Test Report issued under the responsibility of:

TEST REPORT

IEC 60601-1

Part 1: General requirements for basic safety and essential performance

Report Number. ..... :	130300178SHA-001
Date of issue ..... :	2013-04-16
Total number of pages ..... :	127
Applicant's name ..... :	GlobTek, Inc.
Address ..... :	186 Veterans Dr. Northvale, NJ 07647 USA
Test specification:	
Standard ..... :	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1G_PS
Test Report Form(s) Originator .... :	UL
Master TRF ..... :	2012-12

Copyright © 2012 Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE), Geneva, Switzerland. All rights reserved.

This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description ..... :	Medical Power Supply
Trade Mark ..... :	GlobTek
Manufacturer ..... :	GlobTek, Inc.
	186 Veterans Dr. Northvale, NJ 07647 USA
Model/Type reference ..... :	GTM43033-*** (Refer to page 6 for details.)
Ratings ..... :	Input: 100-240V~, 50-60Hz, 0.3A;
	Output: Refer to page 6 for details.

Testing procedure and testing location:			
☒	**CB Testing Laboratory:**	Intertek Testing Services Shanghai	
Testing location/ address..... :		Building No.85 and 86, 1198 Qinzhou Road (North), 200233 Shanghai, China	
☐	**Associated CB Testing Laboratory:**		
Testing location/ address..... :			
Tested by (name + signature) ..... :		Jamie Wu	
Approved by (name + signature) ..... :		Karl Zhong	
☐	**Testing procedure: TMP**		
Testing location/ address..... :			
Tested by (name + signature) ..... :			
Approved by (name + signature) ..... :			
☐	**Testing procedure: WMT**		
Testing location/ address..... :			
Tested by (name + signature) ..... :			
Witnessed by (name + signature).... :			
Approved by (name + signature) ..... :			
☐	**Testing procedure: SMT**		
Testing location/ address..... :			
Tested by (name + signature) ..... :			
Approved by (name + signature) ..... :			
Supervised by (name + signature) .. :			

List of Attachments (including a total number of pages in each attachment):

Photo of EUT: Page 86-90

Circuit Diagram / Layout: Page 91-92

Canada and USA national difference: Page 93-99

Switzerland national difference: Page 100

Plug evaluation: Page 101-127

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
4.11 Power Input	Intertek Testing Services Shanghai
5.7 Humidity Preconditioning	Building 86, 1198 Qinzhou Road (North), Shanghai, China, 200233
5.9.2 Accessible Parts	
7.1.2 Legibility of Markings	
7.1.3 Durability of Markings	
8.4.3 Plug Voltage and/or Energy	
8.5.4 Working Voltage Measurement	
8.7.4 Leakage Current Test	
8.8.3 Dielectric Strength Means	
8.8.4.1 Ball Pressure Test	
8.9.4 Creepage & Clearance Measurements	
11.1 Excessive Temperature	
13.2 Single Fault Conditions	
15.3.2 Push Test	
15.3.4 Drop Test	
15.3.6 Moulding Stress Relief	
15.5.1.2 Transformer Short-Circuit	
15.5.1.3 Transformer Overload	
15.5.2 Transformer Dielectric Strength	

Summary of compliance with National Differences

List of countries addressed:

Canada, USA, Switzerland

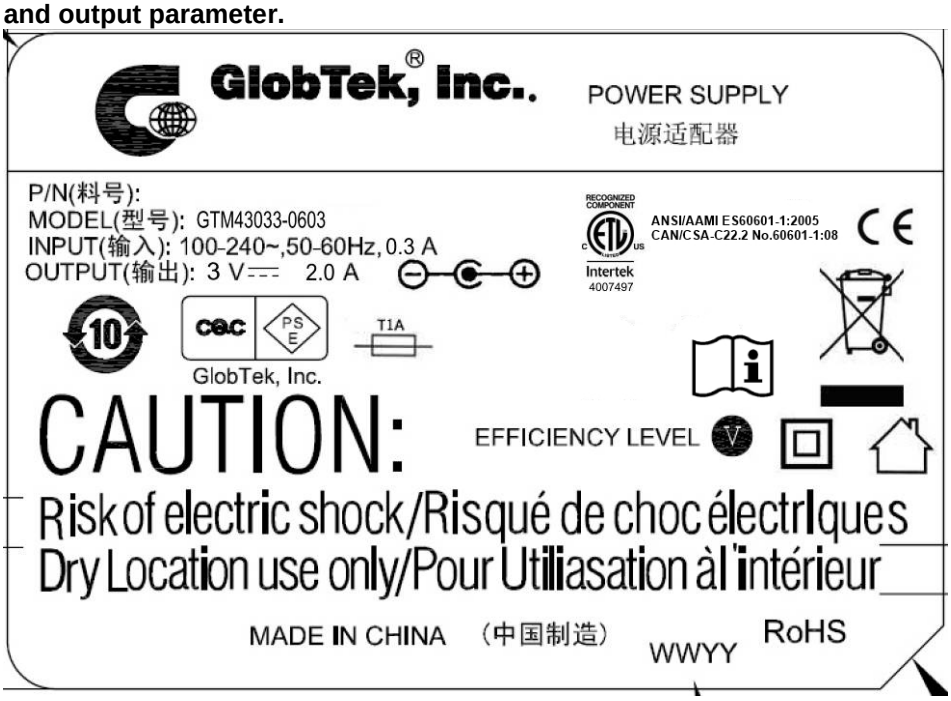
Group- and national differences for the CENELEC countries according to EN 60601-1:2006 + A11:2011.

☒ **The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007).**

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

The marking plates of the other models listed in this report are identical with below except model name and output parameter.



Test item particulars	(see also Clause 6)
Classification of installation and use .....:	~~transportable / portable / stationary / mobile / fixed / permanently installed / hand-held~~ Direct plug-in type: final determination in end product evaluation.
Device type (component/sub-assembly/ equipment/ system.....:	Component
Intended use (Including type of patient, application location) .....:	PSU (external power adapter or internal power supply board)
Mode of operation .....:	Continuous / ~~non-continuous~~
Supply Connection .....:	~~internally powered /permanently installed / appliance coupler / non-detachable cord~~ Direct plug-in type
Accessories and detachable parts included .....:	Plug (Evaluated as attachment)
Other options included.....:	None
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object was not evaluated for the requirement:	N/E
- test object does meet the requirement .....:	P (Pass)
- test object does not meet the requirement .....:	F (Fail)
Abbreviations used in the report:	
- normal condition .....N.C.	- single fault condition.....S.F.C.
- means of Operator protection .....MOOP	- means of Patient protection .....MOPP
Testing .....:	
Date of receipt of test item.....:	2013-03-07
Date (s) of performance of tests .....:	2013-03-07~2013-04-15

General remarks:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing testing laboratory.
"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3rd edition. The Risk Management was excluded from the investigation; this shall be clearly identified in this report and on the accompanying CB Test Certificate.

Additional test data and/or information may be provided in the attachments to this report.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided..:

☒ Yes
☐ Not applicable

.....

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies).....:

Factory 1

GlobTek, Inc.

186 Veterans Dr. Northvale, NJ 07647 USA

Factory 2

GlobTek (Suzhou) Co., Ltd

Building 4, No. 76, Jin Ling East Rd., Suzhou Industrial Park, Suzhou, JiangSu 215021, China

General product information:

Product covered by this report is medical power supply module, which can be used as a part of medical equipment.

The device is direct plug-in power adapter with interchangeable plug portion, which is Class II apparatus. It can be used with different plug types. The evaluation reports of the different plug types are also attached with this report. Two pieces of outer enclosure are enclosed with ultrasonic welding without screw.

All the types are designed for continuous operation and no applied part is defined.

Insulation between mains part and secondary circuits is evaluated as 2MOPP.

Model Similarity:

GTM43033-***

The 1st "*" part denotes the rated output wattage designation, which can be "01" to "06", with interval of 1.

The 2nd "*" part denotes the standard rated output voltage designation, which can be "03", "04" "06","12", "15", "18" , "24", "36" or "48". These standard rated output voltage designations correspond to five isolated transformer models (See the appended table 8.10 for details). Each transformer model is identical in insulation construction including clearance and creepage except number of turns per coil.

The 3rd"*" part is optional, which can be "-0.1" to "-11.9" with interval of 0.1 to denote voltage deviation or blank to indicate no voltage different. The result by subtracting the deviation value from the standard rated output voltage denotes the rated output voltage, with a range of 3 - 48 volts.

Test performed on 3Vdc/2A output adapter model and 48Vdc/0.125A output adapter model as worst condition, and also performed on other output models for reference. Although ME equipment installation and use type are not specified, mechanical strength tests including push test, 1 m height drop test and mould stress relief test are performed considering the usage for adapter model.

Model list

Model	Rated output voltage range	Max. rated output current	Max. rated output power
GTM43033-*03	3Vdc	2A	6W
GTM43033-*04*	3.1-4V	1.94A	6W
GTM43033-*06*	4.1-6V	1.46A	6W
GTM43033-*12*	6.1-12V	0.98A	6W
GTM43033-*15*	12.1-15V	0.50A	6W
GTM43033-*18*	15.1-18V	0.40A	6W
GTM43033-*24*	18.1-24V	0.33A	6W
GTM43033-*36*	24.1-36V	0.25A	6W
GTM43033-*48*	36.1-48V	0.16A	6W

Technical Considerations:

1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:

- **Clause 7.5 (Safety Signs),**
- **Clause 7.9 (Accompanying Documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end product level.),**
- **Clause 8.11.5 (Mains Fuse with High Breaking Capacity),**
- **Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,**
- **Clause 10 (Radiation),**
- **Clause 11.7 (Biocompatibility),**
- **Clause 14 (PEMS),**
- **Clause 16 (ME Systems)**
- **Clause 17 (EMC),**
- **Risk Management was excluded from this investigation.**

