

TECHNICAL REPORT

IEC TR 61010-3-101

First edition
2003-04

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

Part 3-101: Conformity verification report for IEC 61010-2-101:2002 – Particular requirements for in vitro diagnostic (IVD) medical equipment

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

*Partie 3-101:
Rapport de vérification de la conformité
de la CEI 61010-2-101:2002 –
Prescriptions particulières pour appareils médicaux
de diagnostic in vitro (DIV)*



Reference number
IEC/TR 61010-3-101:2003(E)

Publication numbering

As from 1 January 1997 all IEC publications are issued with a designation in the 60000 series. For example, IEC 34-1 is now referred to as IEC 60034-1.

Consolidated editions

The IEC is now publishing consolidated versions of its publications. For example, edition numbers 1.0, 1.1 and 1.2 refer, respectively, to the base publication, the base publication incorporating amendment 1 and the base publication incorporating amendments 1 and 2.

Further information on IEC publications

The technical content of IEC publications is kept under constant review by the IEC, thus ensuring that the content reflects current technology. Information relating to this publication, including its validity, is available in the IEC Catalogue of publications (see below) in addition to new editions, amendments and corrigenda. Information on the subjects under consideration and work in progress undertaken by the technical committee which has prepared this publication, as well as the list of publications issued, is also available from the following:

- **IEC Web Site** (www.iec.ch)

- **Catalogue of IEC publications**

The on-line catalogue on the IEC web site (http://www.iec.ch/searchpub/cur_fut.htm) enables you to search by a variety of criteria including text searches, technical committees and date of publication. On-line information is also available on recently issued publications, withdrawn and replaced publications, as well as corrigenda.

- **IEC Just Published**

This summary of recently issued publications (http://www.iec.ch/online_news/justpub/jp_entry.htm) is also available by email. Please contact the Customer Service Centre (see below) for further information.

- **Customer Service Centre**

If you have any questions regarding this publication or need further assistance, please contact the Customer Service Centre:

Email: custserv@iec.ch
Tel: +41 22 919 02 11
Fax: +41 22 919 03 00

TECHNICAL REPORT

IEC TR 61010-3-101

First edition
2003-04

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

Part 3-101: Conformity verification report for IEC 61010-2-101:2002 – Particular requirements for in vitro diagnostic (IVD) medical equipment

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

*Partie 3-101:
Rapport de vérification de la conformité
de la CEI 61010-2-101:2002 –
Prescriptions particulières pour appareils médicaux
de diagnostic in vitro (DIV)*

© IEC 2003 — Copyright - all rights reserved

No part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

International Electrotechnical Commission, 3, rue de Varembe, PO Box 131, CH-1211 Geneva 20, Switzerland
Telephone: +41 22 919 02 11 Telefax: +41 22 919 03 00 E-mail: inmail@iec.ch Web: www.iec.ch



Commission Electrotechnique Internationale
International Electrotechnical Commission
Международная Электротехническая Комиссия

PRICE CODE **XB**

For price, see current catalogue

CONTENTS

FOREWORD	3
Conformity verification report for IEC 61010-2-101:2002	5
5 Marking and documentation	11
6 Protection against electric shock.....	15
7 Protection against mechanical HAZARDS	21
8 Mechanical resistance to shock and impact.....	21
9 Protection against the spread of fire.....	22
10 Equipment temperature limits and resistance to heat	23
11 Protection against HAZARDS from fluids.....	24
12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure.....	25
13 Protection against liberated gases, explosion and implosion	25
14 Components.....	26
15 Protection by interlocks.....	27
16 Test and measurement equipment	27
Annex F – Routine tests	27
Annex AA – RISK management.	27
Annex BB – Instructions for use for self-test IVD medical equipment.....	27
Annex XX – List of applicable and omitted clauses/subclauses and associated forms in the test report... ..	62
Annex YY – Details of the changes included in the combined CVR for TR IEC 61010-3-101:2003, to reflect the specific requirements of IEC 61010-2-101:2002	67
Table 1 – Documents reviewed	8
Table 2 – Test equipment list	9
Table 3 – List of components and circuits relied on for safety.....	10
Form A.1 to Form 33	28 to 61

INTERNATIONAL ELECTROTECHNICAL COMMISSION

**SAFETY REQUIREMENTS FOR ELECTRICAL EQUIPMENT
FOR MEASUREMENT, CONTROL, AND LABORATORY USE –**
**Part 3-101: Conformity verification report for IEC 61010-2-101:2002
Particular requirements for in vitro
diagnostic (IVD) medical equipment**

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.
- 2) The formal decisions or agreements of the IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested National Committees.
- 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.
- 4) In order to promote international unification, IEC National Committees undertake to apply IEC International Standards transparently to the maximum extent possible in their national and regional standards. Any divergence between the IEC Standard and the corresponding national or regional standard shall be clearly indicated in the latter.
- 5) The IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with one of its standards.
- 6) Attention is drawn to the possibility that some of the elements of this Technical Report may be the subject of patent rights. The IEC shall not be held responsible for identifying any or all such patent rights.

The main task of IEC technical committees is to prepare International Standards. However, a technical committee may propose the publication of a technical report when it has collected data of a different kind from that which is normally published as an International Standard, for example “state of the art”.

IEC 61010-3-101, 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
66/279/DTR	66/317/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 IEC/ISO Directives, Part 2.

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 to assist users of the standard with determining and recording verification of conformity of the equipment under test with the requirements of:

IEC 61010-2-101: 2002

The protocol for completion of this report is contained in publication IEC 61010-3:2003.

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.

WARNING – Experience has shown that if a version is downloaded in Word 97 or Word 2000 and is subsequently converted to Word 6, some of the symbols may have been incorrectly changed in the conversion. Care must, therefore, be taken to verify the symbols used in the converted document.

The committee has decided that the contents of this publication will remain unchanged until 2008. At this date, the publication will be

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

Test item particulars :	
Type of item tested	Measurement / Control / Laboratory
Description of equipment function	:
INSTALLATION/OVERVOLTAGE CATEGORY.....	:
POLLUTION DEGREE	:
Environmental rating	standard / extended (specify):
Equipment mobility.....	portable / hand-held / floorstanding / fixed / built in/ benchmounted/other (specify):
Connection to mains supply.....	Permanent / detachable cord set / non detachable cord set / none
Operating conditions	continuous / short-time / intermittent
Overall size of the equipment (L x W x H)	:
Mass of the equipment (kg)	:
Marked degree of protection to IEC 60529.....	IP _____
Accessories and detachable parts included in the evaluation..... :	
Options included	
Test case verdicts:	
Test case does not apply to the test object.....	N/A
Test object does meet the requirement.....	P(Pass)
Test object does not meet the requirement	F(Fail)
General remarks:	
The test results presented in this report relate only to the item(s) tested. "(see remark #)" refers to a remark appended to the report. "(see Annex #)" refers to an annex appended to the report. "(see Form A.#)" refers to a table appended to the report. Throughout this report a comma (point) is used as the decimal separator.	

Copy of equipment markings :

Summary of test results (information/comments):

Clause	Requirement – Test	Result - Remarks	Verdict
5	MARKING AND DOCUMENTATION		
5.1.1	General		
	Required equipment markings are:		
	visible:		
	From the exterior; or		
	After removing a cover; or		
	Opening a door		
	After removal from a rack or panel		
	Not put on parts which can be removed by an OPERATOR		
	Letter symbols (IEC 60027) used		
	Additional symbols cannot be confused with the international ones.		
5.1.2	Identification		
	Equipment is identified by:		
5.1.2a)	Manufacturer's name or trademark and address		
5.1.2b)	Model number, name or other means		
5.1.2c)	The name and address of the authorized representative of the manufacturer		
	The equipment or packaging or the instructions for use include:		—
	1) The serial-number or the batch code preceded by „LOT“ symbol 102 of Table 1		
	2 i) Indication that the equipment is IVD medical equipment		
	2 ii) Indication that the equipment is self-test IVD medical equipment		
	2 iii) Identification of detachable components		
	2 iv) Expiry date of consumable parts		
5.1.3	Mains supply		
	Equipment is marked as follows:		
5.1.3a)	Nature of supply:		
	1) A.C. RATED mains frequency or range . of frequencies		
	2) D.C. with symbol 1		
5.1.3b)	RATED supply voltage(s) or range..... :		
5.1.3c)	Max. RATED power (W or VA)or input current..... :		
	The measured value not more than 110 %	(See Form A.3)	
	If more than one voltage range:		
	Separate values marked; or		
	Values differ by less than 20 %	(See Form A.3)	
5.1.3d)	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		

