PUBLISHED DOCUMENT

PD IEC TR 61010-3-043: 2002

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

Part 3-043: Conformity verification report for IEC 61010-2-043:1997 — Particular requirements for dry heat sterilizers using either hot air or hot inert gas for treatment of medical materials and for laboratory processes

ICS 11.080.10; 13.260

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National foreword

This Published Document reproduces verbatim IEC TR 61010-3-043:2001.

The UK participation in its preparation was entrusted to Technical Committee EPL/66, Safety requirements for electronic measuring instruments, 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.

From 1 January 1997, all IEC publications have the number 60000 added to the old number. For instance, IEC 27-1 has been renumbered as IEC 60027-1. For a period of time during the change over from one numbering system to the other, publications may contain identifiers from both systems.

Cross-references

The British Standards which implement international publications referred to in this document 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.

This publication is not to be regarded as a British Standard.

This Published Document, having been prepared under the direction of the Electrotechnical Sector Policy and Strategy Committee, was published under the authority of the Standards Policy and Strategy Committee on 8 February 2002

Summary of pages

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TECHNICAL REPORT

IEC TR 61010-3-043

First edition
2001-08

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

Part 3-043: Conformity verification report for IEC 61010-2-043:1997 – Particular requirements for dry heat sterilizers using either hot air or hot inert gas for treatment of medical materials and for laboratory processes

Règles de sécurité pour appareils électriques de mesurage, de régulation et de laboratoire –

Partie 3-043: Rapport de vérification de la conformité de la CEI 61010-2-043:1997 – Prescriptions particulières pour les stérilisateurs à chaleur utilisant de l'air chaud ou un gaz inerte chaud pour le traitement des matériels à usage médical et durant les procédés de traitement de laboratoire

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

Part 3-043: Conformity verification report for IEC 61010-2-043:1997– Particular requirements for dry heat sterilizers using either hot air or hot inert gas for treatment of medical materials and for laboratory processes

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.
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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.
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Technical reports do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

IEC 61010-3-043, which is a technical report, has been prepared by IEC technical committee 66: Safety of measuring, control, and laboratory equipment.

The text of this technical report is based on the following documents:

Committee draft	Report on voting
66/223/CDV	66/230/RVC

Full information on the voting for the approval of this technical report can be found in the report on voting indicated in the above table.

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This publication has been drafted in accordance with the ISO/IEC Directives, Part 3.

This report is a Technical Report and is of a purely informative nature and is therefore by itself not to be regarded as an International Standard. It is for use by test houses and other users to assist them with determining and recording verification of conformity of the equipment under test with the requirements of:

IEC 61010-2-043: 1997

and

IEC 61010-1:1990 + amendment 1:1992 + amendment 2:1995

The protocol for completion of this report is contained in publication IEC 61010-3:1997.

The IEC sells read-only PDF files as a general rule. In the present instance, and quite exceptionally, to enable the user to fill in the forms, a revisable file is included in a pocket affixed to the back cover of this publication.

This file can also be downloaded from the Web as a PDF file. There is, however, at the end of the document, a revisable file containing the forms. Please use the zip/unzip function.

A bilingual version will not be issued.

A French version may be issued.

The committee has decided that the contents of this publication will remain unchanged until 2004. At this date, the publication will be

- reconfirmed;
- withdrawn;
- replaced by a revised edition, or
- amended.

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Conformity Verification Report **IEC 61010-2-043** **Safety requirements for electrical equipment for measurement, control, and laboratory use –** **Part 2-043: Particular requirements for dry heat sterilizers** **using either hot air or hot inert gas for treatment of** **medical materials, and for laboratory processes**	
Report reference No.....: Compiled by (+ signature).....: Approved by (+ signature).....: Date of issue.....:	
Testing organization.....: Address.....: Testing location .....:	
Applicant.....: Address.....:	
Standard.....:	IEC 61010-2-043:1997 and IEC 61010-1:1990 + amendment 1:1992 + amendment 2:1995
Copyright blank test report...:	This report has been prepared by IEC/TC 66, which retains responsibility for any changes or corrections required.
Test procedure.....: Procedure deviation.....: Non-standard test method.....:	
Type of item tested.....:	☐ Laboratory
Trademark..... .....: Model/type reference.....: Manufacturer.....: Rating.....:	
Copy of rating plate:	

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Description of equipment function.....:

INSTALLATION/OVERVOLTAGE CATEGORY:

POLLUTION DEGREE:

Environmental rating: ☐ Standard ☐ Other (specify):

Equipment mobility: ☐Portable ☐Hand-held ☐ Floorstanding ☐ Fixed
☐ Built in ☐Benchmounted ☐Other (specify):

Connection to mains supply: ☐ Permanent ☐Detachable ☐ Non-detachable ☐ None

Operating conditions: ☐Continuous ☐Short-time ☐ Intermittent

Overall size of the equipment (Length x Width x Height):

Mass of the equipment (kg):

Marked degree of protection to IEC 60529: IP___ ___

Accessories and detachable parts included in the evaluation:

Options:

NOTE "(see form A.X)" refers to a form appended to the report.