2. Risk Controls/ Engineering Considerations for component power supply:

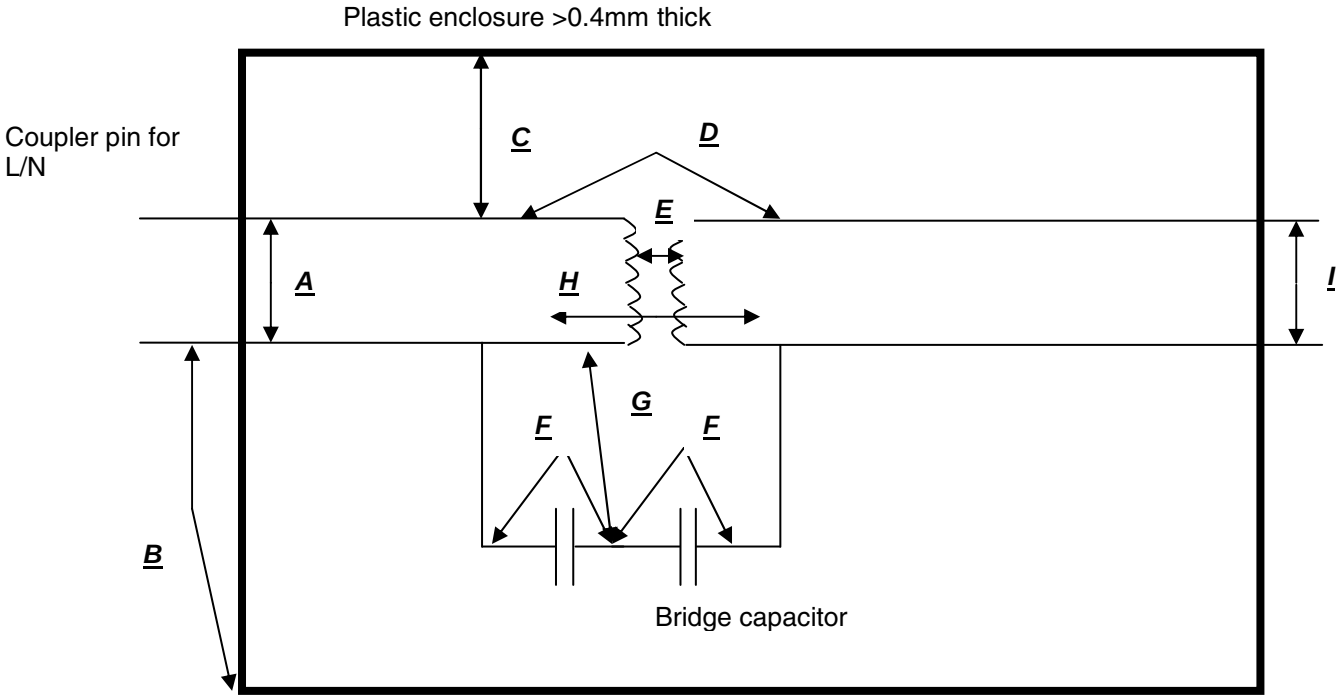
For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the following:

- **For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.**
- **For Power Supplies with No RM: End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1/F2).**
- **For Power Supplies with No RM: End product Risk Management Process to consider the need for simultaneous fault condition testing.**
- **For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.**

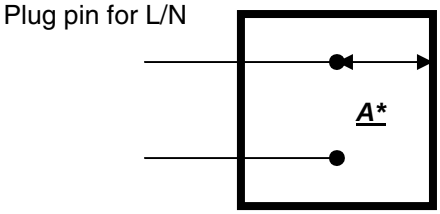
- **For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.**
- **For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.**
- **For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.**
- **For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.**
- **For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.**
- **For Power Supplies with No RM or Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply.**
- **For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply.**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM



Plug portion connector without the power supply correctly attached



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

TABLE: Insulation diagram (measured values)		P
Pollution degree..... :	2	—
Overvoltage category..... :	II	—
Altitude..... :	3000m	—
Additional details on parts considered as applied parts..... :	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
A	BOP	IIIb	240	--	3	2.1[4]	3.8	3.8	Opposite polarity of mains part
A*	2MOOP	IIIb	240	340	4.8	4.7[4]	5.6	5.6	Accessible part to plug pin for plug portion when the connector is plugged in the socket without the power supply correctly attached.
B	2MOOP	IIIb	240	340	4.8	4.7[4]	9.2	9.2	Mains part (plug portion) to outer enclosure (accessible position during normal use)
C	2MOOP	IIIb	240	340	4.8	4.7[4]	5.4	5.4	Internal mains part to accessible outer enclosure
D	2MOPP	IIIb	240[1]	--	7.9[2]	5.0	8.0[3]	8.0[3]	Mains part to secondary circuits (Optocoupler)
E	2MOPP	IIIb	270[1]	--	8.6[2]	7.0	9.0	9.0	Mains part to secondary circuits (Transformer)
F	MOPP (Each) x 2	IIIb	240[1]	--	4.0[2]	2.5	7.0	7.0	Mains part to secondary circuits (Y capacitor x 2)
G	MOPP	IIIb	240[1]		4.0[2]	2.5	4.0[4]	2.6	Mains part to 2nd Y capacitor first pin-out (On PCB trace)
H	2MOPP	IIIb	240[1]	--	7.9[2]	5.0	8.0[4]	7.8	Mains part to secondary circuits (On PCB trace)
I	2MOPP	IIIb	--	Max. 48	--	--	--	--	Accessible part per 8.4.2 c)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Note:

1) The working voltage is highest measured value which acquired by testing all the models listed in the report at the rated input voltage, but not less than the rated input voltage.

2) Linear interpolation is applied to the determination of required creepage.

3) The minimum creepage and clearance is selected from all the types of optocouplers.

4) There is a slot min. 1 mm wide between these two parts.

5) Multiplication factor for MOOP: 1.14; Multiplication factor for MOPP: 1.00.

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4	**GENERAL REQUIREMENTS**		
4.1	**Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse**		**P**
4.2	**A RISK MANAGEMENT PROCESS complying with ISO 14971 was performed ..... :**	RM is not included for component power supply, the acceptability of risk of the power supply is determined as part of the end product.	**N/A**
4.3	**ESSENTIAL PERFORMANCE functions identified according to MANUFACTURER'S policy for RISK acceptability in RISK MANAGEMENT FILE..... :**	RM is not included for component power supply, the acceptability of risk of the power supply is determined as part of the end product.	**N/A**
4.4	**EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE..... :**	RM is not included for component power supply, the expected service life and acceptability of risk of the power supply are determined as part of the end product.	**N/A**
4.5	**Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means equal to or less than RESIDUAL RISKS resulting from requirements of this standard ..... :**	RM is not included, no alternative means of addressing particular risks were considered	**N/A**
4.6	**RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10..... :**	RM is not included in the investigation of component power supply	**N/A**
4.7	**ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2..... :**	RM is not included; component power supply remained Single Fault Safe, acceptability of risk to be determined as part of the end product.	**N/A**
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically ..... :	Test performed, simulated physically	**P**
	RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation	RM is not included for component power supply, the expected service life and acceptability of risk of the power supply are determined as part of the end product.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4.8	**All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, except as specified, or by RISK MANAGEMENT PROCESS ..... :**	All components and wiring used according to applicable rating.	**P**
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following:		**P**
	a) Applicable safety requirements of a relevant IEC or ISO standard		**P**
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		**P**
4.9	**A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK :**	RM not included; components were identified where single fault could cause a hazard as High-Integrity Component. End product to determine the suitability of the component to prevent unacceptable Risk.	**N/A**
	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS selected and evaluated consistent with their conditions of use and reasonable foreseeable misuse during EXPECTED SERVICE LIFE of ME EQUIPMENT by reviewing RISK MANAGEMENT FILE :	RM not included; components were identified where single fault could cause a hazard as High-Integrity Component. End product to determine the suitability of the component to prevent unacceptable Risk.	**N/A**
4.10	**Power supply**		
4.10.1	**ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three ..... :**	Suitable for connection to a SUPPLY MAINS.	**P**
4.10.2	**Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS is 250 V for HAND-HELD ME EQUIPMENT (V) ..... :**	Not hand-held equipment.	**N/A**
	– 250 V d.c. or single-phase a.c., or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V) ..... :	100-240Vac, single phase, less than 4KVA	**P**
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS	100-240Vac, single phase, less than 4KVA	**N/A**
4.11	**Power input**		
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use did not exceed marked rating by more than 10% ..... :	See appended Table 4.11	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range ..... :	See appended Table 4.11	**P**
	Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of relevant voltage range	No such marking.	**N/A**
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage..... :	See appended Table 4.11	**P**
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		
5.1	**TYPE TESTS determined in consideration of Clause 4, in particular 4.2**		**P**
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods..... :	RM not provided: All test were conducted.	**N/A**
	Results of RISK ANALYSIS used to determine combination(s) of simultaneous faults to be tested	RM not included: End product Risk Management must determine the need for simultaneous fault tests.	**N/A**
5.2	**TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected..... :**	Type test on single representative sample.	**P**
5.3	**a) Tests conducted within the environmental conditions specified in technical description**		**P**
	Temperature (ºC), Relative Humidity (%) ..... :	0-40ºC, 20%-80%RH	**—**
	Atmospheric Pressure (kPa)..... :	700-1060hPa (3000m altitude)	**—**
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests		**P**
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained ..... :	Considered in temperature test	**P**
5.4	**a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use and identified during RISK ANALYSIS, except as noted ..... :**	RM not provided, end product Risk Analysis to determine whether or not additional configurations should be considered during testing	**N/A**
	Power supply tested in the following configuration (Horizontal, vertical, etc.)..... :	All the positions are considered during test for power adapter type.	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favourable for the relevant test per instructions for use	EUT is component power supply, not adjustable.	**N/A**
	c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits in technical description ..... :	No cooling liquid used.	**N/A**
	d) Potable water used for cooling	No cooling water used.	**N/A**
5.5	**Supply voltage during tests was the least favourable of the voltages specified in 4.10 or voltages marked on ME EQUIPMENT (V) ..... :**	90/264V considered	**P**
	ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :	60Hz considered	**P**
	ME EQUIPMENT with more than one RATED voltage, or both a.c./ d.c. tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current..... :	90/264V, 60Hz considered	**P**
	ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions ..... :	No alternative accessory	**N/A**
	ME EQUIPMENT connected to a separate power supply as specified in instructions for use	No separate power supply used	**N/A**
5.6	**When failure occurred or probability of future failure detected during sequence of tests, per agreement with manufacturer, all tests affecting results conducted on a new sample**	No such condition	**N/A**
	Alternatively, upon repair and modification of the sample, only the relevant tests conducted	No such condition	**N/A**
5.7	**ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3..... :**	RM not provided, end product Risk Analysis to determine whether or not additional testing should be considered	**P**
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened and detached	No such part.	**N/A**
	ME EQUIPMENT heated to a temperature between T and T + 4 °C for at least 4 h and placed in a humidity chamber with a relative humidity of 93% ± 3 % and an ambient within 2°C of T in the range of + 20°C to + 32°C for 48 h..... ..... :	Pre-condition performed: 26°C, 93%RH for 120 h according to client's request.	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.8	**Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent results of one test on a subsequent test**		**P**
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		
5.9.1	**APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ..... :**	See clause 4.6 Remark	**N/A**
5.9.2	**ACCESSIBLE PARTS**		
5.9.2.1	**Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position**	See appended Table 5.9.2	**P**
	Openings preventing entry of test finger of Fig. 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N		**P**
	When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening	Straight un-jointed test finger can't enter opening.	**N/A**
5.9.2.2	**Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s**	Test hook can't enter opening	**N/A**
	All additional parts that became accessible checked using standard test finger and by inspection	Test hook can't enter opening	**N/A**
5.9.2.3	**Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS ..... :**	No such part.	**N/A**