Clause	Requirement – Test	Result - Remarks	Verdict
5.1.3e)	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; or		
	Symbol 14 with full details in the documentation		
5.1.4	Fuses		
	OPERATOR replaceable fuse marking (see also 5.4.5)..... :		
5.1.5	TERMINALS, connections and operating devices		
	Where necessary for safety, indication of purpose of TERMINALS, connectors, controls and indicators marked		
	If insufficient space, symbol 14 used		
5.1.5.1	TERMINALS		
	Mains supply TERMINALS identified		
	Other TERMINAL marking..... :		
5.1.5.1a)	FUNCTIONAL EARTH TERMINALS (symbol 5 used)		
5.1.5.1b)	PROTECTIVE CONDUCTOR TERMINALS:		
	Symbol 6 is placed close to or on the TERMINAL; or		
	Part of appliance inlet		
5.1.5.1c)	TERMINALS of measuring and control circuits (symbol 7 used)		
5.1.5.1d)	HAZARDOUS LIVE TERMINALS supplied from the interior		
	Standard MAINS socket outlet; or		
	RATINGS marked; or		
	Symbol 14 used		
5.1.5.1e)	ACCESSIBLE FUNCTIONAL EARTH TERMINALS:		
	Self-evident; or		
	Indication (symbol 8 acceptable)		
5.1.5.2	Measuring circuit TERMINALS		
	For TERMINALS other than those permanently connected and not ACCESSIBLE:		
	RATED voltage or current marked		
	Unless clear indication that below limits:		
	Maximum RATED voltage to earth is marked; or		
	For specific connection to other equipment TERMINALS only, and means for identifying provided		
	Appropriate measurement category marked (CAT II, CAT III or CAT IV); or		
	No measurement category marked (CAT I)		
	Required markings are adjacent to TERMINALS; OR		
	If insufficient space:		
	On the RATING plate or scale plate; or		
	TERMINAL is marked with symbol 14		

Clause	Requirement – Test	Result - Remarks	Verdict
5.1.6	Switches and circuit breakers		
	If disconnecting device, on or off position marked		
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	Field-wiring TERMINAL boxes		
	If TERMINAL or ENCLOSURE exceeds 60 °C:	(See 10.3a))	
	Cable temperature RATING marked		
	Marking visible or beside TERMINAL		
5.1.101	Transport and storage		
	Packaging labelled to indicate special conditions for transport or storage		
5.2	Warning markings		
	Visible when ready for NORMAL USE		
	Are near or on applicable parts		
	Symbols and text correct dimensions and colour		
	If necessary marked with symbol 14		
	Statement to isolate or disconnect		
	Potentially infectious equipment marked with symbol 101		
	Equipment that can be hazardous due to the use of chemical substances marked with the appropriate symbol		
	Containers or bags for biohazardous waste material which can be removed from the equipment during NORMAL USE marked with symbol 101		
5.3	Durability of markings		
	The required markings resist the effects of temperature and rubbing, and of solvent and reagents likely to be encountered in NORMAL USE	(See Form A.4)	
5.4	Documentation		
5.4.1	General		
	Equipment is accompanied by documentation which includes:	(For documents see Table 1)	
5.4.1a)	Intended use		
5.4.1b)	Technical specification		
5.4.1c)	Instructions for use		
5.4.1d)	Name and address of manufacturer or supplier		
5.4.1e)	Information specified in 5.4.2 to 5.4.5		
5.4.1f)	If marking of TERMINALS required, definition of measurement category		
5.4.1g)	If CAT 1:		
	Warning		
	RATINGS		
	Warning statements and a clear explanation of warning symbols:		
	Provided in the documentation; or		
	Information is marked on the equipment		

Clause	Requirement – Test	Result - Remarks	Verdict
	Information about any RISKS not reduced to a TOLERABLE RISK level		
	Information included in documentation on:		
	Training; or		
	Protective devices; or		
	Personal protective equipment to reduce RISKS to a TOLERABLE RISK level specified;		
5.4.2	Equipment RATINGS		
	Documentation includes:		
5.4.2a)	Supply voltage or voltage range		
	Frequency or frequency range		
	Power or current RATING		
5.4.2b)	Description of all input and output connections		
5.4.2c)	RATING of insulation of external circuits, when such circuits are nowhere ACCESSIBLE		
5.4.2d)	Statement of the range of environmental conditions		
5.4.2e)	Degree of protection (IEC 60529)		
5.4.3	Equipment transportation, installation and assembly instructions		—
	Documentation for the RESPONSIBLE BODY includes :		—
5.4.3a)	Instructions for transportation after delivery to the RESPONSIBLE BODY		
5.4.3b)	Floor loading requirements		
5.4.3c)	Individual weights of principal heavy subassemblies		
5.4.3d)	Location and mounting instructions		
5.4.3e)	Assembly instructions		
5.4.3f)	Instructions for protective earthing		
5.4.3g)	The sound data required by 12.5.1		
5.4.3h)	Instructions relating to handling, containment and exhaust of hazardous substances		
5.4.3i)	Any drainage systems required		
5.4.3j)	Protective measures relating to hazardous radiation		
5.4.3k)	Connections to the supply		
5.4.3l)	PERMANENTLY CONNECTED EQUIPMENT only:		—
	1) Mains supply requirements and details of connections		
	2) If external switch or circuit-breaker, requirements and location recommendation		
5.4.3m)	Special services including pressure limits		
5.4.4	Equipment operation		
	Instructions for use include:		
5.4.4a)	Details of operating controls		
5.4.4b)	Positioning for disconnection		
5.4.4c)	Interconnection		
5.4.4d)	Specification of intermittent operation limits		
5.4.4e)	Explanation of symbols used		

Clause	Requirement – Test	Result - Remarks	Verdict
5.4.4f)	Any actions by an OPERATOR in case of a malfunction		
5.4.4g)	Cleaning and decontamination (see 11.2) incl. materials		
5.4.4h)	Disposal of waste		
5.4.4i)	Hazardous substances,use, need for training,or personal protection measures		
5.4.4j)	Infectious substances, need to use protective gloves or other protective means		
5.4.4k)	Hazardous vapours, instructions for protection of the mouth, nose or eyes		
5.4.4l)	Hazardous radiation, instructions and requirements for protective devices		
5.4.4m)	A statement about protection impairment if used in a manner not specified by the manufacturer		
5.4.4.101	Self-test IVD medical equipment		
	Instructions for use for self-test equipment comply with annex BB		
5.4.5	Equipment maintenance		
	Instructions include:		
	Sufficient preventive maintenance and inspection information		
	Replacement of hoses, etc.		
	Specific battery type		
	Any manufacturer specified parts		
	RATING and characteristics of fuses		
5.4.101	Removal of equipment from use for repair or disposal		—
	Instructions for the RESPONSIBLE BODY for eliminating or reducing HAZARDS provided		
5.4.102	Transport and storage		—
	Permissible environmental conditions for transport and storage specified:		
	In documentation; and		
	On outside of packaging		
6	PROTECTION AGAINST ELECTRIC SHOCK	(See Form A.5)	
6.1	General		
6.1.1	Requirements		
	ACCESSIBLE parts not HAZADOUS LIVE in NORMAL CONDITION and SINGLE FAULT CONDITION		
	Conformity is checked by the determination of 6.2 and 6.3 followed by the tests of 6.4 to 6.11		
6.1.2	Exceptions		
	Capacitance test	(See Forms A.6 and A.7)	
	Parts not HAZARDOUS LIVE 10 s after interruption of supply		
6.2	Determination of ACCESSIBLE parts	(See Form A.6)	
6.2.1	General examination		
6.2.2	Openings above parts that are HAZARDOUS LIVE		
6.2.3	Openings for pre-set controls		
6.3	Permissible limits for ACCESSIBLE parts		
6.3.1	Values in NORMAL CONDITION	(See Form A.7)	

