SLOVENSKI STANDARD
oSIST prEN IEC 61010-2-040:2019

01-december-2019

Varnostne zahteve za električno opremo za meritve, nadzor in laboratorijsko uporabo - 2-040. del: Posebne zahteve za sterilizatorje in pralnike-dezinfektorje, ki se uporabljajo za obdelavo medicinskih materialov

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

Ta slovenski standard je istoveten z: **prEN IEC 61010-2-040:2019**

ICS:

11.080.10	Sterilizacijska oprema	Sterilizing equipment
19.080	Električno in elektronsko preskušanje	Electrical and electronic testing
71.040.10	Kemijski laboratoriji. Laboratorijska oprema	Chemical laboratories. Laboratory equipment

oSIST prEN IEC 61010-2-040:2019 **en,fr,de**

IEC®

66/699/CDV

COMMITTEE DRAFT FOR VOTE (CDV)

PROJECT NUMBER: **IEC 61010-2-040 ED3**	
DATE OF CIRCULATION: **2019-10-04**	CLOSING DATE FOR VOTING: **2019-12-27**
SUPERSEDES DOCUMENTS: **66/696/RR**	

IEC TC 66 : SAFETY OF MEASURING, CONTROL AND LABORATORY EQUIPMENT			
SECRETARIAT: United Kingdom		SECRETARY: Mr David Hyde	
OF INTEREST TO THE FOLLOWING COMMITTEES: SC 62D		PROPOSED HORIZONTAL STANDARD: ☐ Other TC/SCs are requested to indicate their interest, if any, in this CDV to the secretary.	
FUNCTIONS CONCERNED: ☐ EMC	☐ ENVIRONMENT	☐ QUALITY ASSURANCE	☒ SAFETY
☒ SUBMITTED FOR CENELEC PARALLEL VOTING		☐ NOT SUBMITTED FOR CENELEC PARALLEL VOTING	
Attention IEC-CENELEC parallel voting The attention of IEC National Committees, members of CENELEC, is drawn to the fact that this Committee Draft for Vote (CDV) is submitted for parallel voting. The CENELEC members are invited to vote through the CENELEC online voting system.			

This document is still under study and subject to change. It should not be used for reference purposes.

Recipients of this document are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

TITLE:

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

PROPOSED STABILITY DATE: 2023

NOTE FROM TC/SC OFFICERS:

This CDV is intended only to align IEC 61010-2-040:2015 with IEC 61010-1:2010 and its amendment 1:2016 and provide minor editorial corrections. With this revision IEC 61010-2-040 will be in line with

the latest requirements of IEC 61010-1 + A1.

This document contains no technical changes to already accepted base documents (IEC 61010-1:2010 and its amendment 1:2016 and IEC 61010-2-040:2015) but two;

1. Clause 6.8.3.1 is modified because otherwise it would need a specific European deviation in order to be harmonised to the LVD 2014/35/EU (ref. NAC assessment of IEC 61010-1/A1).

2. In 15.1 as an alternative method, for interlock systems containing electric/electronic or programmable components (E/E/P components) the reliability and design requirements can be determined by applying, for example IEC 62061 (SIL) or ISO 13849 (PL).

Further technical development is reserved for a new amendment or edition to be initiated separately as necessary.

This alignment is realised as a new 3rd edition of IEC 61010-2-040 simply because of document control; the previous edition 2.0 is based on the third edition of IEC 61010-1:2010 (without the Amendment 1:2016) and amending it to incorporate the contents of IEC 61010-1 Amendment 1 would need an unnecessary repeating of the requirements in that amendment 1 that are not particular for the equipment in the scope of IEC 61010-2-040 . Furthermore, technically, one would need to follow 4 documents in parallel to get the full text of this part 2 (61010-1:2010, 61010-1 A1:2016, 61010-2-040:2015, and 61010-2-040 A1).With this approach, and when the consolidated version of IEC 61010-1:2010/A1:2016 conveniently is published, only two documents are needed.

CONTENTS

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.

2) The formal decisions or agreements of 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 IEC National Committees.

3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.

4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.

5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.

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

7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.

8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.

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.

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) Adaptation of text changes introduced by Amendment 1 of IEC 61010-1:2010;

c) Added tolerance for stability of a.c. voltage test equipment to Clause 6.8.3.1;

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

FDIS	Report on voting
66/xxx/FDIS	66/xxx/RVD

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 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 the latest edition of 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 applicable. 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 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*

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.

4.4.2.1 General

Replacement:

Replace the first sentence of the first paragraph bythe following sentence:

Fault conditions shall include those specified in 4.4.2.2 to 4.4.2.14 and 4.4.2.101 to 4.4.2.103.

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.