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Table 1 – Documents attached to this report

Document No	Document description	Number of pages

Documents
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Table 2 – Test equipment list

Item	Type	Equipment No.	Calibration date		Comments
			Last[1)]	Due	

[1)] or interval between calibrations.

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Table 3 – List of components relied on for safety

Unique component reference or location (including drawing reference if required)	Application/Function	Manufacturer and part number (note 1)	RATING (note 2)	Licence number, file number or other documentary evidence of acceptance

NOTE 1 List all manufacturers concerned.

NOTE 2 Electrical, mechanical, flammability, etc.

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Clause Subclause	Requirement	Result	Comments
5	**Marking and documentation**		
5.1.1	**General**		
	Required equipment markings are:		
	a) visible:		
	– from the exterior		
	or		
	– after removing a cover		
	or		
	– opening a door		
	or		
	– after removal from a rack or panel		
	b) not put on parts which can be removed by an OPERATOR		
	c) Letter symbols (IEC 60027) used		
	d) Graphic symbols (IEC 61010-1, Table 1) used		
5.1.2	**Identification**		
	Equipment is identified by:		
	– manufacturer's name or registered trade mark		
	– model number, name or other means		
5.1.3	**Mains supply**		
	Equipment is marked as follows:		
	a) nature of supply:		
	– a.c. RATED mains frequency or range of frequencies		
	– d.c. with symbol 1		
	b) RATED supply voltage(s) or range		
	c) – maximum RATED power (W or VA) or input current		
	If more than one voltage range:		
	– separate values marked		
	or		
F	– values differ by less than 20 % (see Form A.3)		
	d) OPERATOR – set for different RATED supply voltages:		
	– indicates the equipment set voltage		
	– PORTABLE EQUIPMENT indication is visible from the exterior		
	– changing the setting changes the indication		

Result: P = Pass F = Fail NA = Not Applicable

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Clause Subclause	Requirement	Result	Comments
	e) Accessory mains socket-outlets accepting standard mains plugs are marked:		
	– with the voltage, if it is different from the mains supply voltage		
	– for use only with specific equipment		
	If not marked for specific equipment, it is marked with:		
	– the maximum RATED current or power, and maximum permitted leakage current or		
	– symbol 14 with full details in the documentation		
F	The measured value not more than 110 % (see Form A.3)		
5.1.4	**Fuses**		
	OPERATOR replaceable fuse marking (see also 5.4.5)		
5.1.5	**Measuring circuit TERMINALS**		Not applicable
5.1.6	**TERMINALS and operating devices**		
	Where necessary for safety, indication of purpose of TERMINALS, connectors, controls and indicators		
	Mains supply TERMINALS identified		
	Power supply switch on or off position marked if used as disconnecting device		
	TERMINAL marking:		
	a) FUNCTIONAL EARTH TERMINALS		
	b) PROTECTIVE CONDUCTOR TERMINALS:		
	– symbol 6 is placed close to or on the TERMINAL or		
	– part of appliance inlet		
	c) TERMINALS of measuring and control circuits		
	d) TERMINALS supplied from the interior		
	e) ACCESSIBLE FUNCTIONAL EARTH TERMINALS		
	aa) NORMAL USE setting a control could cause a hazard, an indicating device is provided		
5.1.7	**Equipment protected by DOUBLE INSULATION or REINFORCED INSULATION**		
	Protected throughout (symbol 11 used)		
	Only partially protected (symbol 11 not used)		