Clause	Requirement – Test	Result - Remarks	Verdict
6.3.2	Values in SINGLE FAULT CONDITION	(See Form A.8)	
6.4	Protection in NORMAL CONDITION (see 6.2, 6.3.1, 6.7, 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 (6.5.4)		
6.5.1	Protective BONDING		
	ACCESSIBLE conductive parts:		
	Separated by DOUBLE INSULATION or REINFORCED INSULATION; or		
	Bonded to the PROTECTIVE CONDUCTOR TERMINAL; or		
	Separated by screen or BARRIER bonded to PROTECTIVE CONDUCTOR TERMINAL from parts which are HAZARDOUS LIVE		
6.5.1.1	Integrity of PROTECTIVE BONDING		
6.5.1.1a)	PROTECTIVE BONDING consists of directly connected structural parts or discrete conductors or both; and withstands thermal and dynamic stresses		
6.5.1.1b)	Soldered connections:		
	Independently secured		
	Not used for other purposes		
	Screw connections are secured		
6.5.1.1c)	PROTECTIVE BONDING not interrupted		
6.5.1.1d)	Any moveable connection specifically designed, and meets 6.5.1.3		
6.5.1.1e)	No external metal braid of cables used		
6.5.1.1f)	If MAINS supply passes through:		
	Means provided for passing protective conductor;		
	Impedance meets 6.5.1.3.		
6.5.1.1g)	Protective conductors bare or insulated, if insulated, green/yellow		
	Exceptions:		
	1) earthing braids;		
	2) internal protective conductors etc.;		
	Green/yellow not used for other purposes		
6.5.1.1h)	TERMINAL suitable, and meets 6.5.1.2		
6.5.1.2	PROTECTIVE CONDUCTOR TERMINAL		
6.5.1.2a)	Contact surfaces are metal		
6.5.1.2b)	Appliance inlet used		
6.5.1.2c)	For rewirable cords and PERMANENTLY CONNECTED EQUIPMENT, PROTECTIVE CONDUCTOR TERMINAL is close to MAINS supply TERMINALS		
6.5.1.2d)	If no MAINS supply is required, any PROTECTIVE CONDUCTOR TERMINAL:		
	Is near TERMINALS of circuit for which protective earthing is necessary		
	External if other TERMINALS external		
6.5.1.2e)	Equivalent current-carrying capacity to MAINS supply TERMINALS		

Clause	Requirement – Test	Result - Remarks	Verdict
6.5.1.2f)	If plug-in, makes first and breaks last		
6.5.1.2g)	If also used for other bonding purposes, protective conductor:		
	Applied first;		
	Secured independently;		
	Unlikely to be removed by servicing; or		
	Warning marking requires replacement of protective conductor		
6.5.1.2h)	Protective conductor of measuring circuit:		
	1) Current RATING;		
	2) PROTECTIVE BONDING:		
	Not interrupted; or		
	Indirect bonding used (see 6.5.1.5)		
6.5.1.2i)	FUNCTIONAL EARTH TERMINALS allow independent connection		
6.5.1.2j)	If a binding screw:		
	Suitable size for bond wire		
	Not smaller than M 4 (No. 6)		
	At least 3 turns of screw engaged		
	Contact pressure not capable of reduction by deformation of materials		
	Passes tightening torque test	(See Form A.9)	
6.5.1.3	Impedance of PROTECTIVE BONDING of plug-connected equipment	(See Form A.10)	
6.5.1.4	Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT	(See Form A.10)	
6.5.1.5	Indirect bonding for measuring and test equipment	(See Form A.11)	
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.12)	
6.5.3a)	HIGH-INTEGRITY single component used (s. 14.6); or		
6.5.3b)	A combination of components used; or		
6.5.3c)	A combination of BASIC INSULATION and current- or voltage-limiting device used		
	Components, wires and connections are RATED as required		
6.5.4	Automatic disconnection of the supply		
	If used, it meets :		
6.5.4a)	Supplied with the equipment; or		
	Specified by installation instruction		
6.5.4b)	RATED disconnecting time within limit specified		
6.5.4c)	RATED for maximum RATED LOAD		
6.6	Connections to external circuits		
6.6.1	General		
	Connections do not cause ACCESSIBLE parts of the following to become HAZARDOUS LIVE in NORMAL CONDITION or SINGLE FAULT CONDITION:		
6.6.1a)	The external circuits		

Clause	Requirement – Test	Result - Remarks	Verdict
6.6.1b)	The equipment		
	Separation of circuits provided; or		
	Short circuit of separation does not cause a HAZARD		
	Instructions or markings include:		—
	1) RATED conditions for TERMINAL		
	2) Required RATING of external circuit insulation		
6.6.2	TERMINALS for external circuits		
	TERMINALS which receive a charge from an internal capacitor are not HAZARDOUS LIVE	(See Form A.7)	
	High voltage TERMINALS energized from the interior are:		
	Not ACCESSIBLE or		
	When unmated, no HAZARDOUS LIVE voltage; or		
	marked with symbol 12		
6.6.3	Circuits with TERMINALS which are HAZARDOUS LIVE		
	These circuits are:		
	Not connected to ACCESSIBLE conductive parts; or		
	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		
6.6.4	ACCESSIBLE TERMINALS for stranded conductors		
6.6.4a)	No risk of accidental contact because:		
	Located or shielded		
	Self-evident or marked whether connected to ACCESSIBLE conductive parts		
6.6.4b)	ACCESSIBLE TERMINALS will not work loose		
6.7	CLEARANCES and CREEPAGE DISTANCES	(See Form A.5 and A.13)	
6.8	Procedure for dielectric strength tests	(See Form A.5 and A.14)	
6.9	Constructional requirements for protection against electric shock		
6.9.1	General		
	If a failure could cause a HAZARD:		
6.9.1a)	Security of wiring connections		
6.9.1b)	Screws securing removable covers		
6.9.1c)	Accidental loosening		
	Easily damaged materials not used		
	Non-impregnated hygroscopic materials not used		
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:		
6.9.2a)	An insulating coating or BARRIER on the inside; or		
6.9.2b)	CLEARANCES and CREEPAGE DISTANCES cannot be reduced by loosening of parts or wires		

Clause	Requirement – Test	Result - Remarks	Verdict
6.9.3	Over-range indication		
	Unambiguous		
6.10	Connection to MAINS supply source and connections between parts of equipment		
6.10.1	MAINS supply cords		
6.10.1a)	RATED for maximum equipment current (see 5.1.3c)		
	Cable complies with IEC 60227 or IEC 60245 or is a certified cord		
6.10.1b)	Heat-resistant if likely to contact hot parts		
6.10.1c)	Temperature RATING (cord and inlet)		
6.10.1d)	Green/yellow used only for connection to PROTECTIVE CONDUCTOR TERMINALS		
	Detachable cords with IEC 60320 MAINS connectors:		
	Conform to IEC 60799; or		
	Have the current RATING of the MAINS connector		
6.10.2	Fitting of non-detachable MAINS supply cords		
	Non-detachable cord protection:		
6.10.2a)	Inlet or bushing smoothly rounded; or		
6.10.2b)	Insulated cord guard protruding $\geq 5D$		
	The protective earth conductor is the last to take the strain		
6.10.2	Cord anchorages:		
6.10.2a)	Cord is not clamped by direct pressure from a screw		
6.10.2b)	Knots are not used		
6.10.2c)	Cannot push the cord into the equipment to cause a HAZARD		
6.10.2d)	No failure of cord insulation in anchorage with metal parts		
6.10.2e)	Compression bushing:		
	Clamps all types and sizes of MAINS cords; and is suitable for connection to TERMINALS provided; or		
	:		
	It is designed for a specified screened MAINS cord		
6.10.2f)	Cord replacement does not cause a HAZARD and method of strain relief is clear		
	Push-pull test	(See Form A.16)	
6.10.3	Plugs and connectors		
6.10.3a)	MAINS supply plugs, connectors etc., conform with relevant specifications		
6.10.3b)	If equipment supplied at voltages below 6.3.2.a) or from a sole source:		
	Plugs of supply cords do not fit MAINS sockets above RATED supply voltage		
	MAINS-type plugs used only for connection to MAINS supply		
6.10.3c)	Plug pins which receive a charge from an internal capacitor	(See Form A.7)	
6.10.3d)	Accessory MAINS socket outlets:		
	1) Marking if accepts a standard MAINS plug (see 5.1.3e)		
	2) Input has a protective earth conductor if outlet has earth TERMINAL contact		

Clause	Requirement – Test	Result - Remarks	Verdict
6.11	Disconnection from supply source		
6.11.1	General (see 6.11.1.1 to 6.11.2.6)		
	Disconnects all current carrying conductors		
6.11.1.1	Exceptions		
6.11.1.1a)	Equipment supplied by low energy source; or		
6.11.1.1b)	Equipment connected to impedance protected supply; or		
6.11.1.1c)	Equipment constitutes an impedance protected load		
6.11.2	Requirements according to type of equipment		
6.11.2.1	PERMANENTLY CONNECTED EQUIPMENT and multi-phase equipment		
	Employs switch or circuit-breaker		
	If switch or circuit-breaker is not part of the equipment, documentation specifies:		
6.11.2.1a)	Switch or circuit-breaker to be included in building installation		
6.11.2.1b)	Location		
6.11.2.1c)	Marking		
6.11.2.2	Single-phase cord-connected equipment		
	Equipment is provided with:		
6.11.2.2a)	Switch or circuit-breaker; or		
6.11.2.2b)	Appliance coupler (disconnectable without TOOL); or		
6.11.2.2c)	Separable plug (without locking device)		
6.11.2.3	HAZARDS arising from function		
	Emergency switch		
	Emergency switch \leq 1 m from the moving part		
6.11.3	Disconnecting devices		
	Electrically close to the supply		
6.11.3.1	Switches and circuit-breakers		
	When used as disconnection device:		
	Meets IEC 60947-1 and IEC 60947-3		
	Marked to indicate function		
	Not incorporated in MAINS cord		
	Does not interrupt protective earth conductor		
	If has other contacts meets separation requirements of 6.6 and 6.7		
6.11.3.2	Appliance couplers and plugs		
	Where an appliance coupler or separable plug is used as the disconnecting device (see 6.11.2.2):		
	Readily identifiable and easily reached by the OPERATOR		
	Single-phase PORTABLE EQUIPMENT cord length \leq 3 m		
	Protective earth conductor connected first and disconnected last		