6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		
6.2	**CLASS I ME EQUIPMENT, externally powered**	Not Class I.	**N/A**
	CLASS II ME EQUIPMENT, externally powered	Class II only	**P**
	INTERNALLY POWERED ME EQUIPMENT	Not internally powered	**N/A**
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		**N/A**
6.3	**ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN_1N_2) as per IEC 60529 ..... :**	IP20 for adapter model	**N/A**
6.4	**ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use ..... :**	No sterilization required	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
6.5	**ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2**	Power supply not investigated for OXYGEN RICH ENVIRONMENT	**N/A**
6.6	**CONTINUOUS or Non-CONTINUOUS OPERATION ..... :**	Continuous operation	**P**
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		
7.1.1	**RISK of poor USABILITY associated with the design of ME EQUIPMENT'S identification and marking addressed in a USABILITY ENGINEERING PROCESS.. :**	USABILITY ENGINEERING PROCESS not applied for power supply	**N/A**
7.1.2	**Legibility of Markings Test for Markings specified in Clause 7.2-7.6 ..... :**	See Appended Table 7.1.2	**P**
7.1.3	**Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE**		**P**
	a) After tests, adhesive labels didn't loosen up or curl up at edges and markings complied with requirements in Clause 7.1.2 ..... :	See appended Tables 7.1.3 and 8.10	**P**
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test ..... :	See appended Tables 7.1.3 and 8.10	**P**
7.2	**Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		
7.2.1	**At least markings in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ..... :**	See attached copy of Marking Plate	**P**
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS..... :	All required marking provided on name plate。	**N/A**
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	No such condition	**N/A**
	A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01) ..... :	No part intended for a single use.	**N/A**
7.2.2	**MANUFACTURER's name or trademark marked on ME EQUIPMENT and detachable components ..... :**	See attached copy of Marking Plate.	**P**
	Components inspected ..... :	No detachable component.	**—**
	MODEL OR TYPE REFERENCE also marked, except when misidentification would not present an unacceptable RISK ..... :	See attached copy of Marking Plate	**P**
	Software forming part of a PEMS identified with a unique identifier, such as revision level or date of release/issue, and identification are available to designated persons..... :	No software.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.3	**Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS**	See the marking label.	**P**
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	No such safety sign used.	**N/A**
7.2.4	**ACCESSORIES marked with name or trademark of MANUFACTURER or supplier, and with a MODEL or TYPE REFERENCE .....:**	No accessory.	**N/A**
	Accessories inspected .....:	No accessory.	—
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	No accessory.	**N/A**
7.2.5	**MODEL or TYPE REFERENCE of equipment to be connected to ME EQUIPMENT to provide power, is marked adjacent to the relevant connection point when this connection could result in an unacceptable RISK.....:**	Component; Final determination to be performed in the end product	**N/A**
7.2.6	**Connection to the Supply Mains**		
	Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point		**P**
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to supply connection terminals	Not for permanently installed.	**N/A**
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V).....:	100-240V	**P**
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) ..:	Not so marked.	**N/A**
	– Nature of supply (e.g., No. of phases, except single-phase) and type of current.....:	'~' is used.	**P**
	Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all DB: 2002-10) used, optionally, for same parameters .....:		**P**
	– RATED supply frequency or RATED frequency range in hertz .....:	50-60Hz	**P**
	– Symbol 9 of Table D.1 (symbol IEC 60417-5172, DB: 2003-02) used for CLASS II ME EQUIPMENT .....:	Symbol 9 is used for adapter model.	**P**
7.2.7	**RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W).....:**	RATED input in amps: 0.3A	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W) ..... :	No such range provided.	**N/A**
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) ..... :	No such range provided.	**N/A**
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA) ..... :	No such rating provided.	**N/A**
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W)..... :	No such rating provided.	**N/A**
7.2.8	**Output connectors**		
7.2.8.1	**See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT**	No MSO	**N/A**
7.2.8.2	**Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment**		**P**
	Rated Voltage (V), Rated Current (A) .....:	See model similarity	**—**
	Rated Power (W), Output Frequency (Hz) .....:	See model similarity	**—**
7.2.9	**ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2) ..... :**	Ordinary	**N/A**
7.2.10	**Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6):**	No Applied Parts in power supply	**N/A**
7.2.11	**ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION**		**P**
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time..... :	Continuous operation.	**N/A**
7.2.12	**Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder**	No accessible fuse-holder	**N/A**
	Fuse type ..... :	No accessible fuse-holder	**—**
	Voltage (V) and Current (A) rating.....:	No accessible fuse-holder	**—**
	Operating speed (s) and Breaking capacity.....:	No accessible fuse-holder	**—**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.13	**A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR ..... :**	EUT is component power supply only, no physiological effect	**N/A**
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use..... :	Component, to be determined as part of end product.	**N/A**
7.2.14	**HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10)**	No such high voltage terminal device.	**N/A**
7.2.15	**Requirements for cooling provisions marked (e.g., supply of water or air) ..... :**	Component, to be determined as part of end product.	**N/A**
7.2.16	**ME EQUIPMENT with limited mechanical stability**	Component, to be determined in end-product evaluation.	**N/A**
7.2.17	**Packaging marked with special handling instructions for transport and/or storage ..... :**	Component, to be determined as part of end product.	**N/A**
7.2.18	**RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector ..... :**	No external pressure source.	**N/A**
7.2.19	**Symbol 7 of Table D.1 (IEC 60417-5017, DB:2002-10) marked on FUNCTIONAL EARTH TERMINAL..... :**	No FE terminal.	**N/A**
7.2.20	**Protective means, required to be removed to use a particular function of ME EQUIPMENT with alternate applications, marked to indicate the necessity for replacement when the function is no longer needed ..... :**	Component, to be determined as part of end product.	**N/A**
	No marking applied when an interlock provided		**N/A**
7.3	**Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**		
7.3.1	**Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)..... :**	No heating element, no lamp holder.	**N/A**
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL	No heating element, no lamp holder.	**N/A**
7.3.2	**Symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts ..... :**	No such HV part.	**N/A**
7.3.3	**Type of battery and mode of insertion when applicable is marked.....:**	No battery..	**N/A**
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL..... :	No battery.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement by inadequately trained personnel would result in an unacceptable RISK (e.g., excessive temperatures, fire or explosion) ..... :	No battery.	**N/A**
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS ..... :	No battery.	**N/A**
7.3.4	**Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL, marked by type and full rating at the component or by reference to ACCOMPANYING DOCUMENTS**		**P**
	Type ..... :	See the table 8.10.	**—**
	Voltage (V) and Current (A) rating.....:	T1A 250V.	**—**
	Operating speed (s) and Breaking capacity.....:	See the table 8.10.	**—**
7.3.5	**PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, DB: 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1**		**N/A**
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		**P**
7.3.6	**Symbol 7 of Table D.1 (IEC 60417-5017, DB: 2002 - 10) marked on FUNCTIONAL EARTH TERMINALS**	No FE terminal.	**N/A**
7.3.7	**Terminals for supply conductors marked adjacent to terminals**	No hazard if connections are interchanged.	**P**
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	Marked on EUT	**N/A**
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 (Code in IEC 60445)	Not permanently installed	**N/A**
	Marking for connection to a 3-phase supply, if necessary, complies with IEC 60445	Not 3-phase	**N/A**
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		**P**
7.3.8	**"For supply connections, use wiring materials suitable for at least X ℃" (where X > than max temperature measured in terminal box or wiring compartment under NORMAL USE), or equivalent, marked at the point of supply connections**	No such high temperature	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made	No such high temperature	**N/A**
7.4	**Marking of controls and instruments**		
7.4.1	**The "on" & "off" positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 (IEC 60417-5007, DB: 2002-10, and IEC 60417-5008, DB: 2002-10), or**	No power switch	**N/A**
	– indicated by an adjacent indicator light, or		**N/A**
	– indicated by other unambiguous means		**N/A**
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 DB: 2002-10), and		**N/A**
	– status indicated by adjacent indicator light		**N/A**
	– status indicated by other unambiguous means		**N/A**
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 DB: 2002-10), or		**N/A**
	– status indicated by adjacent indicator light		**N/A**
	– status indicated by other unambiguous means		**N/A**
7.4.2	**Different positions of control devices/switches indicated by figures, letters, or other visual means**	No such device.	**N/A**
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE, or	No such device.	**N/A**
	– an indication of direction in which magnitude of the function changes		**N/A**
7.4.3	**Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 31 except the base quantities listed in Table 1 expressed in the indicated units**	No numeric indications of parameters.	**N/A**
	ISO 1000 applied for application of SI units, their multiples, and certain other units		**N/A**
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3		**N/A**
7.5	**Safety signs**		
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010	No safety sign used.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		**N/A**
	Specified colours in ISO 3864-1 used for safety signs .....:		**N/A**
	Safety signs including any supplementary text or symbols described in instructions for use		**N/A**
7.6	**Symbols**		
7.6.1	**Meanings of symbols used for marking described in instructions for use .....:**	Accompanying documents have been checked.	**P**
7.6.2	**Symbols required by this standard conform to IEC or ISO publication referenced**	IEC 60417-5172: CLASS II equipment symbol is used. IEC 60417-5957: For indoor use only symbol is used.	**P**
7.6.3	**Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable**	No such symbol is used.	**N/A**
7.7	**Colours of the insulation of conductors**		
7.7.1	**PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation**	No PE conductor is provided.	**N/A**
7.7.2	**Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations**	No PE conductor is provided.	**N/A**
7.7.3	**Green and yellow insulation identify only following conductors:**	No such following conductor.	**N/A**
	– PROTECTIVE EARTH CONDUCTORS		**N/A**
	– conductors specified in 7.7.2		**N/A**
	– POTENTIAL EQUALIZATION CONDUCTORS		**N/A**
	– FUNCTIONAL EARTH CONDUCTORS		**N/A**
7.7.4	**Neutral conductors of POWER SUPPLY CORDS are "light blue" specified in IEC 60227-1 or IEC 60245-1**	No power supply cord	**N/A**
7.7.5	**Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1**	No power supply cord	**N/A**
7.8	**Indicator lights and controls**		
7.8.1	**Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required)**	No indicator light, no control	**N/A**
	Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required)	No indicator light, no control	**N/A**
	Green indicator lights mean: Ready for use	No indicator light, no control	**N/A**
	Other colours, if used: Meaning other than red, yellow, or green (colour, meaning) .....:	No indicator light, no control	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.8.2	**Red used only for emergency control**	No indicator light, no control	**N/A**
7.9	**ACCOMPANYING DOCUMENTS**	Accompany documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end product level.	**P**
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		
8.1	**Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS**		**P**
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in 8.1a)		**P**
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b).....:	The following needs to be considered in the end product: - interruption of any one power-carrying conductor - unintended movement of a component - accidental detachment of conductors and connectors	**N/A**
	ACCESSIBLE PARTS determined according to 5.9		**P**
	LEAKAGE CURRENTS measured according to 8.7		**P**
8.2	**Requirements related to power sources**		
8.2.1	**When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM**	Connection to mains only	**N/A**
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		**N/A**
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		**N/A**
8.2.2	**No HAZARDOUS SITUATION other than absence of ESSENTIAL PERFORMANCE developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source**	Connection to mains only	**N/A**
	ME EQUIPMENT connected with correct polarity did not present an unacceptable RISK		**N/A**
	Protective devices that can be reset by anyone without a TOOL restore correct operation on reset		**N/A**
8.3	**Classification of APPLIED PARTS**	No Applied Parts	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.4	**Limitation of voltage, current or energy**		
8.4.2	**ACCESSIBLE PARTS including APPLIED PARTS**		
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA) .....:	See appended Table 8.7	**P**
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed	The likelihood of the current flowing through body of OPERATOR to be determined in end-product evaluation	**P**
	– accessible contacts of connectors		**P**
	– contacts of fuseholders accessible during replacement of fuse	No such part.	**N/A**
	– contacts of lampholders accessible after removal of lamp	No such part.	**N/A**
	– parts inside an ACCESS COVER that can be opened without a TOOL, or where a TOOL is needed but the instructions for use instruct an OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER	No such part.	**N/A**
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.).....:	See appended Table 8.4.2	**P**
	Limit of 60 V d.c applied with no more than 10% peak-to-peak ripple, and when ripple larger than specified value, 42.4 V peak limit applied (V d.c.) .....:	See appended Table 8.4.2	**P**
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V (VA or J).....:	See appended Table 8.4.2	**P**
	LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA).....:	See appended Table 8.4.2	**P**
	d) Voltage and energy limits specified in c) above also applied to the following:	No such part.	**N/A**
	– internal parts, other than contacts of plugs, connectors and socket-outlets, touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	No internal part is touchable.	**N/A**
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls using a TOOL		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	No opening.	**N/A**
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N	.	**N/A**
	Test repeated with a TOOL specified in instructions for use		**N/A**
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		**N/A**
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION	No such part.	**N/A**
	A TOOL is required when it is possible to prevent the devices from operating		**N/A**
8.4.3	**Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one s after disconnecting the plug of ME EQUIPMENT or its parts (V).....:**	See appended Table 8.4.3	**P**
	A triggering circuit used to ensure disconnection occurred at peak of supply voltage waveform		**P**
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC...:	See appended Table 8.4.3	**P**
8.4.4	**Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC ...:**	No such part.	**N/A**
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		**N/A**
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, DB: 2002-10), and manual discharging device specified in technical description ..... :		**N/A**
8.5	**Separation of parts**		
8.5.1	**MEANS OF PROTECTION (MOP)**		
8.5.1.1	**TWO MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account Clause 4.6, and flow chart in Fig A.12		**P**
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds replasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		**P**
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		**P**
	Insulation, CREEPAGE, CLEARANCES, components or earth connections not complying with 8.5.1.2 and 8.5.1.3 not considered as MEANS OF PROTECTION, and failure of these parts regarded as NORMAL CONDITION		**P**
8.5.1.2	**MEANS OF PATIENT PROTECTION (MOPP)**		**P**
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6		**P**
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		**P**
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6	No PE connection is provided.	**N/A**
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF PATIENT PROTECTION considered equivalent to one MEANS OF PATIENT PROTECTION	See Appended Tables 8.8.3 and 8.10	**P**
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Two identical Y1 used in series	**P**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) .....:	Each 250V, 1000pF	**—**
8.5.1.3	**MEANS OF OPERATOR PROTECTION (MOOP)**		**P**
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		**P**
	– dielectric strength test of 8.8 at test voltage of Table 6; or		**P**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		**P**
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		**P**
	– limits of Tables 13 to 16 (inclusive); or		**P**
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6, or	No PE connection is provided.	**N/A**
	– requirements and tests of IEC 60950-1 for protective earthing ..... :		**N/A**
	A Y2 capacitor complying with IEC 60384-14 and passing dielectric strength test for one MEANS OF OPERATOR PROTECTION considered equivalent to one MEANS OF OPERATOR PROTECTION..... :	No such component.	**N/A**
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF OPERATOR PROTECTION considered equivalent to two MEANS OF OPERATOR PROTECTION ..... :	No such component.	**N/A**
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		**N/A**
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) .....:		**—**
	Points at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION		**P**
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION .....:	See the insulation diagram.	**P**
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION.....:	See the insulation diagram.	**P**
8.5.2	**Separation of PATIENT CONNECTIONS**	No PATIENT CONNECTIONS	**N/A**
8.5.3	**MAXIMUM MAINS VOLTAGE**		
	– MAXIMUM MAINS VOLTAGE determined to be the highest RATED supply voltage for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, as well as INTERNALLY POWERED ME EQUIPMENT with a means of connection to a SUPPLY MAINS (V).....:	240Vac	**P**
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V	No such condition.	**N/A**
	– MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for poly-phase ME EQUIPMENT (V).....:	No poly-phase supply	**N/A**
	– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V	Not internally powered	**N/A**
8.5.4	**WORKING VOLTAGE**		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V).....:	240Vac	**P**
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V) .....:	See Insulation Diagram and Insulation Table	**P**
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) .....:	See Insulation Diagram and Insulation Table	**P**
8.5.5	**DEFIBRILLATION-PROOF APPLIED PARTS**	No such APPLIED PARTS	**N/A**
8.6	**Protective and functional earthing and potential equalization of ME EQUIPMENT**		
8.6.1	**Requirements of 8.6.2 to 8.6.8 applied**	No earthing.	**N/A**
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		**N/A**