Result: P = Pass F = Fail NA = Not Applicable

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Clause Subclause	Requirement	Result	Comments
5.1.8	**Battery charging**		
	Equipment with means to charge re-chargeable batteries is marked:		
	– to warn against the charging of non-rechargeable batteries		
	– to indicate the type of rechargeable battery used		
5.2	**Warning markings**		
	– visible when ready for NORMAL USE		
	– if necessary, marked with symbol 14		
	– are near or on applicable parts		
	– statement to isolate or disconnect		
	– advice how to avoid contact with ACCESSIBLE HAZARDOUS LIVE parts		
	– easily touched high temperature parts (symbol 13)		
	– if lockable door, to lock and retain key		
	– load type		
5.2.101	**Equipment with high ACCESSIBLE current**		
	If equipment must be permanently connected to protect against high ACCESSIBLE current, a warning marking is provided		
5.2.102	**Hot items falling out of equipment**		
	If hot items can fall onto the equipment support surface, a warning marking is provided		
5.3	**Durability of markings**		
F	The required markings remain clear and legible in NORMAL USE (see Form A.4)		
5.4	**Documentation**		
5.4.1	**General**		
	Equipment is accompanied by documentation which includes:		
	– technical specification		
	– instructions for use		
	– name and address of manufacturer or supplier		
	Definition of INSTALLATION CATEGORY		
	Warning statements and a clear explanation of warning symbols:		
	– provided in the documentation or		
	– information is marked on the equipment		

Result: P = Pass F = Fail NA = Not Applicable

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Clause Subclause	Requirement	Result	Comments
	– instructions on warning signs for country of use		
5.4.2	**Equipment RATINGS**		
	Documentation includes:		
	– supply voltage or voltage range		
	– frequency or frequency range		
	– power or current RATING		
	– a description of all input and output connections		
	– RATING of insulation of external circuits, when such circuits are nowhere ACCESSIBLE		
	– statement of the range of environmental conditions		
5.4.3	**Equipment Installation**		
	Instructions include:		
	– location and mounting instructions including space for maintenance		
	– individual weights of principle heavy subassemblies		
	– assembly instructions		
	– main supply requirements and connections		
	– ventilation		
	– protective earthing		
	– sound power data requirements		
	– requirements for special services		
5.4.3.101	**Drying-out**		
	After transport or storage in humid conditions, equipment could fail to meet the requirements in the standard; instructions shall include a warning		
5.4.4	**Equipment operation**		
	Instructions include:		
	a) operating controls:		
	i) interconnection		
	ii) use		
	b) positioned so that disconnection is difficult		
	c) accessories:		
	i) interconnection		
	ii) suitability		
	iii) detachable parts and special materials		

Result: P = Pass F = Fail NA = Not Applicable

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Clause Subclause	Requirement	Result	Comments
	d) limits for intermittent operation		
	e) explanation of symbols used		
	f) cleaning		
	g) lockable door closure stop:		
	– correct use		
	– retain key		
	h) safe use of override key		
	i) action in case of malfunction		
5.4.5	**Equipment maintenance**		
	Instructions include:		
	i) maintenance on threaded parts		
	ii) safety devices fitted		
	– replacement of hoses, etc.		
	– specific battery type		
	– any manufacturer specified parts		
	– RATING and characteristics of fuses		
6 **F**	**Protection against electric shock** (see Form A.5)		
6.1	**General**		
	Conformity is checked by the determination of 6.2 and 6.3 followed by the tests of 6.4 to 6.12		
	Abestos is not used		
6.1.1	**Exceptions**		
F	Capacitance test (see Forms A.6 and A.7)		
6.2 **F**	**Determination of ACCESSIBLE parts** (see Form A.6)		
6.3	**Permissible limits for ACCESSIBLE parts**		
6.3.1 **F**	**Values in NORMAL CONDITION** (see Form A.7)		
6.3.1.2	**Levels of PERMANENTLY CONNECTED equipment are 1.5 times the values** (see Form A.7)		
6.3.2 **F**	**Values in SINGLE FAULT CONDITION** (see Form A.8)		
6.3.2.2	**Levels of PERMANENTLY CONNECTED equipment are 1,5 times the values** (see Form A.8)		
6.4	**Protection in NORMAL CONDITION** (see 6.8 and 8.1)		

