

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

Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

The European Standard EN 61010-2-101:2002 has the status of a
British Standard

ICS 11.040.55; 19.080

National foreword

This British Standard is the official English language version of EN 61010-2-101:2002. It was derived by CENELEC from IEC 61010-2-101:2002.

The CENELEC common modifications have been implemented at the appropriate places in the text and are indicated by tags (e.g. [C] [CI]).

The UK participation in its preparation was entrusted to Technical Committee LBI/40, Electrical laboratory equipment, 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 committee can be obtained on request to its secretary.

This British Standard is to be read in conjunction with BS EN 61010-1:2001 *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 61010-2-101.

Cross-references

The British Standards which implement international or European publications referred to in this document may be found in the *BSI Catalogue* under the section entitled “International Standards Correspondence Index”, or by using the “Search” facility of the *BSI Electronic Catalogue* or of British Standards Online.

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This British Standard, having been prepared under the direction of the Materials and Chemicals Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 9 December 2002

Summary of pages

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Amendments issued since publication

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**Safety requirements for electrical equipment for measurement,
control, and laboratory use**
**Part 2-101: Particular requirements for in vitro diagnostic (IVD)
medical equipment**
(IEC 61010-2-101:2002, modified)

Règles de sécurité pour appareils
électriques de mesure, de régulation
et de laboratoire
Partie 2-101: Prescriptions particulières
pour les appareils médicaux
de diagnostic in vitro (DIV)
(CEI 61010-2-101:2002, modifiée)

Sicherheitsbestimmungen für elektrische
Mess-, Steuer-, Regel- und Laborgeräte
Teil 2-101: Besondere Anforderungen an
In-Vitro-Diagnostik-(IVD)-Medizingeräte
(IEC 61010-2-101:2002, modifiziert)

This European Standard was approved by CENELEC on 2002-09-01. 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, Hungary, Iceland, Ireland, Italy, Luxembourg, Malta, Netherlands, Norway, Portugal, Slovakia, 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 66/261/FDIS, future edition 1 of IEC 61010-2-101, prepared by IEC TC 66, Safety of measuring, control, and laboratory equipment, together with common modifications prepared by CLC/SR 66 following deliberations in CLC/BTTF 88-1, was submitted to the Unique Acceptance Procedure and was approved by CENELEC as EN 61010-2-101 on 2002-09-01.

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) 2003-09-01
- latest date by which the national standards conflicting
with the EN have to be withdrawn (dow) 2005-09-01

This Part 2-101 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 2-101 supplements or modifies the corresponding clauses of EN 61010-1 so as to convert it into the European Standard: Safety requirements for in vitro diagnostic (IVD) medical equipment.

Where a particular clause or subclause of Part 1 is not mentioned in this Part 2-101, that clause or subclause applies as far as is reasonable. Where this Part 2-101 states "addition", "modification" or "replacement", 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 smaller roman type;
 - *conformity and test: in italic type*;
 - terms used throughout this standard which have been defined in clause 3: SMALL ROMAN CAPITALS.
- 2) subclauses or figures which are additional to those in Part 1 are numbered starting from 101, the additional annexes are lettered AA, BB, etc.

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

Annexes designated "informative" are given for information only.

In this standard, annexes AA and ZA are normative and annex BB is informative.

Annex ZA has been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 61010-2-101:2002 was approved by CENELEC as a European Standard with agreed common modifications.

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

Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

1 Scope and object

This clause of part 1 is applicable except as follows:

1.1 Scope

Replacement:

This part 2 applies to equipment intended for in vitro diagnostic (IVD) medical purposes, including self-test IVD medical purposes.

IVD medical equipment, whether used alone or in combination, is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue samples, derived from the human body, solely or principally for the purpose of providing information concerning one or more of the following:

- a physiological or pathological state; or
- a congenital abnormality;
- the determination of safety and compatibility with potential recipients;
- the monitoring of therapeutic measures.

Self-test IVD medical equipment is intended by the manufacturer for use by lay persons in a home environment.

NOTE If all or part of the equipment falls within the scope of one or more other part 2 standards of IEC 61010 as well as within the scope of this standard, it will also need to meet the requirements of those other part 2 standards.

1.1.2 Equipment excluded from scope

Addition:

Add the following second paragraph:

Products for general laboratory use are not IVD medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.

1.2 Object

1.2.1 Aspects included in scope

Replacement:

Replace the first sentence by the following:

The purpose of the requirements of this standard is to ensure that the design and the methods of construction used provide a high degree of protection at a TOLERABLE RISK for the OPERATOR and the surrounding area, using RISK management where appropriate (see annex AA).

Addition:

Add two new items:

- h) biohazards;
- i) hazardous chemical substances.

1.2.2 Aspects excluded from scope

Addition:

Add a new item and the following note:

- g) the handling or manipulation outside the equipment of material under analysis.

NOTE Requirements covering these subjects are the responsibility of committees preparing relevant standards.

2 Normative references

This clause of part 1 is applicable except as follows:

Additions:

ISO 14971:2000, *Medical devices – Application of risk management to medical devices*

3 Terms and definitions

This clause of part 1 is applicable except as follows:

3.1 Equipment and states of equipment

Additional definitions:

3.101

HARM

physical injury or damage to the health of people, or damage to property or the environment

[ISO/IEC Guide 51:1999, definition 3.3]

3.102

RISK

combination of the probability of occurrence of HARM and the severity of that HARM

[ISO/IEC Guide 51:1999, definition 3.2]

3.103

TOLERABLE RISK

RISK which is accepted in a given context based on the current values of society

[ISO/IEC Guide 51:1999, definition 3.7]

NOTE 1 TOLERABLE RISK is the result of a balance between the ideal of absolute safety, the demands to be met by a product, process or service, and factors such as benefit to the user, suitability of purpose, cost effectiveness, RISK evaluation, conventions of the society concerned, and the state of the art.

NOTE 2 The term "acceptable risk" is used in ISO 14971 in the same sense as TOLERABLE RISK.

3.104

REASONABLY FORESEEABLE MISUSE

use of a product, process or service in a way not intended by the supplier, but which may result from readily predictable human behaviour

[ISO/IEC Guide 51:1999, definition 3.14]

3.105

PERMANENTLY AFFIXED

removable only with a TOOL or by appreciable force and able to withstand the effects of temperature, rubbing, common solvents, reagents and vapours encountered during normal use

3.106

MARKING

inscription, in writing or as a graphical symbol, PERMANENTLY AFFIXED to a product

4 Tests

This clause of part 1 is applicable except as follows:

4.4.1 General

Replacement:

Replace item a) of the first paragraph by:

- a) Equipment and circuit diagrams shall be examined to determine the fault conditions which could arise in NORMAL USE and REASONABLY FORESEEABLE MISUSE, and which could cause a HAZARD.

Deletion:

Delete the first dash.