8.6.2	**PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR .....:**	No protective earth terminal.	**N/A**
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		**N/A**
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside .....:		**N/A**
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		**N/A**
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		**N/A**
8.6.3	**PROTECTIVE EARTH CONNECTION not used for a moving part..... :**	No protective earth terminal.	**N/A**
8.6.4	**a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop**	No protective earth terminal.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits..... :		**N/A**
8.6.5	**Surface coatings**		**N/A**
	Poorly conducting surface coatings on conductive elements removed at the point of contact	No protective earth terminal.	**N/A**
	Coating not removed when requirements for impedance and current-carrying capacity met		**N/A**
8.6.6	**Plugs and sockets**		**N/A**
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections	No protective earth terminal.	**N/A**
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		**N/A**
8.6.7	**Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR**		**N/A**
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	No potential equalization conductor.	**N/A**
	– RISK of accidental disconnection minimized in NORMAL USE		**N/A**
	– Terminal allows conductor to be detached without a TOOL		**N/A**
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		**N/A**
	– Terminal marked with symbol 8 of Table D.1 (i.e., symbol IEC 60417-5021)		**N/A**
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		**N/A**
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		**N/A**
8.6.8	**FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION**	No functional earth terminal.	**N/A**
8.6.9	**Class II ME EQUIPMENT**		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow	No earthing connection.	**N/A**
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring connected to them with a related explanation in technical description .....:		**N/A**
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		
8.7.1	**a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3 ..... :**	See appended Tables 8.7	**P**
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7 ..... :	See appended Tables 8.7	**P**
8.7.2	**Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except**		**P**
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		**N/A**
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		**N/A**
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		**P**
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		**P**
8.7.3	**Allowable Values**		
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b..... :	See appended Table 8.7	**P**
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC}) ..... :	See appended Table 8.7	**P**
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}) ..... :		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710..... :		**N/A**
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device ..... :	See appended Table 8.7	**P**
8.7.4	**LEAKAGE and PATIENT AUXILIARY CURRENTS measurements ..... :**	See appended Table 8.7	**P**
8.8	**Insulation**		
8.8.1	**Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION and insulation between parts of opposite polarity of MAINS PART on SUPPLY MAINS side of mains fuse or OVER-CURRENT RELEASE**		**P**
	Insulation exempted from test (complies with clause 4.8)		**P**
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	No such part.	**N/A**
8.8.2	**Distance through solid insulation or use of thin sheet material**		
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		**P**
	a) 0.4 mm, min, distance through insulation, or	Enclosure is 2.0mm thick	**P**
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		**P**
	– at least two layers of material, each passed the appropriate dielectric strength test, or	See appended Table 8.8.3	**P**
	– three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test		**N/A**
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		**N/A**
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION	See appended Table 8.8.3	**P**
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		**N/A**
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		**N/A**
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	Certified triple insulated wire is used.	**P**
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		**N/A**
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		**N/A**
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		**P**
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		**N/A**
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90°and subject to winding tension.....:	Additional protection by insulating tape.	**P**
	Finished component complied with routine dielectric strength tests of 8.8.3 ..... :		**N/A**
	Tests of Annex L not repeated since material data sheets confirm compliance ..... :	See Table 8.10 and Material Information Attachment	**P**
8.8.3	**Dielectric Strength**		
	Solid insulating materials with a safety function withstood dielectric strength test voltages .... :	See appended Table 8.8.3	**P**
8.8.4	**Insulation other than wire insulation**		
8.8.4.1	**Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT**		**P**
	ME EQUIPMENT and RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests..... :	Final determination in the end-product	**N/A**
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :	No evidence provided	**N/A**
	Tests conducted in absence of satisfactory evidence for resistance to heat..... :	Ball pressure test performed	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using apparatus of Fig 21	See Table 8.8.4.1	**P**
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 ℃ ± 2 °C or ambient indicated in technical description ±2℃ plus temperature rise determined during test of 11.1 of relevant part, if higher (℃)..... .. :	See Table 8.8.4.1	**P**
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION	No such material	**N/A**
8.8.4.2	**Resistance to environmental stress**		
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		**P**
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such material	**N/A**
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No heating conductor	**N/A**
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	No such material	**N/A**
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 ℃ ± 2 ℃ for 96h, and afterwards, left at room temperature for at least 16h	No such material	**N/A**
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**		
8.9.1.1	**CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 11 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15**		**P**
8.9.1.2	**Tables 11 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested**	No such part。	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.3	**Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics**	No such material	**N/A**
8.9.1.4	**When min CREEPAGE derived from Tables 11 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE**	Noted, but no such condition	**N/A**
8.9.1.5	**ME EQUIPMENT RATED to operate at an altitude of 2000 m**		**N/A**
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m).....:	3000m.	**P**
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used to determine multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor	Multiplication factor for MOOP: 1.14. Multiplication factor for MOPP: 1.	**P**
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE		**P**
8.9.1.6	**When WORKING VOLTAGE was between those in Tables 11 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:**		**P**
	– CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) .....:	See Insulation Diagram/Table.	**P**
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) .....:	No such high voltage.	**N/A**
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied	See Insulation Diagram/Table.	**P**
8.9.1.7	**Material groups classified in accordance with Table 9 (Material Group) .....:**	Material group IIIb was assumed.	**N/A**
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112.....:	Material group IIIb was assumed.	**N/A**
	Material of unknown group considered IIIb		**P**
8.9.1.8	**– Pollution degree 1: Micro-environment sealed to exclude dust and moisture**	Pollution degree 2	**N/A**
	– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation	Pollution degree 2	**N/A**
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions	Pollution degree 2	**N/A**
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION	Pollution degree 2	**N/A**
	Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree	No such construction.	**N/A**
8.9.1.9	**Overvoltage category classification; value of MAINS TRANSIENT VOLTAGE determined from overvoltage category per IEC60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10**		**P**
	V_{MT} Peak (V) .....:	2500	—
	V_{MN} r.m.s (V) .....:	300	—
8.9.1.10	**AIR CLEARANCE for MAINS PARTS (operating on RATED MAINS VOLTAGES up to 300 V) were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE**		**P**
8.9.1.11	**SUPPLY MAINS overvoltage category II applied according to IEC 60664-1**		**P**
	For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used	No overvoltage category III	**N/A**
	When PATIENT protection (Table 12) is required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for Cl. 8.9 used	No overvoltage category III	**N/A**
8.9.1.12	**A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15)**	No measurement is taken.	**N/A**
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT		**N/A**
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I		**N/A**
	Table 15 column for circuits not subject to transient overvoltages applied to:		**N/A**
	– d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and		**N/A**
	– circuits in INTERNALLY POWERED ME EQUIPMENT		**N/A**
8.9.1.13	**For PEAK WORKING VOLTAGES above 1400 V peak or d.c. Table 15 not applied since all the following conditions were met:**	No such high peak working voltage.	**N/A**
	– CLEARANCE was at least 5 mm		**N/A**
	– insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or		**N/A**
	– a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and		**N/A**
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I		**N/A**
	Dielectric strength test conducted only across part(s) of the path that are through air when CLEARANCE path was also partly along surface of a non- group I material		**N/A**
8.9.1.14	**Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION**		**P**
8.9.2	**a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied ..... :**	See appended Table 8.9.2	**P**
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths		**P**
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by molding, or there is no reduction of a distance below specified value by deformation or movement of parts		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE		**P**
8.9.3	**Spaces filled by insulating compound**		
8.9.3.1	**Only solid insulation requirements applied where distances between conductive parts filled with insulating compound were such that CLEARANCES and CREEPAGE DISTANCES don't exist**	Certified optocoupler.	**P**
	Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted	Certified optocoupler has conformed to these tests.	**P**
8.9.3.2	**For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6 ..... :**	Certified optocoupler.	**P**
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur	Certified optocoupler has conformed to these tests.	**P**
8.9.3.3	**Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint**	No such construction.	**N/A**
	A winding of solvent-based enameled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		**N/A**
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage ..... :		**N/A**
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage		**N/A**
8.9.3.4	**One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times..... :**	No need.	**N/A**
8.10	**Components and wiring**		
8.10.1	**Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely as indicated in RISK MANAGEMENT FILE ..... :**	All the models have been checked by inspection. No evidence of such risk is found. Final determination in the end-product evaluation.	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.10.2	**Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION ..... :**	All the models have been checked by inspection. No evidence of such risk is found. Final determination in the end-product evaluation.	**P**
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION as indicated in RISK MANAGEMENT FILE		**N/A**
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION	No such construction.	**N/A**
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS due to poor contact	No stranded conductor.	**N/A**
8.10.3	**Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as shown by measurement or using test finger**	No such cord.	**N/A**
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		**N/A**
8.10.4.1	**Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION**	No cord connected hand-held control device, no cord connected foot-operated control device.	**N/A**
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		**N/A**
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		**N/A**
8.10.4.2	**Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at both ends of cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION**	No cord connected hand-held control device, no cord connected foot-operated control device.	**N/A**
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION		**N/A**
8.10.5	**Mechanical protection of wiring**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION..... :	All the models have been checked by inspection. No evidence of such risk is found. Final determination in the end-product evaluation.	**P**
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION as shown by manual tests and RISK MANAGEMENT FILE	All the models have been checked by inspection. No evidence of such risk is found. Final determination in the end-product evaluation.	**P**
8.10.6	**Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE**	No guiding roller.	**N/A**
8.10.7	**a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed.....:**	No insulating sleeve.	**N/A**
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics	No such condition.	**N/A**
	c) Insulated conductors subject to temperatures > 70 ℃ in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation..... :	No such high temperature is acquired by test indicated in 11.1.	**P**
8.11	**MAINS PARTS, components and layout**		
8.11.1	**a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles ..... :**	Plug.	**P**
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	Not permanently installed.	**N/A**
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description ..... :	Plug is incorporated in EUT.	**P**
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE and CLEARANCES in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV ..... :	No mains switch	**N/A**
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	No mains switch	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	e) Direction of movement of actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	No mains switch	**N/A**
	f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a) ..... :	See appended Table 8.10	**P**
	g) A fuse or a semiconductor device not used as an isolating means		**P**
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		**P**
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	No such part.	**N/A**
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient)		**N/A**
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		**N/A**
	Standard test finger of Fig 6 applied		**N/A**
8.11.2	**MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2**	No multiple socket-outlets.	**N/A**
8.11.3	**POWER SUPPLY CORDS**		**N/A**
8.11.3.1	**MAINS PLUG not fitted with more than one POWER SUPPLY CORD**	No power supply cord.	**N/A**
8.11.3.2	**POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design. 53) ..:**	No power supply cord.	**N/A**
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 ℃ touchable by the cord in NORMAL USE .....:		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.3	**NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm^2 Cu) .....:**	No power supply cord.	**N/A**
8.11.3.4	**APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6.....:**	No power supply cord.	**N/A**
8.11.3.5	**Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)**		**N/A**
	a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	No power supply cord.	**N/A**
	b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4:	No power supply cord.	**N/A**
	– insulating material, or		**N/A**
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		**N/A**
	– metal provided with an insulating lining affixed to cord anchorage, except when it is a flexible bushing forming part of the cord guard in 8.11.3.6, and complying with the requirements for one MEANS OF PROTECTION		**N/A**
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	No power supply cord.	**N/A**
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage	No power supply cord.	**N/A**
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails	No power supply cord.	**N/A**
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	No power supply cord.	**N/A**
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18..... :		**N/A**
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		**N/A**
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		**N/A**
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged		**N/A**
8.11.3.6	**POWER SUPPLY CORDS other than for STATIONARY ME EQUIPMENT protected against excessive bending at inlet opening of equipment or of MAINS CONNECTOR by means of an insulating cord guard or by means of an appropriately shaped opening**	No power supply cord.	**N/A**
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		**N/A**
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45°with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g)..... :		**N/A**
	Cord guard of temperature-sensitive material tested at 23 ℃ ± 2 ℃, and flat cords bent in the plane of least resistance		**N/A**
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D..... :		**N/A**
8.11.4	**MAINS TERMINAL DEVICES**		
8.11.4.1	**PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD replaceable by SERVICE PERSONNEL provided with MAINS TERMINAL DEVICES ensuring reliable connection**	No mains terminal device.	**N/A**
	Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away		**N/A**
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors		**N/A**
	Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors		**N/A**
8.11.4.2	**Arrangement of MAINS TERMINAL DEVICES**		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	No mains terminal device.	**N/A**
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6		**N/A**
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3		**N/A**
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		**N/A**
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		**N/A**
8.11.4.3	**Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times**	No mains terminal device.	**N/A**
8.11.4.4	**Terminals with clamping means for a rewirable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by test of 8.11.3.4**	No mains terminal device.	**N/A**
8.11.4.5	**Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD to allow for connection of conductors, and covers fitted without damage to conductors or their insulation**	No mains terminal device.	**N/A**
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test		**N/A**
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection per clause 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT ..... :	See appended Table 8.10. Fuse is provided for each lead.	**P**
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not permanently installed.	**N/A**
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit ..... :	See appended Table 8.10	**P**
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Fuses complying with IEC 60127 have high breaking capacity (1 500 A) and prospective short-circuit current > 35 A or 10 times current rating of the fuse, whichever is greater	EUT is only component, high breaking capacity fuse not used To be evaluated on end product	**N/A**
8.11.6	**Internal wiring of the MAINS PART**		
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE and protective devices is not less than minimum required for POWER SUPPLY CORD as in clause 8.11.3.3 (mm^2 Cu).....:	No internal wire.	**N/A**
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents ..... :	See appended Table 13.2.	**P**
	When necessary, ME EQUIPMENT connected to a SUPPLY MAINS with max available short-circuit fault, and subsequent simulation of a fault in a single insulation in MAINS PART did not result in any of the HAZARDOUS SITUATIONS in 13.1.2		**P**

