the use of a temperature recorder.

k) loading procedure;

l) instructions for safe disposal of parts such as detergent containers, sterilant containers and parts contaminated by pathogenic material;

NOTE 2 Additional requirements on methods of disposal can be specified by national or local authorities.

m) instructions for testing the function of critical safety devices in a safe manner, for example overpressure safety devices (see 11.7.4);

n) if NORMAL USE involves the handling of substances, instructions on correct use and safety provisions. In addition, instructions shall be given on methods of safe handling before disposal, and recommendations on disposal (also see Note 2 above);

o) details of methods of reducing burn HAZARDS from surfaces permitted to exceed the temperature limits specified in Table 19;

p) guidelines to be followed in cases of emergency in which eye or skin contact or inhalation could occur, such as release of toxic material or pathogenic material, or leakage from a sterilizing agent container or disinfectant container or enzymatic, alkaline or acidic detergent container;

These guidelines shall also be prominently displayed on or near the equipment

q) instructions for safely replenishing containers of dosing chemicals (see 13.102);

r) if a HAZARD could result from the use of equipment with a type of LOAD other than those for which it is intended, there shall be an appropriate warning in the instructions, and a warning marking (see 5.2) shall state the types of LOAD which can be used. If small equipment has insufficient space for this warning marking, symbol 14 of Table 1 shall be marked;

s) instructions for inspection, replenishment, and storage of consumable materials which could cause a HAZARD, including details of HAZARDS which could arise from the introduction of incorrect quantities of recommended consumable materials, also procedures and details of the protection needed to minimize such HAZARDS;

t) identification of residual risks and instructions on necessary protective procedures (see Clause 17).

5.4.5 Equipment maintenance and service

Replacement:

Replace the text by the following new text:

Instructions shall be provided to the RESPONSIBLE BODY in sufficient detail to permit safe maintenance and inspection of the equipment and to ensure continued safety of the equipment after the maintenance and inspection procedure.

Instructions shall include:

a) details of maintenance required on parts subject to wear and tear if failure could lead to a HAZARD;

b) inspection and replacement, if necessary, of any hoses/pipes or other parts containing fluids, if their failure could cause a HAZARD;

c) details of safety devices fitted together with their settings and replacement procedures;

d) procedures for making the equipment safe prior to maintenance;

e) maintenance schedules and repair procedures, including ambient lighting level (see 11.102) and any special precautions necessary to protect against HAZARDS during maintenance;

f) methods of safe handling for repair or disposal of any part containing or contaminated by toxic and/or pathogenic material;

NOTE 1 Requirements on methods of disposal can be specified by national or local authorities.

NOTE 2 Aspects of environmental impact are addressed in ISO 14971 and IEC 61508).

g) battery types for equipment using replaceable batteries;

h) ratings and characteristics of replaceable fuses;

i) a list of parts (if any), restricted to examination and/or supply by the manufacturer or the manufacturer's agent;

j) residual RISKS (see Clause 17) and protective measures for these RISKS;

k) verification of the safe state of the equipment after repair.

Conformity is checked by inspection.

Addition:

Add the following two new subclauses:

5.4.101 OPERATOR training

5.4.101.1 General

In order that OPERATORS are adequately trained in the safe use of the equipment, the manufacturer's instructions shall state that the RESPONSIBLE BODY should ensure:

a) that all personnel who operate or maintain the equipment are trained in its operation and in its safe use;

b) that, if exposure limits (i.e. STEL or LTEL) or permissible working environmental concentration limit (see note to 13.1) could be exceeded during NORMAL USE, personnel working with toxic chemicals, gases, and vapours are given comprehensive instruction in the process. This instruction includes information on relevant health HAZARDS, national regulations, methods for safe use, and methods to detect escape of the agent;

c) that there is regular training of all personnel concerned with the operation and maintenance of the equipment, including emergency procedures for any toxic, flammable,