Clause	Requirement – Test	Result - Remarks	Verdict
7	PROTECTION AGAINST MECHANICAL HAZARDS		
7.1	General		
	Conformity is checked by 7.2 to 7.6		
7.2	Moving parts		
	Moving parts not able to crush, etc. (see also 6.11.2.3)		
	If OPERATOR access permitted:		
	a) Access requires TOOL		
	b) Statement about training		
	c) Warning markings or symbol 14		
7.3	Stability		
	Marking of non-automatic means		
	Conformity tests:		
7.3a)	10° tilt test		
7.3b)	multi-directional force test		
7.3c)	downward force test		
7.4	Provisions for lifting and carrying		
	Handles or grips withstand four times weight		
	Equipment >18 kg :		
	Has means for lifting or carrying; or		
	Directions in documentation		
7.5	Wall mounting		
	Mounting brackets withstand four times weight		
7.6	Expelled parts		
	Equipment contains or limits the energy		
	Protection not removable without the aid of a TOOL		
8	MECHANICAL RESISTANCE TO SHOCK AND IMPACT		
	After the tests of 8.1 to 8.2:		
	Voltage tests	(See Form A.14)	
	Inspections:		
8a)	HAZARDOUS LIVE parts not accessible		
8b)	ENCLOSURE shows no cracks (HAZARD)		
8c)	CLEARANCES not less than their permitted values	(See Form A.13)	
8d)	BARRIERS not damaged or loosened		
8e)	No moving parts exposed, except permitted by 7.2		
8f)	No damage which could cause spread of fire		
8.1	ENCLOSURE rigidity test	(See Form A.15)	
8.2	Drop test	(See Form A.15)	
8.101	Transport and storage		—
	Records of tests performed by the manufacturer show conformity	(See test records attached)	

Clause	Requirement – Test	Result - Remarks	Verdict
9	PROTECTION AGAINST THE SPREAD OF FIRE		
	Conformity for each source of HAZARD or area of the equipment is checked by one of the following:	(See Form A.17)	
9a)	Fault test of 4.4; or	(See Forms A.1 and A.2)	
9b)	Application of 9.1 (eliminating or reducing the sources of ignition); or		
9c)	Application of 9.2 (containment of fire within the equipment)		
9.1	Eliminating or reducing the sources of ignition within the equipment		
9.1a)	1) Limited-energy circuit (see 9.3); or		
	2) Insulation meets the requirements for BASIC INSULATION; or	(See Form A.5 and A.14)	
	Bridging the insulation does not cause ignition	(See Form A.2)	
9.1b)	Surface temperature of liquids and parts (see 9.4.a)		
9.1c)	No ignition in circuits designed to produce heat	(See Form A.2)	
9.2	Containment of the fire within the equipment, should it occur		
9.2a)	Energizing of the equipment is controlled by an OPERATOR held switch		
9.2b)	ENCLOSURE conforms with constructional requirements of 9.2.1; and		
	Requirements of 9.4b) or c) are met		
9.2.1	Constructional requirements		
9.2.1a)	Insulated wires have flammability classification FV1 or better	(See Table 3 or Form A.18)	
	Connectors and insulating material have flammability classification FV2 or better	(See Table 3 or Form A.18)	
9.2.1b)	The ENCLOSURE is constructed as follows :	(See Form A.17)	
	1) Bottom constructed with:		
	No openings; or		
	Extent as specified in figure 7; or		
	Baffles as specified in figure 6; or		
	Perforated as specified in table 12; or		
	Metal screen with a mesh		
	2) Sides have no openings as specified in figure 7		
	3) Material of ENCLOSURE and any baffle or flame BARRIER is made of.....:		
	Metal (except magnesium); or		
	Non metallic materials have flammability classification FV1 or better	(See Table 3 or Form A.18)	
	4) ENCLOSURE and any baffle or flame BARRIER have adequate rigidity		
9.3	Limited-energy circuit		
9.3a)	Potential not more than 30 r.m.s. and 42.4 V peak, or 60 V d.c.		
9.3b)	Current limited by one of following means:		
	1) Inherently or by impedance; or		
	2) Overcurrent protective device; or		

Clause	Requirement – Test	Result - Remarks	Verdict
	3) A regulating network limits also in SINGLE FAULT CONDITION		
9.3c)	Is separated by at least BASIC INSULATION		
	If Overcurrent protective device used:		
	Fuse or a non adjustable electromechanical device		
9.4	Requirements for equipment containing or using flammable liquids		
	Flammable liquids contained in or specified for use with equipment do not cause spread of fire		
	Risk is reduced to a tolerable level :	(See Form A.20)	
9.4a)	The temperature of surface or parts in contact with flammable liquids is 25 °C below fire point	(See 10.3b))	
9.4b)	The quantity of liquid is limited		
9.4c)	Flames are contained within the equipment		
	Detailed instructions for risk-reduction provided		
9.5	Overcurrent protection		
	Devices not in the protective conductor		
	Fuses or single-pole circuit-breakers not fitted in neutral (multi-phase)		
9.5.1	PERMANENTLY CONNECTED EQUIPMENT		
	Overcurrent device:		
	Fitted within the equipment; or		
	Specified in manufacturer's instructions		
9.5.2	Other equipment		
	Protection within the equipment		
10	EQUIPMENT TEMPERATURE LIMITS AND RESISTANCE TO HEAT		
10.1	Surface temperature limits for protection against burns		
	Easily touched surfaces within the limits	(See Form A.21A)	
	Heated surfaces necessary for functional reasons exceeding specified values:		
	Are recognizable as such by appearance or function; or		
	Are marked with symbol 13		
	Guards are not removable without TOOL		
10.2	Temperatures of windings	(See Form A.21B)	
	Limits not exceeded in:		
	NORMAL CONDITION		
	SINGLE FAULT CONDITION		
10.3	Other temperature measurements	(See Form A.21A)	
	Following measurements conducted if applicable:		
10.3a)	Value of 60 °C of field-wiring TERMINAL box not exceeded		
10.3b)	Surface of flammable liquids and parts in contact with this liquids		
10.3c)	Surface of non-metallic ENCLOSURES		
10.3d)	Parts made of insulating material supporting parts connected to MAINS supply		
10.3e)	TERMINALS carrying a current more than 0.5 A		

Clause	Requirement – Test	Result - Remarks	Verdict
10.4	Conduct of temperature test		
10.5	Resistance to heat		
10.5.1	Integrity of CLEARANCE and CREEPAGE DISTANCES	(See Form A.13)	
10.5.2	Non-metallic ENCLOSURES	(See Forms A.22)	
	After treatment:		
	No HAZARDOUS LIVE parts ACCESSIBLE;		
	Tests of 8.1 and 8.2	(See Form A.13)	
	In case of doubt, tests of 6.8 (without humidity preconditioning)	(See Form A.14)	
10.5.3	Insulating material		
10.5.3a)	Parts supporting parts connected to MAINS supply	(See 10.3d))	
10.5.3b)	TERMINALS carrying a current more than 0.5 A	(See 10.3e))	
	In case of doubt, examination of material data		
	If not conclusive:,		
	1) Ball pressure test; or	(See Form A.23)	
	2) Vicat softening test of ISO 306	(See Form A.23)	
11	PROTECTION AGAINST HAZARDS FROM FLUIDS		
11.1	General		
11.2	Cleaning	(See Form A.24)	
11.3	Spillage	(See Form A.24)	
	Potentially aggressive substances (such as corrosive, toxic or flammable liquids) taken into account		
	Potentially aggressive substances compatible with contacted parts of the equipment		
11.4	Overflow	(See Form A.24)	
11.5	Battery electrolyte		
	Battery electrolyte leakage presents no hazard		
11.6	Specially protected equipment	(See Form A.24)	
11.7	Fluid pressure and leakage		
11.7.1	Maximum pressure		
	Maximum pressure of any part does not exceed P_{RATED}		
11.7.2	Leakage and rupture at high pressure	(See Form A.25)	
	Test to IEC 60335 (refrigeration only)		
11.7.3	Leakage from low-pressure parts	(See Form A.25)	
11.7.4	Overpressure safety device		
	Does not operate in NORMAL USE		
	Meets ISO 4126-1; and		
	It conforms with:		
11.7.4a)	Connected as close as possible to parts intended to be protected		
11.7.4b)	Easy access for inspection, maintenance and repair		
11.7.4c)	Adjustment only with TOOL		
11.7.4d)	No discharge towards person		
11.7.4e)	No HAZARD from deposit of discharged material		
11.7.4f)	Adequate discharge capacity		