9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		
9.1	**ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)**		**P**
9.2	**HAZARDS associated with moving parts**	Final determination in the end product.	**N/A**
9.3	**Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK avoided or covered .....:**	No rough surface / sharp edge.	**P**
9.4	**Instability HAZARDS**	Component, to be determined as part of end product	**N/A**
9.5	**Expelled parts HAZARD**	No such parts	**N/A**
9.6	**Acoustic energy (including infra- and ultrasound) and vibration**	Component, to be determined as part of end product	**N/A**
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**	No such parts	**N/A**
9.8	**HAZARDS associated with support systems**	Component, to be determined in the end product.	**N/A**

10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		
	RADIATION HAZARDS	Not applicable to component power supply	**N/A**

11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.1	**Excessive temperatures in ME EQUIPMENT**		
11.1.1	**Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T.....:**	See appended Table 11.1.1.	**P**
	Surfaces of test corner did not exceed 90 ℃		**P**
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	No thermal cut-out	**N/A**
11.1.2	**Temperature of APPLIED PARTS**	No such parts	**N/A**
11.1.3	**Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE.....:**	See appended Table 11.1.3. Acceptability of obtained values to be determined in the end product.	**N/A**
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE	Test corner used	**N/A**
11.1.4	**GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL**	No such guards	**N/A**
11.2	**Fire prevention**		
11.2.1	**ENCLOSURE has strength and rigidity necessary to prevent a fire caused by reasonably foreseeable misuse and met mechanical strength tests for ENCLOSURES in 15.3**		**P**
11.2.2	**Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS**	Component, not evaluated for use with Oxygen Rich Environment	**N/A**
11.2.3	**SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered**	Component, not evaluated for use with Oxygen Rich Environment	**N/A**
11.3	**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 .....:	Final determination to be competed in the end product evaluation.	**N/A**
	Constructional requirements were met, or		**P**
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials	See appended Table 8.10	**P**
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data .....:	See appended Table 8.10	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings	UL 94 approved	**N/A**
	b) Fire ENCLOSURE met following:		**P**
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm		**P**
	2) No openings on the sides within the area included within the inclined line C in Fig 39		**P**
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and made of appropriate metal or of non-metallic materials, except constructions based on Table 25 and a mesh; FV-2 or better for TRANSPORTABLE ME EQUIPMENT, FV-1 or better for fixed EQUIPMENT, or STATIONARY EQUIPMENT per IEC 60695-11-10, determined by ENCLOSURE examination or flammability classification based on 11.3a) .....:	See appended Table 8.10	**P**
11.4	**ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics**	Not evaluated for use in the presence of flammable anesthetics.	**N/A**
11.5	**ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents**	Not evaluated for use in the presence of flammable agent.	**N/A**
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT**	Final determination to be competed in the end product	**N/A**
11.6.5	**Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code) .....:	Final determination to be competed in the end product. EUT is ordinary.	**N/A**
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in a SINGLE FAULT CONDITION	EUT is ordinary.	**N/A**
11.7	**ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented per ISO 10993**	Component, to be determined in end-product evaluation.	**N/A**
11.8	**Interruption and restoration of power supply did not result in a HAZARDOUS SITUATION, except interruption of its intended function**	Component, to be determined in end-product evaluation.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		
	RISKS associated with accuracy of controls and instruments.....:	Not applicable to component power supply	**N/A**
	PROTECTION AGAINST HAZARDOUS OUTPUT .....:	Not applicable to component power supply	**N/A**
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		
13.1	**Specific HAZARDOUS SITUATIONS**		
13.1.1	**None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2**		**P**
13.1.2	**Emissions, deformation of ENCLOSURE or exceeding maximum temperature**		
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		**P**
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		**P**
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3 .....:	See appended Tables 11.1.1, 11.1.2.1, and 11.1.2.2	**P**
	–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 ℃ were not exceeded		**P**
	Limits for windings in Tables 26, 27, and 31 not exceeded		**P**
	Table 22 not exceeded in all other cases		**P**
	Temperatures measured according to 11.1.3		**P**
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:	Test wasn't exempted.	**N/A**
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit, or		**N/A**
	– Parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation		**N/A**
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	Fuse only	**P**
13.1.3	**– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed .....:**	See appended Table 8.7	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed.....:	See appended Table 8.7	**P**
13.1.4	**ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS**	Component, to be determined in end product evaluation.	**N/A**
13.2	**SINGLE FAULT CONDITIONS**		
13.2.1	**During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) applied in least favourable combination :**	See appended Table 13.2	**P**
13.2.2 – 13.2.12	**ME EQUIPMENT complied with 13.2.2 -13.2.12 .....:**	See appended Table 13.2	**P**
13.2.13	**ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to room temperature**		**P**
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		**P**
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 ℃ higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		**P**
13.2.13.2	**ME EQUIPMENT with heating elements**	No Heating Elements provided	**N/A**
13.2.13.3	**ME EQUIPMENT with motors**	No motors provided in power supply	**N/A**
13.2.13.4	**ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION**		
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 ℃ in one hour, or a protective device operated	Continuous operation.	**N/A**
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		**N/A**
	Motor winding temperatures did not exceed values in 13.2.10.....:		**N/A**
	Insulation Class.....:		**—**
	Maximum temperature measured (°C) .....:		**—**

