

Safety requirements for electrical equipment for measurement, control, and laboratory use —

**Part 2-045: Particular requirements for
washer disinfectors used in medical,
pharmaceutical, veterinary and
laboratory fields**

The European Standard EN 61010-2-045:2000 has the status of a
British Standard

ICS 11.080.20

National foreword

This British Standard is the official English language version of EN 61010-2-045:2000. It is identical with IEC 61010-2-045:2000.

The UK participation in its preparation was entrusted by Technical Committee LBI/35, Sterilizers, autoclaves and disinfectors, to Subcommittee LBI/35/1, Sterilizers — Electrical and operator safety, which has the responsibility to:

- aid enquirers to understand the text;
- present to the responsible international/European committee any enquiries on the interpretation, or proposals for change, and keep the UK interests informed;
- monitor related international and European developments and promulgate them in the UK.

A list of organizations represented on this subcommittee can be obtained on request to its secretary.

This British Standard supersedes some provisions of BS 2745-1:1993, which is subject to amendment. In the interim period, the requirements of this British Standard override any conflicting requirements of BS 2745-1.

This British Standard is to be read in conjunction with BS EN 61010-1:1993 *Safety requirements for electrical equipment for measurement, control, and laboratory use, Part 1: General requirements*, which it supplements or modifies as detailed in the Foreword to EN 61010-2-045.

Cross-references

The British Standards which implement these international or European publications may be found in the BSI Standards Catalogue under the section entitled “International Standards Correspondence Index”, or by using the “Find” facility of the BSI Standards Electronic Catalogue.

Additional Information. Subclauses or figures which are additional to those in BS EN 61010-1:1993 are numbered starting from 101.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

This British Standard, having been prepared under the direction of the Sector Committee for Materials and Chemicals, was published under the authority of the Standards Committee and comes into effect on 15 July 2001

Summary of pages

This document comprises a front cover, an inside front cover, the EN title page, pages 2 to 27 and a back cover.

The BSI copyright date displayed in this document indicates when the document was last issued.

Amendments issued since publication

Amd. No.	Date	Comments

© BSI 07-2001

ISBN 0 580 37587 0

**Safety requirements for electrical equipment for measurement,
control, and laboratory use**
**Part 2-045: Particular requirements for washer disinfectors
used in medical, pharmaceutical, veterinary and laboratory fields**
(IEC 61010-2-045:2000)

Règles de sécurité pour appareils
électriques de mesure, de régulation et
de laboratoire
Partie 2-045: Prescriptions particulières
pour appareils de désinfection/lavage
utilisés dans les domaines médical,
pharmaceutique, vétérinaire et en
laboratoire
(CEI 61010-2-045:2000)

Sicherheitsbestimmungen für elektrische
Mess-, Steuer-, Regel- und Laborgeräte
Teil 2-045: Besondere Anforderungen an
Reinigungs-/Desinfektionsgeräte für
medizinische, pharmazeutische,
veterinäre und Laboranwendungen
(IEC 61010-2-045:2000)

This European Standard was approved by CENELEC on 2000-11-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 66/229/FDIS, future edition 1 of IEC 61010-2-045, 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 61010-2-45 on 2000-11-01.

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) 2001-08-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2003-11-01

This part 2-045 is to be used in conjunction with EN 61010-1:1993 and its amendment A2:1995, Safety requirements for electrical equipment for measurement, control and laboratory use -- Part 1: General requirements.

This part 2-045 supplements or modifies the corresponding clauses of EN 61010-1.

Where a particular clause or subclause of part 1 is not mentioned in this part 2-045, that clause or subclause applies as far as is reasonable. Where this part 2-045 states "addition", "modification" or "replacement", the relevant text of part 1 is to be adapted accordingly.

In this standard, 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.

Subclauses which are additional to those in part 1 are numbered starting from 101.

Annexes designated "normative" are part of the body of the standard.

Annexes designated "informative" are given for information only.

In this standard, annex ZA normative and annex L and M are informative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61010-2-045:2000 was approved by CENELEC as a European Standard without any modification.

In the official version, for annex L, Bibliography, the following note has to be added for the standard indicated:

IEC 60230¹⁾ NOTE: Harmonized as HD 48 S1:1977 (not modified).

¹⁾ IEC 60230 was issued in 1966.