Clause	Requirement – Test	Result - Remarks	Verdict
11.7.4g)	No shut-off valve between overpressure safety device and protected parts		
12	PROTECTION AGAINST RADIATION, INCLUDING LASER SOURCES, AND AGAINST SONIC AND ULTRASONIC PRESSURE		
12.1	General		
	Equipment provides protection		
12.2	Equipment producing ionizing radiation		
12.2.1	Ionizing radiation	(See Form A.26)	
12.2.2	Accelerated electrons		
12.3	Ultra-violet (UV) radiation	(Conformity test under consideration)	
12.4	Micro-wave radiation		
	Power density does not exceed 10 W/m ²		
12.5	Sonic and ultrasonic pressure		
12.5.1	Sound level	(See Form A.27)	
12.5.2	Ultrasonic pressure	(See Form A.27)	
12.6	Laser sources (IEC 60825-1)		
13	PROTECTION AGAINST LIBERATED GASES AND SUBSTANCES, EXPLOSION AND IMPLOSION		
13.1	Poisonous and injurious gases and substances		
	Attached data/test reports demonstrate conformity (in NC and SFC)	(See Form A.1)	
	Dangerous amounts of poisonous or injurious gases or substances not liberated in NORMAL CONDITION or in SINGLE FAULT CONDITION	Attach any data/test reports used to demonstrate conformity	
	If potentially hazardous substances are liberated:		—
	OPERATOR not be wetted nor able to inhale quantities likely to be hazardous		
	protective covers or similar means of protection		
13	PROTECTION AGAINST LIBERATED GASES, EXPLOSION AND IMPLOSION		
13.1	Poisonous and injurious gases		
	Attached data/test reports demonstrate conformity		
13.2	Explosion and implosion		
13.2.1	Components		
	Components liable to explode:		
	Pressure release device provided; or		
	Apparatus incorporates OPERATOR protection (see also 7.6)		
	Pressure release device:		
	Discharge without danger		
	Cannot be obstructed		
13.2.2	Batteries and battery charging		
	If explosion or fire HAZARD could occur:		
	Protection incorporated in the equipment; or		
	Instructions specify batteries with built-in protection		
	If wrong type of battery used:		

Clause	Requirement – Test	Result - Remarks	Verdict
	No HAZARD; or		
	Warning by marking and in instructions		
	Equipment with means to charge rechargeable batteries:		
	Warning against the charging of non-rechargeable batteries; and		
	Type of rechargeable battery indicated; or		
	Symbol 14 used		
	Battery compartment design, no fire or explosive HAZARD		
	Single component failure	(See Form A.28)	
	Polarity reversal test	(See Form A.28)	
13.2.3	Implosion of cathode ray tubes		
	If maximum face dimensions > 160 mm		
	Intrinsically protected and correctly mounted; or		
	ENCLOSURE provides protection		
	If non-intrinsically protected:		
	Screen not removable without TOOL		
	If glass screen, not in contact with surface of tube		
13.2.4	Equipment RATED for high pressure	(See 11.7)	
14	COMPONENTS		
14.1	General		
	Where safety is involved, components meet relevant requirements	(See Table 3)	
14.2	Motors		
14.2.1	Motor temperatures		
	Does not present a HAZARD when stopped or prevented from starting; or	(See Form A.21B)	
	Protected by overtemperature or thermal protection device conform with 14.3		
14.2.2	Series excitation motors		
	Connected direct to device, if overspeeding causes a HAZARD		
14.3	Overtemperature protection devices	(See Form A.29)	
14.3a)	Reliable function is ensured		
14.3b)	RATED to interrupt maximum current and voltage		
14.3c)	Does not operate in NORMAL USE		
	Non-self resetting in self-test IVD equipment		
14.4	Fuse holders		
	No access to HAZARDOUS LIVE parts		
14.5	Mains voltage selecting devices		
	Accidental change not possible		
14.6	HIGH INTEGRITY components		
	Used in applicable positions	(See Table 3)	
	Conforms with IEC publications		
	Single electronic device not used		
14.7	Mains transformers tested outside equipment	(See Forms A.30 and A.31)	

Clause	Requirement – Test	Result - Remarks	Verdict
14.8	Printed circuit boards		
	Data shows conformity with FV-1 of IEC 60707 or better; or		
	Test shows conformity with FV-1 of IEC 60707 or better; or	See Form A.18	
	Thin film flexible PCB with limited-energy circuit used		
14.9	Circuits or components used as transient overvoltage limiting devices		
	After test, no sign of overload or degradation		
15	PROTECTION BY INTERLOCKS		
15.1	General		
	Interlocks are designed to remove a hazard before OPERATOR exposed		
15.2	Prevention of reactivation		
15.3	Reliability		
	Single fault unlikely to occur; or		
	Cannot cause a HAZARD		
16	TEST AND MEASUREMENT EQUIPMENT		
16.1	Current measuring circuits	(See Form A.32)	
16.2	Multifunction meters and similar equipment	(See Form A.33)	
	No HAZARD from:		
	RATED input voltage combinations		
	Settings of functions		
	Settings of range controls		
ANNEX F	ROUTINE TESTS		
	Manufacturer's declaration		
ANNEX AA	RISK management		
	Conformity demonstrated	(See document attached)	
ANNEX BB	Instructions for use for self-test IVD medical equipment		
	Instructions comply		

4.4.2	TABLE: Summary of SINGLE FAULT CONDITIONS			Form A.1
Subclause	Title	Does not apply	Carried out	Comments
4.4.2.1	PROTECTIVE IMPEDANCE			
4.4.2.2	Protective conductor			
4.4.2.3	Equipment or parts for short-term or intermittent operation			
4.4.2.4	Motors			
4.4.2.5	Capacitors			
4.4.2.6	Mains transformers Attach drawing of MAINS Tx's showing all protective devices (see Forms A.29 and A.30)			
4.4.2.7	Outputs			
4.4.2.8	Equipment for more than one supply			
4.4.2.9	Cooling (see note) – air holes closed – fans stopped – coolant stopped			
4.4.2.10	Heating devices (see note) – timer overridden – temperature controller overridden – loss of cooling liquid – overfilled or empty or both			
4.4.2.11	Insulation between circuits and parts			
4.4.2.12	Interlocks			
4.4.2.101	Incorrect voltage selection			
List below all SINGLE FAULT CONDITIONS not covered by 4.4.2.1 to 4.4.2.101:				
13.1	Poisonous and injurious gases and substances			
NOTE – Record surface temperatures of flammable liquids and parts in contact with them in Form A.20A				
Supplementary information: See Form A.2 for details of tests.				