14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		
	Requirements of this clause not applied to power supply	No Such Parts/ PESS not relied upon for Basic Safety or Essential Performance	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15	**CONSTRUCTION OF ME EQUIPMENT**		
15.1	**RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS, as confirmed by examination of RISK MANAGEMENT FILE .....:**	Final determination to be competed in the end product.	**N/A**
15.2	**Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance**	Final determination to be competed in the end product.	**N/A**
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		**N/A**
15.3	**Mechanical strength**		
15.3.1	**Mold stress relief, push, impact, drop, and rough handling tests did not result in unacceptable RISK and ME EQUIPMENT displayed adequate mechanical strength**		**P**
15.3.2	**Push test conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular (30mm) plane surface, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable test tool .....:**	See Appended Table 15.3.	**P**
	No damage resulting in an unacceptable RISK sustained as determined by examination of RISK MANAGEMENT FILE	See Appended Table 15.3.	**P**
15.3.3	**Impact test conducted by subjecting a complete ENCLOSURE or its largest non-reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m .....:**	Impact test was not performed on adapter model.	**N/A**
	Test not applied to flat panel displays, platen glass of ME EQUIPMENT, or cathode ray tubes	No such part.	**N/A**
	No damage resulting in an unacceptable RISK sustained as shown in RISK MANAGEMENT FILE	Impact test was not performed on adapter model.	**N/A**
15.3.4	**Drop test**		
15.3.4.1	**Sample of HAND-HELD ME EQUIPMENT and HAND-HELD part with SAFE WORKING LOAD allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm ± 5 mm thick hardwood board lying flat on a concrete or rigid base .....:**	ME equipment type is not specified. Considered the usage of adapter model, 1m height drop test is performed. See Appended Table 15.3	**P**
	No unacceptable RISK resulted	No damage	**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.3.4.2	**Sample of PORTABLE ME EQUIPMENT and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 ± 5 mm thick hardwood board lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE (cm)..... :**		**N/A**
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		**N/A**
15.3.5	**Rough handling tests for MOBILE ME EQUIPMENT**	Not mobile ME equipment.	**N/A**
15.3.6	**Examination of ENCLOSURE made from molded or formed thermoplastic material indicated that material distortion due to release of internal stresses by molding or forming operations will not result in an unacceptable RISK**		**P**
	Mold-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10℃ over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 ℃ ....:	70 ℃	**P**
	No damage resulting in an unacceptable RISK	No damage.	**P**
15.3.7	**INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT**	Component, to be determined in end product evaluation.	**N/A**
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK	Component, to be determined in end product evaluation.	**N/A**
15.4	**ME EQUIPMENT components and general assembly**		
15.4.1	**Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular .....:**	Final determination to be competed in the end product.	**N/A**
15.4.2	**Temperature and overload control devices**		
15.4.2.1	**a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could result in a HAZARDOUS SITUATION by resetting action as verified by review of RISK MANAGEMENT FILE .....:**	No such part.	**N/A**
	b) THERMAL CUT-OUTS with a safety function to be reset by a soldering operation affecting operating value not fitted in ME EQUIPMENT as verified by examination of design and RISK MANAGEMENT FILE .....:	No such part.	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) An independent non-SELF-RESETTING THERMAL CUT-OUT is, additionally, provided where a failure of a THERMOSTAT could constitute a HAZARD as verified by examination of design and RISK MANAGEMENT FILE .....:	No such part.	**N/A**
	d) Based on design and RISK MANAGEMENT FILE review, loss of function of ME EQUIPMENT due to operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION	No such part.	**N/A**
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS	No such part.	**N/A**
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following tests:		**N/A**
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 1999, clauses 15, 17, J.15, and J.17 as applicable		**N/A**
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13.....:	See appended Table 13.2	**N/A**
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified according to appropriate standards		**N/A**
	In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) operated 200 times		**N/A**
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		**N/A**
	When certification based on IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety-related function is not available, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		**N/A**
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		**N/A**
15.4.2.2	**Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS**		**N/A**
15.4.3	**Batteries**		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.3.1	**Battery housings from which gases can escape during charging or discharging likely to result in a HAZARD ventilated to minimize RISK of accumulation and ignition as verified by review of design and RISK MANAGEMENT FILE.....:**	No such part.	**N/A**
	Battery compartments prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as verified by examination of design and RISK MANAGEMENT FILE		**N/A**
15.4.3.2	**Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery.....:**	Final determination to be competed in the end product.	**N/A**
15.4.3.3	**Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design .....:**	Final determination to be competed in the end product.	**N/A**
15.4.3.4	**Lithium batteries that could become a HAZARD complied with appropriate tests of IEC 60086-4**	Final determination to be competed in the end product.	**N/A**
	Tests of IEC 60086-4 waived on the lithium battery based on examination of design		**N/A**
15.4.3.5	**A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire caused by excessive currents when (in case of a short circuit) layout of internal wiring, cross-sectional area, rating of connected components can result in a fire .....:**	Final determination to be competed in the end product.	**N/A**
	Protective device has adequate breaking capacity to interrupt the maximum fault current		**N/A**
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is included in RISK MANAGEMENT FILE		**N/A**
15.4.4	**Indicator lights provided to indicate ME EQUIPMENT is ready for NORMAL USE, except when apparent to OPERATOR from normal operating position, and marking of 7.4.1 are insufficient for this purpose .....:**	Final determination to be competed in the end product.	**N/A**
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s, except when apparent to OPERATOR from normal operating position		**N/A**
	Indicator lights provided on ME EQUIPMENT to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION		**N/A**
	Colours of indicator lights complied with 7.8.1		**N/A**
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.5	**Pre-set controls**	No such part in power supply.	**N/A**
15.4.6	**Actuating parts of controls of ME EQUIPMENT**	No such part in power supply.	**N/A**
15.4.7	**Cord-connected HAND-HELD and foot-operated control devices**	No such part in power supply.	**N/A**
15.4.8	**Aluminium wires less than 16 mm^2 in cross-sectional area are not used**	No such wire.	**N/A**
15.4.9	**Oil container in PORTABLE ME EQUIPMENT**	No such parts in power supply	**N/A**
15.5	**MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5**		
15.5.1	**Overheating**		
15.5.1.1	**Transformers of ME EQUIPMENT are protected against overheating in the event of short circuit or overload of output windings and comply with this Clause and tests of 15.5.1.2 – 3 .....:**	See appended Tables 15.5.1.2 and 15.5.1.3	**P**
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		**P**
	Dielectric strength test of 8.8.3 conducted on transformer after short circuit and overload tests .....:	See appended Table 15.5.2	**P**
15.5.1.2	**Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved .....:**	See appended Table 15.5.1.2	**P**
	Short circuit applied directly across output windings for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2		**N/A**
15.5.1.3	**Multiple overload tests conducted on windings with more than one protective device to evaluate worst-case NORMAL USE loading and protection :**	No more than one protective device	**N/A**
15.5.2	**Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION**		**P**
	Dielectric strength tests were conducted in accordance with requirements of this clause with no breakdown of insulation system and no detectable deterioration of transformer .....:	See appended Table 15.5.2	**P**
15.5.3	**Transformers forming MEANS OF PROTECTION as required by 8.5 comply with IEC 61558-1:1997, Clause 5.12 .....:**	Evaluated according to 60601-1	**N/A**
16	**ME SYSTEMS**		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Evaluation of ME SYSTEMS.....:	Component power supply; compliance determined in the end product	**N/A**
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review .:	Not applicable to component power supply system; to be determined in the end product	**N/A**
ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		
	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurs	Not evaluated for use with Flammable Anesthetics Mixture	**N/A**
ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		
L.1	**BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters**	Approved TIW is used in mains transformer.	**N/A**
L.2	**Wire construction**		
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component	Approved TIW is used in mains transformer.	**N/A**
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		**N/A**
L.3	**Type Test**		
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified	Approved TIW is used in mains transformer.	**N/A**
	Temperature (°C)..... .....:		**—**
	Humidity (%) .....:		**—**
L.3.1	**Dielectric strength**		
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with test voltages at least twice Tables 6 & 7, but not less than below with no breakdown:	Approved TIW is used in mains transformer.	**N/A**
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V).....:		**N/A**
	– 6000 V for REINFORCED INSULATION (V).....:		**N/A**
L.3.2	**Flexibility and adherence**		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1	Approved TIW is used in mains transformer.	**N/A**
	Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown		**N/A**
	Test voltage was at least the voltage in Tables 6 and 7but not less than the following:		**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V).....:		**N/A**
	– 3000 V for REINFORCED INSULATION (V) .....:		**N/A**
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa .....:		**N/A**
L.3.3	**Heat Shock**		
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3, except test voltage applied between the wire and mandrel	Approved TIW is used in mains transformer.	**N/A**
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V).....:		**N/A**
	– 3000 V for REINFORCED INSULATION (V) .....:		**N/A**
	Oven temperature based on Table L.2 (°C) .....:		**—**
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2) .....:		**N/A**
	Dielectric strength test conducted at room temperature after removal from the oven		**N/A**
L.3.4	**Retention of electric strength after bending**		
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests	Approved TIW is used in mains transformer.	**N/A**
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		**N/A**
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V).....:		**N/A**
	– 3000 V for REINFORCED INSULATION (V) .....:		**N/A**
	Test voltage applied between the shot and conductor.		**N/A**
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2).....:		**N/A**
L.4	**Tests during manufacture**		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
L.4.1	**Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3..... :**	Approved TIW is used in mains transformer.	**N/A**
L.4.2	**Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:**	Approved TIW is used in mains transformer.	**N/A**
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		**N/A**
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)..... :		**N/A**
L.4.3	**Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)**	Approved TIW is used in mains transformer.	**N/A**
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:		**N/A**
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION		**N/A**
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

