

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**

The European Standard EN 61010-2-040:2005 has the status of a
British Standard

ICS 19.080; 71.040.10

National foreword

This British Standard is the official English language version of EN 61010-2-040:2005. It is identical with IEC 61010-2-040:2005. It supersedes BS EN 61010-2-041:1997, BS EN 61010-2-042:1997, BS EN 61010-2-043:1998 and BS EN 61010-2-045:2001 which are withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EPL/66, Safety of measuring, control and laboratory equipment, which has the responsibility to:

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- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep UK interests informed;
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English 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**
(IEC 61010-2-040:2005)

Règles de sécurité pour appareils
électriques de mesure, de régulation
et de laboratoire
Partie 2-040: Exigences particulières
pour stériliseurs et laveurs désinfecteurs
utilisés pour traiter le matériel médical
(CEI 61010-2-040:2005)

Sicherheitsbestimmungen für elektrische
Mess-, Steuer-, Regel- und Laborgeräte
Teil 2-040: Besondere Anforderungen an
Sterilisatoren und Reinigungs-
Desinfektionsgeräte für die Behandlung
medizinischen Materials
(IEC 61010-2-040:2005)

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CENELEC

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Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

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Foreword

The text of document 66/353/FDIS, future edition 1 of IEC 61010-2-040, prepared by IEC TC 66, Safety of measuring, control, and laboratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 61010-2-040 on 2005-06-01.

This European Standard supersedes EN 61010-2-041:1996 + corrigendum September 1996, EN 61010-2-042:1997, EN 61010-2-043:1997 and EN 61010-2-045:2000.

This Part 2-040 is to be used in conjunction with EN 61010-1:2001, Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements. Consideration may be given to future editions of, or amendments to, EN 61010-1.

This Part 2-040 supplements or modifies the corresponding clauses of EN 61010-1:2001 so as to convert it into the European Standard "Safety requirements for sterilizers and washer-disinfectors used to treat medical materials".

Where a particular clause or subclause of Part 1 is not mentioned in this Part 2-040, that clause or subclause applies as far as is reasonable. Where this part states "addition", "modification", "replacement" or "deletion", the relevant text of Part 1 is to 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*: *italic type*;
 - terms used throughout this standard which have been defined in Clause 3: SMALL ROMAN CAPITALS;
- 2) subclauses, figures, tables and notes which are additional to those in Part 1 are numbered starting from 101.

The following dates were fixed:

- | | | |
|--|-------|------------|
| – latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement | (dop) | 2006-03-01 |
| – latest date by which the national standards conflicting with the EN have to be withdrawn | (dow) | 2008-06-01 |

Annex ZA has been added by CENELEC.

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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:

This International Standard 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 are:

- a) STERILIZERS and disinfectors using steam;
- b) STERILIZERS and disinfectors using toxic gas, toxic aerosol or toxic vapour;
- c) STERILIZERS and disinfectors using hot air or hot inert gas, and
- d) washer disinfectors.

1.1.2 Equipment excluded from scope

Add the following note to item g)

NOTE IEC 60601-1(definition 2.2.15 modified) 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.

Add the following new second paragraph:

This standard also does not apply to the following types of equipment:

- aa) equipment for use in hazardous gas atmospheres (see IEC 60079) except for an atmosphere created inside equipment by the use of a flammable sterilizing agent (see 13.0);
- bb) environmental cabinets (see IEC 61010-1);
- cc) laboratory equipment for the heating of materials for other purposes than sterilization or disinfection (see IEC 61010-2-010);
- dd) laundry equipment (see IEC 60335, Parts 2-4, 2-7, and 2-11, and ISO 10472), unless designed for disinfecting medical materials;
- ee) dishwashers (see IEC 60335, Parts 2-5 and 2-58).

1.2.1 Aspects included in scope

Replacement:

Replace item g) and the note by the following new text and note:

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

NOTE Attention is drawn to the existence of additional requirements which may be specified by national authorities responsible for the health and safety of labour forces. In particular, national and other regulations or codes apply for the safety of automatic loading and unloading systems.

1.2.2 Aspects excluded from scope

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.