5.3		TABLE: Durability of markings				Form A.4
Marking method (see note)			Test Agent			
1)			A Water			
2)			B Isopropyl alcohol			
3)			C Solvents and reagents likely to be used in NORMAL USE(specify)			
4)			D (specify agent)			
5)			E (specify agent)			
NOTE – Where applicable include print method, label material, ink or paint type, fixing method, adhesive and surface to which marking is fixed.						
Marking location			Marking method (see above)			
Identification (5.1.2)						
Mains supply (5.1.3)						
Fuses (5.1.4)						
TERMINALS (5.1.5.1)						
Measuring circuit TERMINALS (5.1.5.2)						
Switches and circuit breakers (5.1.6)						
DOUBLE/REINFORCED equipment (5.1.7)						
Field wiring TERMINAL boxes (5.1.8)						
Warning marking (5.2)						
Battery charging (13.2.2)						
Method	Test agent	Remains legible Verdict	Label loose Verdict	Curled edges Verdict	Comments	

TABLE: Protection against electric shock - Block diagram of system							Form A.5			
POLLUTION degree ...:										
Requirements according to subclauses 6.4 to 6.8 and annex D										
Location or description	Required insulation type (note 1)	Maximum working Voltage (note 2)	CREEPAGE DISTANCE (note 3)				CLEARANCE (note 3) mm	Test voltage (note 2) V	Comments	
			PWB mm	CTI	Other mm	CTI				
NOTE 1 – Type of insulation: BI = BASIC INSULATION DI = DOUBLE INSULATION PI = PROTECTIVE IMPEDANCE RI = REINFORCED INSULATION SI = SUPPLEMENTARY INSULATION			NOTE 2 – Types of voltage Peak impulse test voltage (pulse) r.m.s. d.c. peak				NOTE 3 POLLUTION DEGREES, which differ from these, should be shown under "Comments".			
Supplementary Information:										

6.5.1.3	TABLE: Bonding impedance of plug connected equipment			Form A.10
ACCESSIBLE part under test	Test current A	Voltage attained after 1 min V	Calculated resistance (maximum allowed 0,1) Ω	Verdict

Supplementary information:

6.5.1.4	TABLE: Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT			
ACCESSIBLE part under test	Test current A	Voltage attained after 1 min (maximum 10 V) V	Verdict	

Supplementary information:

6.5.1.5	TABLE: Indirect bonding for measuring and test equipment			Form A.11
ACCESSIBLE part under test	Voltage attained V	Time for voltage to drop to allowable levels s	Verdict	
a) Voltage limiting device	-	-	-	
Supplementary Information:				
ACCESSIBLE part under test	Voltage applied V	Time for device to trip s	Verdict	
b) Voltage-sensitive tripping device	-	-	-	
Supplementary Information:				

6.5.3	TABLE: PROTECTIVE IMPEDANCE		Form A.12
A HIGH INTEGRITY single component			
Component	Location	Comments	
A combination of components			
Component	Location	Comments	
A combination of BASIC INSULATION and a current or voltage limiting device			
Component	Location	Comments	
Supplementary information:			

8.1	ENCLOSURE rigidity test			Form A.15
8.2	Drop test			
8.1.1	Static test			
	Material of ENCLOSURE	Preparation for the test	Comments	Verdict
	Plastic / Non-metallic	Operated at an ambient temperature of°C for.....h	Reason:	
	Location	-	-	-
	1			
	2			
	3			
8.1.2	Dynamic test			
	ENCLOSURE material	Preparation for the test	Comments	-
	Plastic / Non-metallic	Cooled to.....°C	Reason:	
	Location	Steel sphere to: top/side/bottom	-	-
	1			
	2			
8.2.1.1	Corner drop test			
	Dropped on corner	Raised up to:	Comments	-
	1	100 mm / 30°		
	2	100 mm / 30°		
	3	100 mm / 30°		
	4	100 mm / 30°		
8.2.1.2	Face drop test			
	Dropped on face	Raised up to:	Comments	-
	1	25 mm /30°		
	2	25 mm /30°		
	3	25 mm /30°		
	4	25 mm /30°		
8.2.2	HAND -HELD EQUIPMENT and direct plug-in equipment			
	ENCLOSURE material	Preparation for the test	Comments	-
	Plastic / Non-metallic	Cooled to°C		
	Landed on side / edge / corner			

9	TABLE: Protection against the spread of fire			Form A.17
Item	Source of HAZARD or area of the equipment considered (circuit, component, liquid etc.)	Protection Method (9a, 9b or 9c)	Protection details	Verdict
Supplementary information:				

9.2.1	TABLE: Constructional requirements		Form A.18	
14.8	Printed circuit boards			
Material tested				
Generic name				
Material manufacturer				
Type.....				
Colour				
Conditioning details				
		Sample 1	Sample 2	Sample 3
Thickness of specimen	mm			
Duration of flaming after first Application	s			
Duration of flaming plus glowing After second application	s			
Specimen burns to holding clamp	Yes/No			
Cotton ignited	Yes/No			
Sample result	Pass/Fail			
Supplementary information				

9.4	TABLE: Requirements for equipment containing or using flammable liquids		Form A.20
Type of liquid	9.4 Flammable liquids		Verdict
	b) quantity	c) Containment	
Supplementary information:			

10.5.2	TABLE: Resistance to heat of non-metallic ENCLOSURES		Form A.22
	Test method used:		
	Non operative treatment.....: []		
	Empty ENCLOSURE.....: []		
	Operative treatment.....: []		
	Temperature during tests		
	ENCLOSURE samples tested were		
Description	Material	Comments	Verdict
Dielectric strength test (6.8)		V	r.m.s./peak/d.c.
Supplementary information:			

10.5.3	TABLE: Insulating Materials			Form A.23
10.5.3a)	Ball-pressure test			
	Max. allowed impression diameter..... :	2 mm		
Part	Test temperature °C	Impression Diameter (mm)	Verdict	
Supplementary information:				
10.5.3b)	Vicat softening test (ISO 306)			
Part	Vicat softening temperature °C	Thickness of sample (mm)	Verdict	
Supplementary information:				

11.7.2	TABLE: Leakage and rupture at high pressure					Form A.25
Part	Maximum permissible working pressure MPa	Test pressure MPa	Leakage Yes/No	Burst Yes/No	Comments	
Supplementary information:						
11.7.3	Leakage from low-pressure parts					
Part	Test pressure MPa	Leakage Yes / No	Comments			
Supplementary information:						

12.2.1	TABLE: Ionizing radiation			Form A 26
Locations tested	Measured values μSv/h	Verdict	Comments	
Supplementary information:				

12.5.1	TABLE: Sound level		Form A.27
Locations tested	Measured values dBA		Calculated maximum sound pressure level
At operator's normal position			
At bystanders' positions	–		–
a)			
b)			
c)			
d)			
e)			
Supplementary information:			
12.5.2	Ultrasonic pressure		
Locations tested	Measured values		Comments
	dB	kHz	
At OPERATOR'S normal position			
At 1 m from the ENCLOSURE	–	–	–
a)			
b)			
c)			
d)			
e)			
NOTE – No limit is specified at present, but a limit of 110 dB above the reference pressure value of 20 µPa is under consideration for applicable frequencies between 20 kHz and 100 kHz.			
Supplementary information:			

13.2.2	TABLE: Batteries	Form A.28
Battery load and charging circuit diagram:		
Battery type		
Battery manufacturer/model/catalogue No.....		
Battery RATINGS		
Reverse polarity instalment test		
Single component failures	Verdict	
Component	Open circuit	Short circuit
Supplementary information:		

4.4.2.6	TABLE: Mains transformer			Form A.31
14.7.2	Overload tests (for MAINS transformers)			
Type..... :				
Manufacturer				
Test in equipment				
Test on bench				
Test repeated inside equipment (see 14.7)				
Optional – Insulation class (IEC 60085) of the lowest RATED winding				
Winding identification				
Type of Protector for winding (see note 1)				
Elapsed time				
Current, A	primary			
	secondary			
Winding temperature, °C	primary			
(see note 2)	secondary			
Tissue paper / cheesecloth	OK ?			
(Pass / Fail)				
Voltage tests (see note 3)				
primary to secondary	_____ V _____			
	—			
primary to core	_____ V _____			
	—			
secondary to secondary	_____ V _____			
	—			
secondary to core	_____ V _____			
	—			
Verdict				
NOTE 1	Primary fuse	- PF / () A		
	Secondary fuse	- SF / () A		
	Overtemperature protection	- OP / () °C		
	Impedance protection	- Z		
NOTE 2	Indicate method of measurement	TC = with thermocouple		
		R = resistance method		
	If resistance method is used, record resistance in cold and warm condition in FormA.21B			
NOTE 3	Record the voltage applied and the type of voltage (r.m.s. / d.c. / peak) and for results use			
	NB = no breakdown or B = breakdown			
Supplementary information:				

16.1	TABLE: Current measuring circuits				Form A.32
<p>These tests are performed with all types and models of current transformers without internal protection, and which are specified by the manufacturer for use with the equipment</p>					
a) Current transformers					
Type/Model	RATED current A	Test current A	Interrupt Yes / No	Verdict	Comments
Supplementary information:					
b) Range changing switches					
Type / Model	Maximum rated current of switch A	Cycling test Verdict	Comments		
Supplementary information:					

LICENSED TO MECON Limited. - RANCHI/BANGALORE
FOR INTERNAL USE AT THIS LOCATION ONLY. SUPPLIED BY BOOK SUPPLY BUREAU.

16.2	TABLE: Multifunctional meters and similar equipment	Form A. 33
	Function switch position	
	Maximum RATED voltage applied (V)	
	Measurement category.....	
	Test source limit (KVA).....	
Maximum RATED voltage applied (V) :		
Measuring TERMINALS	Range	Verdict
Maximum RATED voltage applied (V) :		
Measuring TERMINALS	Range	Verdict
Supplementary information:		

LICENSED TO MECON Limited. - RANCHI/BANGALORE
 FOR INTERNAL USE AT THIS LOCATION ONLY. SUPPLIED BY BOOK SUPPLY BUREAU.