4.2	**RM TABLE: Risk Management Process for ME Equipment or ME Systems**	**N/A**

4.3	**TABLE: essential performance**	**N/A**

4.3	**RM RESULTS TABLE: Essential Performance**	**N/A**

4.5	**RM RESULTS TABLE: Equivalent Safety for ME Equipment of ME System**	**N/A**

4.6	**RM RESULTS TABLE: ME Equipment or system parts contacting the patient**	**N/A**

4.7	**RM RESULTS TABLE: Single Fault Condition for ME Equipment**	**N/A**

4.8	**RM RESULTS TABLE: Components of ME Equipment**	**N/A**

4.9	**RM RESULTS TABLE: Use of components with high-integrity characteristics**	**N/A**

4.11	**TABLE: Power Input**	**P**

Operating Conditions / Ratings	Voltage (V)	Frequency (Hz)	Current (A)	Power (W or ~~VA~~)	Power factor (cos φ)
For Model GTM43033-0603, with 3dc/2A output					
Normal condition	**90**	**50/60**	**0.156**	**8.55**	**<0.9**
Normal condition	**100**	**50/60**	**0.142**	**8.44**	**<0.9**
Normal condition	**240**	**50/60**	**0.081**	**8.66**	**<0.9**
Normal condition	**264**	**50/60**	**0.076**	**8.80**	**<0.9**
For Model GTM43033-0612-3.0, with 9dc/0.67A output					
Normal condition	**90**	**50/60**	**0.146**	**7.94**	**<0.9**
Normal condition	**100**	**50/60**	**0.132**	**7.88**	**<0.9**
Normal condition	**240**	**50/60**	**0.075**	**8.32**	**<0.9**
Normal condition	**264**	**50/60**	**0.072**	**8.46**	**<0.9**
For Model GTM43033-0636, with 36dc/0.167A output					
Normal condition	**90**	**50/60**	**0.138**	**7.50**	**<0.9**
Normal condition	**100**	**50/60**	**0.126**	**7.45**	**<0.9**
Normal condition	**240**	**50/60**	**0.078**	**7.77**	**<0.9**
Normal condition	**264**	**50/60**	**0.070**	**7.93**	**<0.9**
For Model GTM43033-0648, with 48dc/0.125A output					
Normal condition	**90**	**50/60**	**0.133**	**7.30**	**<0.9**
Normal condition	**100**	**50/60**	**0.127**	**7.37**	**<0.9**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Normal condition	**240**	**50/60**	**0.072**	**7.87**	**<0.9**
Normal condition	**264**	**50/60**	**0.059**	**8.20**	**<0.9**
Supplementary Information:					

5.1	**RM RESULTS TABLE: Type Tests**	**N/A**

5.4 a)	**RM RESULTS TABLE: Other Conditions**	**N/A**

5.7	**RM RESULTS TABLE: Humidity preconditioning treatment**	**N/A**

5.9.2	**TABLE: Determination of ACCESSIBLE parts**	**P**

Location	Determination method (NOTE1)	Comments
Enclosure	**Test finger, test hook**	**Can't insert**

Supplementary information:

NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.

5.9.2.3	**RM RESULTS TABLE: Actuating mechanisms**	**N/A**

7.1.2	**TABLE: Legibility of Marking**	**P**

Markings tested	Ambient illuminance (lx)	Remarks
Outside Markings (Clause 7.2) .....:	**100-1500 lx**	**Clearly legible**
Inside Markings (Clause 7.3) .....:	**-**	**N/A**
Controls & Instruments (Clause 7.4) .....:	**-**	**N/A**
Safety Signs (Clause 7.5).....:	**-**	**N/A**
Symbols (Clause 7.6).....:	**-**	**N/A**

Supplementary information:

Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20), reads marking at ambient luminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

7.1.3	**TABLE: Durability of marking test**	**P**

Characteristics of the Marking Label tested:		Remarks
Material of Marking Label .....:	**See Table 8.10**	**Pass**
Ink/other printing material or process.....:	**See Table 8.10**	**Pass**
Material (composition) of Warning Label .....:	**-**	**N/A**
Ink/other printing material or process.....:	**-**	**N/A**
Other.....:	**-**	**N/A**

Supplementary information:

Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

soaked with methylated spirit, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

7.2.2	**RM RESULTS TABLE: Identification**	**N/A**
7.2.5	**RM RESULTS TABLE: ME EQUIPMENT powered from other equipment**	**N/A**
7.2.13	**RM RESULTS TABLE: Physiological effects (safety signs and warning)**	**N/A**
7.2.17	**RM RESULTS TABLE: Protective packaging**	**N/A**
7.3.3	**RM RESULTS TABLE: Batteries**	**N/A**
7.3.7	**RM RESULTS TABLE: Supply terminals**	**N/A**
7.4.2	**RM RESULTS TABLE: Control devices**	**N/A**
7.5	**RM RESULTS TABLE: Safety signs**	**N/A**
7.9.1	**RM RESULTS TABLE: General accompanying documents (See Table C.4)**	**N/A**
7.9.2.4	**RM RESULTS TABLE: Electrical power source**	**N/A**
7.9.3.2	**RM RESULTS TABLE: Replacement of fuses, power supply cords, other parts**	**N/A**
8.1 b(1)	**RM RESULTS TABLE: Fundamental rule of protection against electric shock - interruption of any one power-carrying conductor**	**N/A**
8.1 b(2)	**RM RESULTS TABLE: Fundamental rule of protection against electric shock - unintended movement of a component**	**N/A**
8.1 b(3)	**RM RESULTS TABLE: Fundamental rule of protection against electric shock - accidental detachment of conductors and connectors**	**N/A**
8.2.2	**RM RESULTS TABLE: Connection to an external d.c. power sources**	**N/A**
8.3 d	**RM RESULTS TABLE: Requirements of Type BF or CF Applied Parts**	**N/A**

8.4.2/8.5.4	**TABLE: TABLE: Working Voltage / Power Measurement**	**P**

Test supply voltage/frequency (V/Hz)[1] ..... : 264V / 60Hz

Location From/To	Measured values					Remarks
	Vrms	Vpk or Vdc	Peak-to-peak ripple[2]	Power W/VA	Energy (J)	
Transformer, primary to	**Max.**	**--**	**--**	**--**	**--**	**For all models**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.4.2/8.5.4	TABLE: TABLE: Working Voltage / Power Measurement					P
secondary	**270Vrms**					
Optocoupler primary to secondary	**Max. 240Vrms**	**--**	**--**	**--**	**--**	**For all models**
Y capacitor primary to secondary	**Max. 240Vrms**	**--**	**--**	**--**	**--**	**For all models**
Secondary output connector	**--**	**<60Vdc**	**<10%**	**--**	**--**	**For all models**

Supplementary Information:

1. The input supply voltage to the ME EQUIPMENT shall be the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.
2. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2

8.4.2 c	RM RESULTS TABLE: Accessible parts including applied parts	N/A

8.4.3	TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply	P

Maximum allowable voltage (V) .....:	60

Voltage measured (V)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2										
48Vdc/0.125A model	**5**	**3**	**4**	**3**	**6**	**5**	**3**	**5**	**1**	**3**
5Vdc/3A model	**4**	**1**	**3**	**6**	**6**	**4**	**3**	**2**	**4**	**3**
Plug pin 1 and plug earth pin	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**
Plug pin 2 and plug earth pin	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**
Plug pin 1 and enclosure	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**
Plug pin 2 and enclosure	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**

Maximum allowable stored charge when measured voltage exceeded 60 v (µc) ..... :	45

Calculated stored charge (µc)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**
Plug pin 1 and plug earth pin	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**
Plug pin 2 and plug earth pin	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**	**--**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--
Supplementary information:										

8.4.4	TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT	N/A

Maximum allowable residual voltage (V):	60 V
Maximum allowable stored charge when residual voltage exceeded 60 V :	45 µC

Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)	Measured residual voltage (V)	Calculated stored charge (µC)	Remarks
--	--	--	--
Supplementary information:			

8.5.2.2	RM RESULTS TABLE: Type B applied parts	N/A

8.5.2.3	RM RESULTS TABLE: PATIENT Leads	N/A

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies	N/A

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time	N/A

8.5.5.2	TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load	N/A

8.6.3	RM RESULTS TABLE: Protective earthing of moving parts	N/A

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS	N/A

Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part	--	--	--	100
ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part	--	--	--	100

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS				N/A
ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part	--	--	--	200	
Supplementary information: --					

8.7	TABLE: leakage current			P
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
--	- -	- -	- -	- -
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
NC	264	60	10.0	For all models, from L/N to accessible enclosure
SFC, interrupt one conductor	264	60	22.7	
SFC, one Y1 capacitor is short circuited.	264	60	34.4	
NC	264	60	69.5	For all models, from L/N to output terminal (+)
SFC, interrupt one conductor	264	60	71.3	
SFC, one Y1 capacitor is short circuited.	264	60	95.3	
NC	264	60	38.4	For all models, from L/N to output terminal (-)
SFC, interrupt one conductor	264	60	52.7	
SFC, one Y1 capacitor is short circuited.	264	60	71.6	

Supplementary information:

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

Note 3: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

ER - Earth leakage current
TC – Touch current
MD - Measuring device
NC - Normal condition
SFC - Single fault condition

A - After humidity conditioning
B - Before humidity conditioning
1 - Switch closed or set to normal polarity
0 - Switch open or set to reversed polarity

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)			P
Insulation under test	Insulation Type (1	Reference Voltage	A.C. test	Dielectric

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

(area from insulation diagram)	or 2 MOOP/MOPP)	PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.	voltages in V r.m.s[1]	breakdown after 1 minute Yes/No[2]
B/C (Mains part to outer accessible part)	2 MOOP	340	--	3000	No breakdown
D (Mains part to secondary circuits) (On optocoupler)	2 MOPP	340	--	4000	No breakdown
E (Mains part to secondary circuits) (On transformer)	2 MOPP	340	--	4000	No breakdown
F (Mains part to secondary circuits) (On 2 bridge Y capacitor)	2 MOPP	340	--	4000	No breakdown
H (Mains part to secondary circuits) (On PCB trace)	2 MOPP	340	--	4000	No breakdown

Supplementary information:

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.
[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts		P
	Allowed impression diameter (mm) ..... :	**≤ 2 mm**	—
	Force (N) ..... :	**20**	—

Part/material	Test temperature (°C)	Impression diameter (mm)
Enclosure		
SE1X (pass 125degC ball pressure test)	--	--
C2950	75	1.1
CX7211	75	1.1
LN-1250P	75	1.0
PA-765A	75	1.1
EXCY0098	75	1.0
LN-1250G	75	1.0
Blade holder		
SE1X	125	1.0
Bobbin of Mains transformer		
T375J	125	1.3
PM-9820	125	1.3
CP-J-8800	125	1.4

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

8.8.4.1	**RM RESULTS TABLE: Mechanical strength and resistance to heat**	**N/A**

8.9.2	**TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4**	**N/A**

Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1]	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks
--	--	--	--

