

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

**Part 2-042: Particular requirements for
autoclaves and sterilizers using toxic
gas for the treatment of medical
materials, and for laboratory processes**

The European Standard EN 61010-2-042:1997 has the status of a
British Standard

ICS 11.080

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ISBN 0 580 27585 X

Amendments issued since publication

Amd. No.	Date	Comments

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National foreword

This British Standard is the English language version of EN 61010-2-042:1997. It is identical with IEC 61010-2-042:1997.

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 Parts 1 and 6 of BS 3970, which are subject to amendment. In the interim period, the requirements of this British Standard override any conflicting requirements of BS 3970.

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 61010-2-042.

Cross-references

Attention is drawn to the fact that Annex ZA lists normative references to international publications with their corresponding European publications. 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 using the “Find” facility of the BSI Standards Electronic Catalogue.

Additional information. The following print types are used in this standard:

requirements and definitions:	in roman type;
test procedures:	<i>in italic type;</i>
explanatory text:	in small roman type;
terms defined in clause 3:	IN SMALL CAPITALS.

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.

Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, the EN title page, pages 2 to 16, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

ICS 11.080

Descriptors: Safety, electrical equipment, autoclaves, sterilizers, toxic gas, treatment of medical materials, laboratory process

English version

**Safety requirements for electrical equipment for
measurement, control, and laboratory use
Part 2-042: Particular requirements for autoclaves and
sterilizers using toxic gas for the treatment of medical
materials, and for laboratory processes**

(IEC 61010-2-042:1997)

Règles de sécurité pour appareils
électriques de mesurage, de régulation
et de laboratoire
Partie 2-042: Prescriptions particulières
pour autoclaves et stérilisateur utilisant
des gaz toxiques pour le traitement des
matériels à usage médical et durant les
procédés de traitement de laboratoire
(CEI 61010-2-042:1997)

Sicherheitsbestimmungen für elektrische
Meß-, Steuer-, Regel und Laborgeräte
Teil 2-042: Besondere Anforderungen
an Autoklaven und Sterilisatoren bei
Verwendung toxischer Gase zur
Behandlung medizinischer Materialien
und für Laboranwendungen
(IEC 61010-2-042:1997)

This European Standard was approved by CENELEC on 1997-03-11. 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, 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

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Foreword

The text of document 66/154/FDIS, future edition 1 of IEC 61010-2-042, 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 61010-2-042 on 1997-03-11.

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) 1998-01-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 1998-01-01

For products which have complied with the relevant national standard before 1998-01-01, as shown by the manufacturer or by a certification body, this previous standard may continue to apply for production until 2003-01-01.

This part 2 supplements or modifies the corresponding clauses of EN 61010-1:1993. Where a particular clause or subclause of part 1 is not mentioned in this part 2, that clause or subclause applies as far as is reasonable. Where this part 2 states “addition”, “modification” or “replacement”, the relevant text of part 1 is to be adapted accordingly.

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.

In this standard, Annex ZA is normative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61010-2-042:1997 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 60073 NOTE Harmonized as EN 60073:1993, which is superseded by EN 60073:1996 (not modified).

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Introduction

Sterilizing equipment utilizing toxic gas, above or below atmospheric pressure, has many potentially hazardous parts in its construction which require additional safety requirements to those given in IEC 61010-1. These particularly include protection of the OPERATOR and surroundings against the unintentional escape of toxic gas.

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

1 Scope and object

This clause of part 1 is applicable except as follows:

1.1 Scope

Replacement:

This standard applies to AUTOCLAVES and STERILIZERS, including those with an automatic loading and unloading system, which incorporate a CHAMBER using toxic gas intended for the treatment of medical materials, and for laboratory processes, for example for sterilization.

NOTE 1 National and other regulations or codes apply for the safety of automatic loading and unloading systems.

NOTE 2 In general it is considered that automatic control of the sterilization cycle is essential for the safe operation of equipment using toxic gases because a manual control system might present serious hazards (see 1.2) to the OPERATOR.

NOTE 3 The principal sterilant gases in use are ethylene oxide and formaldehyde.

NOTE 4 For some applications, the CHAMBER may be operated at a pressure above or below atmospheric pressure.

NOTE 5 All pressures are specified in absolute terms. Atmospheric pressure (1 bar) $\geq$ 100 kPa.

NOTE 6 The word AUTOCLAVES includes STERILIZERS unless specifically stated otherwise.

Where an AUTOCLAVE incorporates a steam generator having its own PRESSURE VESSEL within the same enclosure for the purpose of humidifying the LOAD, the applicable safety requirements specified in this standard apply also to the steam generator.

1.1.2 Equipment excluded from the scope

Modification:

Add the following text at the end of the last dash:

except for an atmosphere created by the AUTOCLAVE itself (see 13.2.103.1).

Addition:

Add the following new dash and notes:

— environmental cabinets.

NOTE 1 Since all AUTOCLAVES covered by this part 2 use toxic gas, other types using only steam or dry heat for sterilization are not included.

NOTE 2 This standard does not deal with special requirements for washer disinfectors, nor with protection against high-risk microbiological hazards associated with the LOAD, nor with requirements for the design of the PRESSURE VESSEL itself.

1.2 Object

Modification:

Insert in the sixth dash after the word “gases” the following text:

(including the non-intentional escape of toxic gas)

1.4 Environmental conditions

Replacement:

Replace the first dash by the following:

— indoor use, and outdoor use if specified by the manufacturer (see 11.6 of part 1).

2 Normative references

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

Additions:

2.1 IEC standards

60079: *Electrical apparatus for explosive gas atmospheres.*

2.2 ISO standards

6718:1991, *Bursting discs and bursting disc devices.*

3 Definitions

This clause of part 1 is applicable except as follows:

3.1 Equipment and states of equipment

Additional definitions:

3.1.101 AUTOCLAVE

Equipment which incorporates a PRESSURE VESSEL or vacuum vessel for the purpose of subjecting a LOAD to a prescribed set of conditions, for example for sterilization.

3.1.102 OPERATING CYCLE

The complete set of stages of the process that is carried out in a preset sequence normally regulated by an AUTOMATIC CONTROLLER.

3.2 Parts and accessories

Additional definitions:

3.2.101 AUTOMATIC CONTROLLER

Device which causes an AUTOCLAVE to carry out an OPERATING CYCLE at preset conditions of time, temperature, pressure, sterilant gas concentration, etc.

3.2.102 CHAMBER

Part of an AUTOCLAVE which receives the LOAD and in which the process takes place.

3.2.103 LOAD

Equipment and materials put into an AUTOCLAVE to be processed through an OPERATING CYCLE.