2 Normative references

This clause of Part 1 is applicable except as follows:

Additions:

IEC 60079 (all parts), *Electrical apparatus for explosive gas atmospheres*

IEC 61770, *Electrical appliances connected to the water MAINS – Avoidance of back-siphonage and failure of hose-sets*

ISO 3585, *Borosilicate glass 3.3 – Properties*

ISO 6718, *Bursting discs and bursting disc devices*

3 Terms and definitions

This clause of Part 1 is applicable except as follows:

Addition:

3.2.101

CHAMBER

the 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 and which can also be used to deliver a sub-lethal process for the treatment of materials

3.2.104**PRESSURE VESSEL**

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

NOTE 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**

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

NOTE Loading and unloading are not part of the OPERATING CYCLE.

3.5.2**HAZARD**

Add the following new note:

NOTE 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.

4 Tests

This clause of Part 1 is applicable except as follows:

Additions:

4.3.2.3 Covers and removable parts

Add the following new second paragraph:

Covers 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.

4.3.2.11 Duty cycle

Add the following new second paragraph:

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

Add the following new subclause

4.3.2.101 Non-electrical supplies and systems

These shall be set to the least favourable RATED values.

4.4.2.4 Motors

Add the following new second paragraph:

If it is impracticable to test a motor in place, a separate identical motor shall be tested.

4.4.2.10 Heating devices

Add the following new item:

aa) loss of feed-water shall be simulated.

4.4.2.12 Interlocks

Add the following new third paragraph:

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

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 system 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 minute 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, 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:

Add the following new subclause:

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.

5.2 Warning markings

Replace the fifth paragraph by the following new paragraph:

Warning markings are specified in 5.1.5.1 c), 5.4.3 r), 6.1.2 b), 6.5.1.2 g), 6.6.2, 7.2 c), 7.3, 7.102 b), 7.102c), 10.1, the third paragraph (the first new additional paragraph) of Clause 9, 13.2.2, and 14.103.

5.4.1 General

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

- aa) if a PRESSURE VESSEL is an integral part of the equipment, a declaration that it complies with the PRESSURE VESSEL regulations and codes applicable in the country of intended use, as specified in 14.101;
- bb) if NORMAL USE involves the handling of hazardous substances, documentation shall include necessary information on its constituents.

5.4.2 Equipment ratings

Add the following new item to the first paragraph, after item e):

- aa) for each non-electrical supply, the RATED ranges of pressure and flow-rate.

5.4.3 Equipment installation

Replacement:

Replace the text of the subclause by the following:

Instructions shall include details of the following, if applicable:

- a) location and mounting instructions, including the space required for safe and efficient maintenance;
- b) individual weights of principal heavy subassemblies;
- c) overall weight and floor loading requirements;
- d) assembly instructions;
- e) MAINS supply requirements and connections, including the temperature RATING of any cable required to meet 5.1.8;
- f) for PERMANENTLY CONNECTED EQUIPMENT, requirements for any external switch or circuit-breaker (see 6.11.2.1) and external overcurrent protection devices (see 9.5.1) and a recommendation that the switch or circuit-breaker be near the equipment;
- g) ventilation and drainage requirements (see 11.101, 13.1.103.1 and Note 2 to 13.1.101.4);
- h) instructions for protective earthing;
- i) sound power data and requirements (see 12.5.1);
- j) requirements for special services, for example air, cooling liquid;
- k) requirements related to hazardous gas atmospheres (see 13.0);
- l) instructions to position the equipment so that it is not difficult to operate the disconnecting device;

- m) instructions relating to the handling and containment of hazardous substances, including any need for additional equipment that may be required to control emissions (see 11.101, 13.1.101.3. and the note to 13.1.104);
- n) a warning if a HAZARD could be caused by hot items falling from the equipment (see the third paragraph (the first new paragraph) of Clause 9);
- o) requirements for material used in the installation of the STERILIZER which may come in contact with sterilant (see 13.1.103.4 and 13.2.101).

Conformity is checked by inspection.

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);
 NOTE Such a ventilation system should 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 (see 13.1.101.2);
- 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 syphonage – see 11.104).

Conformity is checked by inspection.

5.4.4 Equipment operation

Replace the text by the following new text:

Instructions for use shall include, if applicable:

- 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 required by Part 1 and used on the equipment;
- 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))