Result: P = Pass F = Fail NA = Not Applicable

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Clause Subclause	Requirement	Result	Comments
6.5	**Protection in SINGLE FAULT CONDITION**		
	Additional protection is provided by:		
	– one or more of 6.5.1 to 6.5.3		
	or		
	– automatic disconnection of the supply		
6.5.1	**Protective earthing**		
	ACCESSIBLE conductive parts:		
	– bonded to the protective conductor terminal		
	or		
	– separated by screen or BARRIER from parts which are HAZARDOUS LIVE		
	(For indirect bonding of measurement and test equipment, see 6.5.1.4)		
6.5.1.1	**PROTECTIVE BONDING**		
	PROTECTIVE BONDING consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses		
6.5.1.2 F	**Bonding impedance of plug-connected equipment** (see Form A.9)		
6.5.1.3 F	**Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT** (see Form A.9)		
6.5.1.4 F	**Indirect bonding for measuring and test equipment** (see Form A.9)		
6.5.2	**DOUBLE INSULATION and REINFORCED INSULATION** (see 6.7, 6.8 and 6.9.2)		
6.5.3 F	**PROTECTIVE IMPEDANCE** (see Form A.10)		
	Components wires and connections are RATED as required		
6.5.4	**Built-in panel meters**		
	If, after building-in, the requirements of 6.5.1 to 6.5.3 are not met, the panel meter:		
	– has no ACCESSIBLE conductive parts		
	– has basic insulation of accessible surfaces		
	– has DOUBLE/REINFORCED INSULATION of ACCESSIBLE surface of parts intended to be grasped		
6.6	**External circuits**		
6.6.1 F	**Separation of internal circuits** (see list in Forms A.1 and A.5)		
	If the other internal circuit exceeds the values of 6.3.2 in NORMAL CONDITION and only BASIC INSULATION:		

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Clause Subclause	Requirement	Result	Comments
	a) short-circuit could not make external circuit HAZARDOUS LIVE		
	b) manufacturer's instructions include:		
	– a statement that the TERMINAL for external circuits is for use only with equipment which has no live parts which are ACCESSIBLE		
	– the RATING of the insulation required for external circuits		
	– the connection to be used at the remote end of external circuits		
	– the type of equipment which may be connected to the TERMINAL		
6.6.2	**TERMINALS for external circuits**		
	ACCESSIBLE TERMINALS are not HAZARDOUS LIVE, except as permitted by 6.1.1		
	The following terminals are not hazardous live:		
	– PROTECTIVE CONDUCTOR TERMINALS		
	– FUNCTIONAL EARTH TERMINALS		
	– headphone TERMINALS		
F	TERMINALS which receive a charge from an internal capacitor (see Form A.7)		
	High-voltage TERMINALS energized from the interior are:		
	– not accessible or – marked		
6.6.3	**Circuits with TERMINALS which are HAZARDOUS LIVE**		
	These circuits:		
	– are not connected to ACCESSIBLE conductive parts or – are connected to ACCESSIBLE conductive parts, but are not mains circuits and have one TERMINAL contact at earth potential		
	No ACCESSIBLE conductive parts are HAZARDOUS LIVE		
6.7 F	**CLEARANCES and CREEPAGE DISTANCES** (see annex D of IEC 61010-1 and Form A.11)		
6.8 F	**Dielectric strength tests** (see annex E of IEC 61010-1 and Form A.12)		
	Protection against the spread of fire (see 9.1)		

Result: P = Pass F = Fail NA = Not Applicable

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Clause Subclause	Requirement	Result	Comments
6.9	**Constructional requirements for protection against electric shock**		
6.9.1	**General**		
	In circuits exceeding the values of 6.3.2:		
	– security of wiring connections		
	– screws securing removable covers		
	– accidental loosening		
6.9.2	**ENCLOSURES of equipment with DOUBLE INSULATION or REINFORCED INSULATION**		
	ENCLOSURE surrounds all metal parts except for small metal parts which are separated		
	ENCLOSURES or parts made of insulating material		
	Protection for metal ENCLOSURES or parts by:		
	– protective impedance or – an insulating coating or BARRIER on the inside or – CLEARANCES and CREEPAGE DISTANCES cannot be reduced by loosening of parts or wires		
6.9.3	**Equipment using PROTECTIVE BONDING**		
	a) OPERATOR removable parts		
	b) Movable conductive connections		
	c) Exterior metal braids of cables		
	d) Mains passed through the equipment		
	e) Protective earthing conductors green/yellow		
	Exceptions:		
	– earthing braids		
	– internal protective conductors		
	f) Equipment using PROTECTIVE BONDING		
6.9.4	**Over-range indication**		
6.10	**Connection to mains supply source and connections between parts of equipment**		
6.10.1	**Mains supply cords**		
	RATED for maximum equipment current (see 5.1.3c)		
	Cable complies with IEC 60227 or IEC 60245 or is a certified cord		
	Heat resistant if likely to contact hot parts		

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