

TECHNICAL REPORT

IEC TR 61010-3-041

First edition
1999-10

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

**Part 3-041:
Conformity verification report for
IEC 61010-2-041:1995, Particular requirements
for autoclaves using steam for the treatment of
medical materials, and for laboratory processes**

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

*Partie 3-041:
Rapport de vérification de la conformité de la
CEI 61010-2-041:1995, Prescriptions particulières pour
autoclaves utilisant de la vapeur pour le traitement des
matériels à usage médical et durant les procédés de
traitement de laboratoire*



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* See web site address on title page.

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT
FOR MEASUREMENT, CONTROL, AND LABORATORY USE –****Part 3-041: Conformity verification report for IEC 61010-2-041:1995,
Particular requirements for autoclaves using steam
for the 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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Technical reports do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

IEC 61010-3-041, 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:

Enquiry draft	Report on voting
66/193/CDV	66/217/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.

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 testhouses and other users to assist them with determining and recording verification of conformity of the equipment under test with the requirements of

IEC 61010-2-041: 1997,
and
IEC 61010-1: 1990 + amendment 1: 1992
or
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. Requirements which apply only to amendment 2 to IEC 61010-1 are indicated by "(AM 2)" in the first column. Requirements deleted by amendment 2 to IEC 61010-1 are indicated by "(AM 1 only)" in the second column.

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 publication can 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.

Conformity Verification Report IEC 61010-2-041 Safety requirements for electrical equipment for measurement, control, and laboratory use: Part 2-041: Particular requirements for autoclaves using steam for the 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 61010-2-041:1995 and IEC 61010-1:1990 + amendment 1:1992 or 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 référence : Manufacturer : Rating..... :	
Copy of rating plate:	

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 × Width × 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.

Table 1 – Documents attached to this report

[illegible]

Table 2 – Test equipment list

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

¹⁾ or interval between calibrations.

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.				



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		
	– PRESSURE VESSEL markings (see 5.1.102)		
	If jacket pressure differs from CHAMBER, data for both marked on PRESSURE VESSEL		
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		
(AM 2)	If more than one voltage range:		
	– separate values marked		
	or		
	– values differ by less than 20 % (see Form A.3)		
F			

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

Clause Subclause	Requirement	Result	Comments
5.1.4	d) equipment which can be set for different RATED supply voltages:		
	– for PORTABLE EQUIPMENT, indication is visible from the exterior		
	– if the supply voltage can be altered without the use of a tool, changing the setting also changes the indication		
	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		
	The measured value not more than 110 %		
	F (see Form A.3)		
	Fuses		
	OPERATOR replaceable fuse marking (see also 5.4.5)		
	5.1.5 Measuring circuit TERMINALS		
	(AM 2) RATED maximum working voltage or current marked		
	Unless clear indication that below limits:		
	– maximum RATED voltage to earth is marked		
	or		
	– for specific connection only, and means for identifying provided		
	– is adjacent to TERMINALS		
	or		
	– if insufficient space		
	– on the RATING plate or scale plate		
	or		
	– if the TERMINAL is marked with symbol 14		
(AM 2)	INSTALLATION CATEGORY marked		
(AM 2)	TERMINALS permanently connected and not ACCESSIBLE		

Clause Subclause	Requirement	Result	Comments
5.1.6	TERMINALS and operating devices		
	Where necessary for safety, indication of purpose of TERMINALS, connectors, controls and indicators		
(AM 2)	Mains supply TERMINALS identified		
(AM 2)	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		
	f) position on or off of power supply switch (AM 1 only)		
	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)		
5.1.8	Battery charging		
	Equipment with means to charge rechargeable batteries is marked:		
	– to warn against the charging of non-rechargeable batteries		
	– to indicate the type of rechargeable battery used		
5.1.101	Overpressure safety device		
	Identification includes:		
	– model number, etc.		
	– pressure setting		
	– if bursting disc:		
	– pressure		
	– temperature		

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

Clause Subclause	Requirement	Result	Comments
5.1.102	PRESSURE VESSEL markings In all cases, markings include a) name of the manufacturer b) serial number c) identification number of door (may be the same as the serial number) d) maximum working pressure e) maximum working temperature f) minimum working pressure g) test pressure h) construction standard applies i) the CHAMBER volume in litres		
5.2	Warning markings – visible when ready for NORMAL USE – if necessary marked with symbol 14 – are near or on applicable parts (AM 2) – statement to isolate or disconnect – advice on how to avoid contact with ACCESSIBLE HAZARDOUS LIVE parts – TERMINAL voltage exceeding 1 kV (symbol 12) – easily touched high-temperature parts (symbol 13) – warning for more than 2 s (AM 1 only) – instruction to lock and retain key – LOAD type warning		
5.3	Durability of markings 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		