Annex XX

List of applicable and omitted clauses/subclauses in the test report

If any clauses and subclauses are considered to be not applicable to the equipment under test and are omitted from the test report itself, the following list of contents is to be attached with these omitted clauses and subclauses clearly identified with a line through them. If there are no omitted clauses/subclauses, annex A is not required and need not be attached.

Summary of tests

- 5 Marking and documentation
 - 5.1.1 General
 - 5.1.2 Identification
 - 5.1.3 Mains supply
 - 5.1.4 Fuses
 - 5.1.5 TERMINALS, connections and operating devices
 - 5.1.6 Switches and circuit-breakers
 - 5.1.7 Equipment protected by DOUBLE INSULATION or REINFORCED INSULATION
 - 5.1.8 Field-wiring TERMINAL boxes
 - 5.1.101 Transport and storage
- 5.2 Warning markings
- 5.3 Durability of markings
- 5.4 Documentation
 - 5.4.1 General
 - 5.4.2 Equipment RATINGS
 - 5.4.3 Equipment installation
 - 5.4.4 Equipment operation
 - 5.4.4.101 Self-test IVD medical equipment
 - 5.4.5 Equipment maintenance
 - 5.4.101 Removal of equipment from use for repair or disposal
 - 5.4.102 Transport and storage
- 6 Protection against electric shock
 - 6.1 General
 - 6.1.1 Requirements
 - 6.1.2 Exceptions
 - 6.2 Determination of ACCESSIBLE parts
 - 6.2.1 Examination
 - 6.2.2 Openings above parts that are HAZARDOUS LIVE
 - 6.2.3 Openings for pre-set controls
 - 6.3 Permissible limits for ACCESSIBLE parts
 - 6.3.1 Values in NORMAL CONDITION
 - 6.2.3 Values in SINGLE FAULT CONDITION

- 6.4 Protection in NORMAL CONDITION
- 6.5 Protection in SINGLE FAULT CONDITION
 - 6.5.1 PROTECTIVE BONDING
 - 6.5.1.1 Integrity of protective bonding
 - 6.5.1.2 PROTECTIVE CONDUCTOR TERMINAL
 - 6.5.1.3 Impedance of PROTECTIVE BONDING of plug-connected equipment
 - 6.5.1.4 Bonding impedance of PERMANENTLY CONNECTED EQUIPMENT
 - 6.5.1.5 Indirect bonding for test and measurement equipment
 - 6.5.2 DOUBLE INSULATION and REINFORCED INSULATION
 - 6.5.3 PROTECTIVE IMPEDANCE
 - 6.5.4 Automatic disconnection of the supply
- 6.6 Connection to external circuits
 - 6.6.1 General
 - 6.6.2 TERMINALS for external circuits
 - 6.6.3 Circuits with TERMINALS which are HAZARDOUS LIVE
 - 6.6.4 ACCESSIBLE TERMINALS for stranded conductors
- 6.7 CLEARANCES and CREEPAGE DISTANCES
- 6.8 Procedure for dielectric strength tests
 - 6.8.1 Reference test earth
 - 6.8.2 Humidity preconditioning
 - 6.8.3 Conduct of tests
 - 6.8.4 Voltage tests
- 6.9 Constructional requirements for protection against electric shock
 - 6.9.1 General
 - 6.9.2 ENCLOSURES of equipment with DOUBLE INSULATION or REINFORCED INSULATION
 - 6.9.3 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
 - 6.10.2 Fitting of non-detachable MAINS supply cords
 - 6.10.3 Plugs and connectors
- 6.11 Disconnection from supply source
 - 6.11.1 General
 - 6.11.1.1 Exceptions
 - 6.11.2 Requirements according to type of equipment
 - 6.11.2.1 PERMANENTLY CONNECTED EQUIPMENT and multi-phase equipment
 - 6.11.2.2 Single-phase cord-connected equipment
 - 6.11.2.3 Hazards arising from function
 - 6.11.3 Disconnecting devices
 - 6.11.3.1 Switches and circuit-breakers
 - 6.11.3.2 Appliance couplers and plugs
- 7 Protection against mechanical HAZARDS
 - 7.1 General
 - 7.2 Moving parts
 - 7.3 Stability
 - 7.4 Provisions for lifting and carrying
 - 7.5 Wall mounting
 - 7.6 Expelled parts
- 8 Mechanical resistance to shock and impact
 - 8.1 ENCLOSURE rigidity test
 - 8.2 Drop test
 - 8.2.1 Equipment other than HAND-HELD EQUIPMENT and direct plug-in equipment
 - 8.2.2 HAND-HELD EQUIPMENT and direct plug-in equipment

- 8.101 Transport and storage
- 9 Protection against the spread of fire
 - 9.1 Eliminating or reducing the sources of ignition within the equipment
 - 9.2 Containment of fire within the equipment, should it occur
 - 9.2.1 Constructional requirements
 - 9.3 Limited-energy circuit
 - 9.4 Requirements for equipment containing or using flammable liquids
 - 9.5 Overcurrent protection
 - 9.5.1 PERMANENTLY CONNECTED EQUIPMENT
 - 9.5.2 Other equipment
- 10 Equipment temperature limits and resistance to heat
 - 10.1 Surface temperature limits for protection against burns
 - 10.2 Temperatures of windings
 - 10.3 Other temperature measurements
 - 10.4 Conduct of temperature tests
 - 10.5 Resistance to heat
 - 10.5.1 Integrity of CLEARANCES and CREEPAGE DISTANCES
 - 10.5.2 Non-metallic ENCLOSURES
 - 10.5.3 Insulating material
- 11 Protection against HAZARDS from fluids
 - 11.1 General
 - 11.2 Cleaning
 - 11.3 Spillage
 - 11.4 Overflow
 - 11.5 Battery electrolyte
 - 11.6 Specially protected equipment
 - 11.7 Fluid pressure and leakage
 - 11.7.1 Maximum pressure
 - 11.7.2 Leakage and rupture at high pressure
 - 11.7.3 Leakage from low-pressure parts
 - 11.7.4 Overpressure safety device
- 12 Protection against radiation, including laser sources, and against sonic and ultrasonic pressure
 - 12.1 General
 - 12.2 Equipment producing ionizing radiation
 - 12.2.1 Ionizing radiation
 - 12.2.2 Accelerated electrons
 - 12.3 Ultra-violet (UV) radiation
 - 12.4 Microwave radiation
 - 12.5 Sonic and ultrasonic pressure
 - 12.5.1 Sound level
 - 12.5.2 Ultrasonic pressure
 - 12.6 Laser sources

- 13 Protection against liberated gases, explosion and implosion
 - 13.1 Poisonous and injurious gases and substances
 - 13.2 Explosion and implosion
 - 13.2.1 Components
 - 13.2.2 Batteries and battery charging
 - 13.2.3 Implosion of cathode ray tubes
 - 13.2.4 Equipment RATED for high pressures
- 14 Components
 - 14.1 General
 - 14.2 Motors
 - 14.2.1 Motor temperatures
 - 14.2.2 Series excitation motors
 - 14.3 Overtemperature protection devices
 - 14.4 Fuse holders
 - 14.5 Mains voltage selecting devices
 - 14.6 HIGH INTEGRITY components
 - 14.7 Mains transformers tested outside equipment
 - 14.8 Printed circuit boards
 - 14.9 Circuits or components used as transient overvoltage limiting devices
- 15 Protection by interlocks
 - 15.1 General
 - 15.2 Prevention of reactivation
 - 15.3 Reliability
 - 15.4 Test and measurement equipment
- 16.1 Current measuring circuits
- 16.2 Multifunction meters and similar equipment

Annexes

F Routine tests

AA Risk management

BB Instructions for use for self-test IVD medical equipment

Forms

- A.1
- A.2
- A.3
- A.4
- A.5
- A.6
- A.7
- A.8
- A.9
- A.10
- A.11
- A.12
- A.13
- A.14
- A.15
- A.16

A.17
A.18
A.19
A.20
A.21A
A.21B
A.22
A.23
A.24
A.25
A.26
A.27
A.28
A.29
A.30
A.31
A.32
A.33

Annex YY

This annex details the changes introduced in the combined document for TR 61010-3-101, to reflect the specific requirements of IEC 61010-2-101