CONTENTS

	Page
INTRODUCTION	4
Clause	
1 Scope and object	5
2 Normative references.....	5
3 Definitions	6
4 Tests	7
5 Marking and documentation	9
6 Protection against electric shock.....	13
7 Protection against mechanical hazards	14
8 Mechanical resistance to shock and impact	18
9 Equipment temperature limits and protection against the spread of fire	18
10 Resistance to heat.....	19
11 Protection against hazards from fluids	19
12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure	21
13 Protection against liberated gases, explosion and implosion, and pathogenic substances.....	21
14 Components	22
15 Protection by interlocks.....	24
16 Measuring circuits.....	25
Annexes	26
Annex ZA (normative) Normative references to international publications with their corresponding European publications	27

INTRODUCTION

Washer disinfector equipment can be potentially hazardous in its construction and requires additional safety requirements to those given in part 1 and its amendments 1 and 2.

Other existing national and international standards and regulations also need to be considered since they may supplement this standard.

SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT FOR MEASUREMENT, CONTROL, AND LABORATORY USE –

Part 2-045: Particular requirements for washer disinfectors used in medical, pharmaceutical, veterinary and laboratory fields

1 Scope and object

This clause of part 1 is applicable except as follows:

1.1 Scope

Replacement:

This International Standard applies to WASHER DISINFECTORS and other equipment incorporating washing and disinfection processes for the treatment of soiled items used in the medical, veterinary, pharmaceutical, and laboratory fields.

NOTE This equipment may have one or more CHAMBERS and a loading and unloading system.

1.1.1 Aspects excluded from scope

Addition:

- EMC requirements, which are covered by IEC 61326-1.

1.1.2 Equipment excluded from scope

Addition:

Add two new dashes as follows:

- laundry equipment;
- dishwashers.

1.2 Object

Replacement:

Replace the sixth dash by the following:

- liberated gases, and pathogenic substances, explosion and implosion (see clause 13).

2 Normative references

This clause of IEC 61010-1:1990 (including its amendments 1:1992 and 2:1995) is applicable except as follows:

Addition:

2.1 IEC standards

60073:1996, *Basic and safety principles for man-machine interface, marking and identification – Coding principles for indication devices and actuators*

60252:1993, *AC motor capacitors*

61326-1:1997, *Electrical equipment for measurement control and laboratory use – EMC requirements – Part 1: General requirements*

61770:1998, *Electrical appliances connected to the water mains – Avoidance of back-siphonage and failure of hose-sets*

3 Definitions

This clause of part 1 is applicable except as follows:

3.1 Equipment and states of equipment

Additional definitions:

3.1.101

WASHER DISINFECTOR

equipment intended to clean and disinfect medical devices and other articles used in the context of medical, dental, pharmaceutical and veterinary practice

3.1.102

operating cycle

complete set of stages of the process that is carried out in a sequence regulated by the AUTOMATIC CONTROLLER

NOTE Most WASHER DISINFECTORS also permit operation under manual control.

3.2 Parts and accessories

3.2.101

AUTOMATIC CONTROLLER

device that, in response to predetermined cycle variables, operates the equipment sequentially through the stages of the process

3.2.102

CHAMBER

that part of the equipment in which the LOAD is processed

3.2.103

LOAD

items to be processed through an OPERATING CYCLE

NOTE Where the word 'load' appears in part 1 (in lower case), it does not have the meaning of the above definition.

3.2.104

PRESSURE VESSEL

container designed to retain a gas or liquid at a pressure above or below atmospheric pressure

3.2.105

DOOR

lid or similar device provided as a means of either closing or closing and sealing an opening to a CHAMBER

4 Tests

This clause of part 1 is applicable except as follows:

4.3.2 State of equipment

In the first paragraph, replace 4.3.16 by 4.3.101.

4.3.9 Controls

Replacement:

Replace the text by the following:

Controls which an OPERATOR can adjust by hand shall be set to any position except that mains selection devices shall be set to the correct values.

Additional subclauses:

4.3.13.101 Continuous operation

Equipment for continuous operation shall be tested without any interval between consecutive OPERATING CYCLES.

NOTE This is to allow for thermal stabilization prior to testing.

4.3.101 Non-electrical supplies and systems

These shall be set to the least favourable values specified in the manufacturer's instructions.

4.4.2.2 Protective conductor

Replacement:

Replace the text by the following text:

The protective conductor shall be interrupted, except for PERMANENTLY CONNECTED EQUIPMENT or equipment whose protective conductor and its connection meet the HIGH INTEGRITY requirements of 14.6. A connector in accordance with IEC 60309 is considered to meet these requirements.

NOTE Other plugs and sockets are described in IEC Technical Report 60083:1997, *Plugs and socket-outlets for domestic and similar general use standardized in member countries of the IEC*.

4.4.2.4 Motors

Add the following new sentence:

If it is impracticable to stop a motor quickly, an identical motor can be tested separately.