SLOVENSKI PREDSTANDARD

OSIST prEN 61010-2-040:2004

april 2004

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

ICS 11.080.10

Referenčna številka
OSIST prEN 61010-2-040:2004(en)

66/339/CDV

COMMITTEE DRAFT FOR VOTE (CDV)
PROJET DE COMITÉ POUR VOTE (CDV)

	Project number Numéro de projet IEC 61010-2-040 Ed. 1.0	
IEC/TC or SC: **66** CEI/CE ou SC:	Date of circulation Date de diffusion **2004-02-13**	Closing date for voting (Voting mandatory for P-members) Date de clôture du vote (Vote obligatoire pour les membres (P)) **2004-07-16**
Titre du CE/SC: SECURITE DES APPAREILS DE MESURE, DE COMMANDE ET DE LABORATOIRE	TC/SC Title: Safety of measuring, control and laboratory equipment	
Secretary: Nick Bradfield (United Kingdom) Secrétaire:		
Also of interest to the following committees Intéresse également les comités suivants ISO/TC 198	Supersedes document Remplace le document 66/293/CD and 66/312/CC	
Functions concerned Fonctions concernées ☒ Safety / Sécurité ☐ EMC / CEM ☐ Environment / Environnement ☐ Quality assurance / Assurance qualité		

Titre : CEI 61010-2-040: Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire - Partie 2-040: Prescriptions particulières pour stérilisateurs et laveurs désinfecteurs utilisés pour traiter le matériel médical

Title : 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

Note d'introduction : Ce document consolide les exigences des quatre normes existantes, CEI 61010-2-041, -2-042, -2-043, & -2-045, et les alignent avec la 2e édition de la CEI 61010-1. Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire – Première partie : Prescriptions générales

Introductory note: This document consolidates the requirements of four existing standards, IEC 61010-2-041, -2-042, -2-043, & -2-045, and aligns them with the second edition of IEC 61010-1:Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

ATTENTION	ATTENTION
CDV soumis en parallèle au vote (CEI) et à l'enquête (CENELEC)	**Parallel IEC CDV/CENELEC Enquiry**

CONTENTS

INTERNATIONAL ELECTROTECHNICAL COMMISSION

____

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

FOREWORD

1) The IEC (International Electrotechnical Commission) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of the 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, the IEC publishes International Standards. 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. The IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
3) The documents produced have the form of recommendations for international use and are published in the form of standards, technical specifications, technical reports or guides and they are accepted by the National Committees in that sense.
4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
6) Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 61010-2-040 has been prepared by technical committee 66:

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

FDIS	Report on voting
XX/XX/FDIS	XX/XX/RVD

This document consolidates the requirements of four standards, IEC 61010-2-041, -2-042, -2-043, & -2-045, which are withdrawn and aligns them with the second edition of IEC 61010-1:Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

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.

The committee has decided that the contents of this publication will remain unchanged until ______. 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

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. Such equipment includes the following types:

a) sterilizers using steam within the absolute pressure range 0 to 500 kPa;

b) sterilizers using toxic gas, toxic aerosol, or toxic vapour as a sterilant within the absolute pressure range 0 to 700 kPa;

c) sterilizers operating at approximately atmospheric pressure and using hot air or hot inert gas;

d) washer disinfectors and other equipment which both washes and disinfects;

e) other types of sterilization and disinfection equipment.

1.1.2 Equipment excluded from scope

Add the following note to item g)

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.

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, *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:

Add the following five new subclauses:

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

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

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 for continuous operation shall 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 0.9 and 1.1 times the RATED voltage for one cycle. The voltage shall then be set to 0.9 of the RATED voltage for 5 min. The voltage shall then be reduced at a rate of 1 V per 5 s 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 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.

5.2 Warning markings

Replace the fifth paragraph by the following new paragraph:

Warning markings are specified in 5.1.5.1 c), 5.4.4 r), 6.1.2 b), 6.5.1.2 g), 6.6.2, 7.2 c), 7.3, 7.102 b), 10.1, paragraph two of 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 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 paragraph 3 of clause 9).

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;

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))

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 may include any special methods of interpreting data recorded or noted during the OPERATING CYCLE , to detect failure or trends that may 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 may 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 of Table 15;