Clause Subclause	Requirement	Comments	Verdict
5	MARKING AND DOCUMENTATION		
5.1.1	General		
Addition			
	Additional symbols cannot be confused with the international ones.		
5.1.2	Identification		
	Equipment is identified by:		
Replace items 5.1.2a) and b) by the following new items 5.1.2a) to c)			
5.1.2a)	Manufacturer's name or trademark and address		
5.1.2b)	Model number, name or other means		
5.1.2c)	The name and address of the authorized representative of the manufacturer		
	The equipment or packaging or the instructions for use include:		
	1) The serial-number or the batch code preceded by „LOT“ symbol 102 of table 1		
	2 i) Indication that the equipment is IVD medical equipment		
	2 ii) Indication that the equipment is self-test IVD medical equipment		
	2 iii) Identification of detachable components		
	2 iv) Expiry date of consumable parts		
Addition			
5.1.101	Transport and storage		
	Packaging labelled to indicate special conditions for transport or storage		
5.2	Warning markings		

Clause Subclause	Requirement	Comments	Verdict
Additions			
	Potentially infectious equipment marked with symbol 101		
	Equipment that can be hazardous due to the use of chemical substances marked with the appropriate symbol		
	Containers or bags for biohazardous waste material which can be removed from the equipment during NORMAL USE marked with symbol 101		
5.3	Durability of markings		
Addition			
	The required markings resist the effects of temperature and rubbing, and of solvent and reagents likely to be encountered in NORMAL USE	(see Form A.4)	
5.4	Documentation		
5.4.1	General		
Additions			
5.4.1g)	If CAT 1:		
	Information about any RISKS not reduced to a TOLERABLE RISK level		
	Information included in documentation on:		
	Training; or		
	Protective devices; or		
	Personal protective equipment to reduce RISKS to a TOLERABLE RISK level specified;		
5.4.3	Replace the title and texts by the following new 5.4.3:		
5.4.3	Equipment transportation, installation and assembly instructions		
	Documentation for the RESPONSIBLE BODY includes :		
5.4.3a)	Instructions for transportation after delivery to the RESPONSIBLE BODY		
5.4.3b)	Floor loading requirements		
5.4.3c)	Individual weights of principal heavy subassemblies		
5.4.3d)	Location and mounting instructions		
5.4.3e)	Assembly instructions		
5.4.3f)	Instructions for protective earthing		
5.4.3g)	The sound data required by 12.5.1		

Clause Subclause	Requirement	Comments	Verdict
5.4.3h)	Instructions relating to handling, containment and exhaust of hazardous substances		
5.4.3l)	Any drainage systems required		
5.4.3j)	Protective measures relating to hazardous radiation		
5.4.3k)	Connections to the supply		
5.4.3l)	PERMANENTLY CONNECTED EQUIPMENT only:		
	1) Mains supply requirements and details of connections		
	2) If external switch or circuit-breaker, requirements and location recommendation		
5.4.3m)	Special services including pressure limits		
5.4.4	Equipment operation		
	Instructions for use include:		
Replace items 5.4.4f) to i) by the following new items 5.4.4f) to m)			
5.4.4f)	Any actions by an OPERATOR in case of a malfunction		
5.4.4g)	Cleaning and decontamination (see 11.2) incl. materials		
5.4.4h)	Disposal of waste		
5.4.4i)	Hazardous substances, use, need for training, or personal protection measures		
5.4.4j)	Infectious substances, need to use protective gloves or other protective means		
5.4.4k)	Hazardous vapours, instructions for protection of the mouth, nose or eyes		
5.4.4l)	Hazardous radiation, instructions and requirements for protective devices		
5.4.4m)	A statement about protection impairment if used in a manner not specified by the manufacturer		
5.4.4.101	1.1.1.1.1.1 Self-test IVD medical equipment		
	Instructions for use for self-test equipment comply with annex BB		
Additions			
5.4.101	Removal of equipment from use for repair or disposal		
	Instructions for the RESPONSIBLE BODY for eliminating or reducing HAZARDS provided		

Clause Subclause	Requirement	Comments	Verdict
5.4.102	Transport and storage		
	Permissible environmental conditions for transport and storage specified:		
	In documentation; and		
	On outside of packaging		
8	MECHANICAL RESISTANCE TO SHOCK AND IMPACT		
Addition			
8.101	Transport and storage		
	Records of tests performed by the manufacturer show conformity	(See test records attached)	
11	PROTECTION AGAINST HAZARDS FROM FLUIDS		
11.3	Spillage	(See Form A.23)	
Additions			
	Potentially aggressive substances (such as corrosive, toxic or flammable liquids) taken into account		
	Potentially aggressive substances compatible with contacted parts of the equipment		
13	Replace the titles and texts for clause 13 and subclause 13.1 as follows:		
13	PROTECTION AGAINST LIBERATED GASES AND SUBSTANCES, EXPLOSION AND IMPLOSION		
13.1	Poisonous and injurious gases and substances		
	Attached data/test reports demonstrate conformity (in NC and SFC)	(See Form A.1)	
	Dangerous amounts of poisonous or injurious gases or substances not liberated in NORMAL CONDITION or in SINGLE FAULT CONDITION	Attach any data/test reports used to demonstrate conformity	
	If potentially hazardous substances are liberated:		
	OPERATOR not be wetted nor able to inhale quantities likely to be hazardous		
	protective covers or similar means of protection		
14.3	Overtemperature protection devices	(See Form A.28)	
Addition			
14.3c)	Does not operate in NORMAL USE		
	Non-self resetting in self-test IVD equipment		
15	PROTECTION BY INTERLOCKS		

Clause Subclause	Requirement	Comments	Verdict
Addition			
Annex AA	RISK management		
	Conformity demonstrated	(See document attached)	
Amendment of Form A.1 by additions			

Subclause	Title	Does not apply	Carried out	Comments
Addition				
4.4.2.101	Incorrect voltage selection			
List below all SINGLE FAULT CONDITIONS not covered by 4.4.2.1 to 4.4.2.101:				
Addition				
13.1	Poisonous and injurious gases and substances			

LICENSED TO MECON Limited. - RANCHI/BANGALORE
FOR INTERNAL USE AT THIS LOCATION ONLY, SUPPLIED BY BOOK SUPPLY BUREAU.



Standards Survey

The IEC would like to offer you the best quality standards possible. To make sure that we continue to meet your needs, your feedback is essential. Would you please take a minute to answer the questions overleaf and fax them to us at +41 22 919 03 00 or mail them to the address below. Thank you!

Customer Service Centre (CSC)

International Electrotechnical Commission

3, rue de Varembé

1211 Genève 20

Switzerland

or

Fax to: **IEC/CSC** at +41 22 919 03 00

Thank you for your contribution to the standards-making process.

A Prioritaire

Nicht frankieren
Ne pas affranchir



Non affrancare
No stamp required

RÉPONSE PAYÉE

SUISSE

Customer Service Centre (CSC)

International Electrotechnical Commission

3, rue de Varembé

1211 GENEVA 20

Switzerland



Q1 Please report on **ONE STANDARD** and **ONE STANDARD ONLY**. Enter the exact number of the standard: (e.g. 60601-1-1)

.....

Q2 Please tell us in what capacity(ies) you bought the standard (tick all that apply). I am the/a:

- purchasing agent
- librarian
- researcher
- design engineer
- safety engineer
- testing engineer
- marketing specialist
- other.....

Q3 I work for/in/as a: (tick all that apply)

- manufacturing
- consultant
- government
- test/certification facility
- public utility
- education
- military
- other.....

Q4 This standard will be used for: (tick all that apply)

- general reference
- product research
- product design/development
- specifications
- tenders
- quality assessment
- certification
- technical documentation
- thesis
- manufacturing
- other.....

Q5 This standard meets my needs: (tick one)

- not at all
- nearly
- fairly well
- exactly

Q6 If you ticked NOT AT ALL in Question 5 the reason is: (tick all that apply)

- standard is out of date
- standard is incomplete
- standard is too academic
- standard is too superficial
- title is misleading
- I made the wrong choice
- other

Q7 Please assess the standard in the following categories, using the numbers:

- (1) unacceptable,
- (2) below average,
- (3) average,
- (4) above average,
- (5) exceptional,
- (6) not applicable

- timeliness.....
- quality of writing.....
- technical contents.....
- logic of arrangement of contents
- tables, charts, graphs, figures.....
- other

Q8 I read/use the: (tick one)

- French text only
- English text only
- both English and French texts

Q9 Please share any comment on any aspect of the IEC that you would like us to know:

.....



LICENSED TO MECON Limited. - RANCHI/BANGALORE
FOR INTERNAL USE AT THIS LOCATION ONLY, SUPPLIED BY BOOK SUPPLY BUREAU.

ISBN 2-8318-6961-7



9 782831 869612

ICS 19.080; 71.040.10