Clause Subclause	Requirement	Result	Comments
5.4.2	– instructions for use		
	– name and address of manufacturer or supplier		
	(AM 2) Definition of INSTALLATION CATEGORY		
	Warning statements and a clear explanation of warning symbols:		
	– provided in the documentation		
	or		
	– information is marked on the equipment		
	– PRESSURE VESSEL conformity declaration		
	– instructions on warning signs for country of use		
	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		
	Documentation includes instructions for		
	a) location and mounting		
	b) weights		
	c) floor loading		
	d) assembly		
	e) mains		
	– supply		
	– connections		
	f) protective earthing		
	g) sound power		
	– data		
	– requirements (see 12.5.1)		

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

Clause Subclause	Requirement	Result	Comments
5.4.4	Equipment operation		
	Instructions for use include		
	a) operating controls:		
	– identification		
	– use		
	b) not to be positioned so that disconnection is difficult		
	c) accessories:		
	– interconnection		
	– suitability		
	– detachable parts		
	– special materials		
	d) specification of intermittent operation limits		
	e) explanation of symbols used		
	f) cleaning		
	g) lockable door closure stop:		
	– correct use		
	– retain key		
	h) safe use of the override key		
	i) action in case of malfunction		
5.4.5	Equipment maintenance		
	Instructions include		
	– special precautions for safety		
	– threaded parts		
	– safety devices		
	(AM 2) – replacement of hoses, etc.		
	– specific battery type		
	– any manufacturer specified parts		
	– RATING and characteristics of fuses		

Clause Subclause	Requirement	Result	Comments
6	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 Asbestos not used		
6.1.1	Exceptions		
F	Capacitance test (see Forms A.6 and A.7)		
6.2	Determination of ACCESSIBLE parts (see Form A.6)		
6.3	Permissible limits for ACCESSIBLE parts		
6.3.1	Values in NORMAL CONDITION (see Form A.7)		
F			
6.3.2	Values in SINGLE FAULT CONDITION (see Form A.8)		
F			
6.4	Protection in NORMAL CONDITION (see 6.8 and 8.1)		
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	Bonding impedance of plug-connected equipment (see Form A.9)		
F			
6.5.1.3	Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT (see Form A.9)		
F			
6.5.1.4	Indirect bonding for measuring and test equipment (see Form A.9)		
F			

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

Clause Subclause	Requirement	Result	Comments
6.5.2	DOUBLE INSULATION and REINFORCED INSULATION (see 6.7, 6.8 and 6.9.2)		
6.5.3	PROTECTIVE IMPEDANCE (see Form A.10)		
F	Components wires and connections are RATED as required		
6.5.4	Built-in equipment (AM 1 only) or Built-in panel meters		
(AM 2)	If, after building in, the requirements of 6.5.1 to 6.5.3 are not met:		
(AM 2)	– equipment (AM 1 only) or – 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	Separation of internal circuits (see list in Forms A.1 and A.5)		
F	If the other internal circuit exceeds the values of 6.3.2 in NORMAL CONDITION and only BASIC INSULATION:		
	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		

Clause Subclause	Requirement	Result	Comments
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 (AM 2)		
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)		
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		

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

Clause Subclause	Requirement	Result	Comments
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 (AM 2)	Over-range indication Unambiguous		
6.10 (AM 2)	Connection to mains supply source (AM 2 only) or Connection to mains supply source and connections between parts of equipment		
6.10.1	Mains supply cords RATED for maximum equipment current (see 5.1.3 c)) Cable complies with IEC 60227 or IEC 60245 or is a certified cord (AM 2) Heat resistant if likely to contact hot parts (AM 2) Temperature RATING (cord and inlet) Green/yellow used only for connection to PROTECTIVE CONDUCTOR TERMINALS		

Clause Subclause	Requirement	Result	Comments
6.10.2 6.10.2.1 6.10.2.2	Combination of conductors (AM 1 only):		
	– all have same degree of insulation		
	or		
	– no hazard from short circuits		
	Detachable cords with IEC 60320 mains connectors:		
	– comply with IEC 60799		
	or		
	– have the current RATING of the mains connector		
	Fitting of non-detachable mains supply cords		
	Cord entry		
	Non-detachable cord protection:		
	– inlet smoothly rounded with radius $\geq 1,5 D$		
	or		
	– insulated cord guard protruding $\geq 5 D$		
	Cord anchorage		
	The protective earth conductor is the last to take the strain		
	Cord anchorages:		
	– the cord is not clamped by direct pressure from a screw		
	– knots are not used		
	– cannot push the cord into the equipment to cause a hazard		
	– no failure of cord insulation in anchorage with metal parts		
	– compression bushing:		
	a) clamps all types and sizes of mains cords and		
	b) is suitable		
	i) for connection to TERMINALS provided		
	or		
	ii) it is designed for screened mains cord		
	– cord replacement does not cause a hazard and method of strain relief is clear		
F	Push-pull test (see Form A.13)		