Supplementary information:
Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE

8.9.3.2	**Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts**	**N/A**

Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No
1	68 h at T1 ± 2 °C = ___°C [1]	--	--
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
2	68 h at T1 ± 2 °C = ___°C [1]	--	--
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
3	68 h at T1 ± 2 °C = ___°C [1]	--	--
	1 h at 25 °C ± 2 °C		
	2 h at 0 °C ± 2 °C		
	1 or more h at 25 °C ± 2 °C		
4	68 h at T1 ± 2 °C = ___°C [1]	--	--

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.2	**Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts**		**N/A**
Test Sequence No.	**Each test duration and temperature**	**Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**
	1 h at 25 ℃ ± 2 ℃		
	2 h at 0 ℃ ± 2 ℃		
	1 or more h at 25 ℃ ± 2 ℃		

Supplementary information:

[1] T1 = 10 ℃ above the maximum temperature of relevant part determined per 11.1.1, or 85 ℃, the higher of the two. 10 ℃ not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.4	Table: Thermal cycling tests on one sample of cemented joint (see 8.9.3.3)		N/A
Test Sequence No.	**Each test duration and temperature**	**Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**
1	68 h at T1 ± 2 ℃ = ___℃ [1]	--	--
	1 h at 25 ℃ ± 2 ℃		
	2 h at 0 ℃ ± 2 ℃		
	1 or more h at 25 ℃ ± 2 ℃		
2	68 h at T1 ± 2 ℃ = ___℃ [1]	--	--
	1 h at 25 ℃ ± 2 ℃		
	2 h at 0 ℃ ± 2 ℃		
	1 or more h at 25 ℃ ± 2 ℃		
3	68 h at T1 ± 2 ℃ = ___℃ [1]	--	--
	1 h at 25 ℃ ± 2 ℃		
	2 h at 0 ℃ ± 2 ℃		
	1 or more h at 25 ℃ ± 2 ℃		
4	68 h at T1 ± 2 ℃ = ___℃ [1]	--	--
	1 h at 25 ℃ ± 2 ℃		
	2 h at 0 ℃ ± 2 ℃		
	1 or more h at 25 ℃ ± 2 ℃		

Supplementary information:

[1] T1 = 10 ℃ above the maximum temperature of relevant part determined per 11.1.1, or 85 ℃, the higher of the two. 10 ℃ not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.

8.10	TABLE: List of critical components				P
Component/ Part No.	**Manufacturer/ Trademark**	**Type No./model No./**	**Technical data**	**Standard No./, Edition**	**Mark(s) & Certificates of conformity [1]**
PCB	TECHNI TECHNOLOGY LTD	T2A T2B T4	Min 1.6 mm thickness, min. V-0, 130℃	UL 796	UL E154355
Alt.	DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1	Min 1.6 mm thickness, min. V-0, 130℃	UL 796	UL E243157
Alt.	CHEERFUL ELECTRONIC	03 03A	Min 1.6 mm thickness, min. V-0, 130℃	UL 796	UL E199724

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Alt.	DONGGUAN DAYSUN ELECTRONIC CO LTD	DS2	Min 1.6 mm thickness, min. V-0, 130℃	UL 796	UL E251754
Alt.	SUZHOU CITY YILIHUA ELECTRONICS CO LTD	YLH-1	Min 1.6 mm thickness, min. V-0, 130℃	UL 796	UL E251781
Alt.	SHANGHAI AREX PRECISION ELECTRONIC CO LTD	02V0	Min 1.6 mm thickness, min. V-0, 130℃	UL 796	UL E186016
Alt.	BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A	Min 1.6 mm thickness, min. V-0, 130℃	UL 796	UL E177671
Fuse (FS1, FS2)	Conquer Electronics Co., Ltd.	MST	T1A, 250V, Rated breaking capacity 100A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40017118 UL E82636
Alt.	Ever Island Electric Co., Ltd. and Walter Electric	2010	T1A, 250V, Rated breaking capacity 130A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40018781 UL E220181
Alt.	Bel Fuse Ltd.	RST	T1A, 250V, Rated breaking capacity 100A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40011144 UL E20624
Alt.	Cooper Bussmann LLC	SS-5	T1A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40015513 UL E19180
Alt.	Walter Electronic Co. Ltd.	ICP series	T1A, 250V, Rated breaking capacity 50A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40012824 UL E56092
Alt.	Das & Sons International Ltd.	385T series	T1A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40008524 UL E205718
Alt.	Shenzhen Lanson Electronics Co. Ltd.	SMT	T1A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40012592 UL E221465
Ripple capacitor (C2)	Interchangeable	Interchangeable	Min. 400 V, 105℃, min. 6.8 µF	Applicable parts of IEC 60601-1	Tested within appliance
Y-Capacitor (CY1, CY2) (optional)	TDK-EPC CORPORATION	CD	Type Y1, max. 1000pF, min. 250V, min. 125℃	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 138526 UL E37861

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Alt.	SUCCESS ELECTRONICS CO LTD	SE, SB	Type Y1, max. 1000pF, min. 250V, min. 125℃	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40008996 UL E114280
Alt.	MURATA MFG CO LTD	KX	Type Y1, max. 1000pF, min. 250V, min. 125℃	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40002831 UL E37921
Alt.	WALSIN TECHNOLOGY CORP	AH	Type Y1, max. 1000pF, min. 250V, min. 125℃	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40001804 UL E146544
Alt.	JYA-NAY CO LTD	JN	Type Y1, max. 1000pF, min. 250V min. 125℃	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40001831 UL E201384
Alt.	HAOHUA ELECTRONIC CO	CT7	Type Y1, max. 1000pF, min. 250V, min. 125℃	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40003902 UL E233106
Alt.	HONGZHI ENTERPRISES LTD	Y	Type Y1, max. 1000pF, min. 250V, min. 125℃	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40004354 UL E192572
Alt.	JERRO ELECTRONICS CORP	JX-series	Type Y1, max. 1000pF, min. 250V, min. 125℃	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40032158 UL E333001
Varistor (MOV1) (optional)	JOYIN CO LTD	07N471K 10N471K 14N471K	300Vac	IEC 61051-2 UL 1449	VDE 005937 UL E325508
Alt.	CENTRA SCIENCE CORP	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40008220 UL E316325
Alt.	THINKING ELECTRONIC INDUSTRIAL CO LTD	TVR07471K TVR10471K TVR14471K	300Vac	IEC 61051-2 UL 1449	VDE 005944 UL E314979
Alt.	SUCCESS ELECTRONICS CO LTD	SVR07D471K SVR10D471K SVR14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40030401 UL E330256
Alt.	CERAMATE TECHNICAL CO LTD	GNR07D471K GNR10D471K GND14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40031745 UL E315429
Alt.	BRIGHTKING (SHENZHEN) CO LTD	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40027827 UL E327997

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Alt.	LIEN SHUN ELECTRONICS CO LTD	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40005858 UL E315524
Alt.	HONGZHI ENTERPRISES LTD	HEL-7D471K HEL-10D471K HEL-14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40008621 UL E324904
Alt.	GUANGXI NEW FUTURE INFORMATION INDUSTRY CO LTD	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40030322 UL E323753
Optocoupler (U1)	LITE-ON Technology Corporation	LTV-817C	2MOPP at working voltage 250Vrms, 100℃	IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007	SIQ CB Report No.T223-0437/12
Alt.	Everlight Electronics Co., Ltd.	EL817	2MOPP at working voltage 250Vrms, 100℃	IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007	SIQ CB Report No.T223-0106/13
Transformer (T1)	GlobTek BOAM ZhongTong	XF00852 (3-3.9V) XF00857 (4-8.9V) XF00853 (9-15V) XF00862 (15.1-35.9V) XF00850 (36-48V)	Class A, with critical component listed below	IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007	Tested with appliance
-Triple-insulated wire (Secondary)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	Min.130℃	UL 2353 UL 60601-1	UL E211989
-Alt.	COSMOLINK CO LTD	TIW-M	Min.130℃	UL 2353 UL 60601-1	UL E213764
-Alt.	FURUKAWA ELECTRIC CO LTD	TEX-E	Min.130℃	UL 2353 UL 60601-1	UL E206440
-Bobbin	CHANG CHUN PLASTICS CO LTD	T375J T375HF	V-0, 150℃, thickness 0.45 mm min.	UL 94 UL 746 A/B/C/D	UL E59481
-Alt.	SUMITOMO BAKELITE CO LTD	PM-9820	V-0, 150℃, thickness 0.45 mm min.	UL 94 UL 746 A/B/C/D	UL E41429
-Alt.	HITACHI CHEMICAL CO LTD	CP-J-8800	V-0, 150℃, thickness 0.45 mm min.	UL 94 UL 746 A/B/C/D	UL E42956

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

-Insulating tape	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1 1350T-1	Min.130℃	UL 510	UL E17385
-Alt.	BONDTEC PACIFIC CO LTD	370S	Min.130℃	UL 510	UL E175868
-Alt.	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ CT	Min.130℃	UL 510	UL E165111
-Alt.	JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A	Min.130℃	UL 510	UL E246950
-Alt.	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	Min.130℃	UL 510	UL E246820
Enclosure	SABIC INNOVATIVE PLASTICS B V	SE1X	Min. V-1 at 1.5 mm thickness, 105℃	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	C2950	Min. V-0 at 1.5 mm thickness, 75℃	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	CX7211 EXCY0098	Min. V-1 at 1.25 mm thickness, 85℃	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	TEIJIN CHEMICALS LTD	LN-1250P LN-1250G	Min. V-0 at 1.5 mm thickness, 115℃	UL 94 UL 746 A/B/C/D	UL E50075
Alt.	CHI MEI Corporation	PA-765A	Min. V-1 at 1.5 mm thickness, 80℃	UL 94 UL 746 A/B/C/D	UL E56070
Alt.	CHI MEI Corporation	PC-540	Min. V-0 at 1.5 mm thickness, 70℃	UL 94 UL 746 A/B/C/D	UL E56070
Blade holder	SABIC INNOVATIVE PLASTICS B V	SE1X	Min. V-1 at 1.5 mm thickness, 105℃	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	C2950	Min. V-0 at 1.5 mm thickness, 75℃	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	CX7211 EXCY0098	Min. V-1 at 1.25 mm thickness, 85℃	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	TEIJIN CHEMICALS LTD	LN-1250P LN-1250G	Min. V-0 at 1.5 mm thickness, 115℃	UL 94 UL 746 A/B/C/D	UL E50075
Alt.	CHI MEI Corporation	PA-765A	Min. V-1 at 1.5 mm thickness, 80℃	UL 94 UL 746 A/B/C/D	UL E56070

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Alt.	CHI MEI Corporation	PC-540	Min. V-0 at 1.5 mm thickness, 70℃	UL 94 UL 746 A/B/C/D	UL E56070
Output cord	Interchangeable	Interchangeable	Min. 24AWG, min. 300V, min. 80℃	---	UL approved
Label	DONGGUAN XIANGQUAN PRINTING CO LTD	Type XQ03	Rated min 80℃ Suitable for use on the plastic enclosure	UL 969	UL MH27594
Alt.	FAN JA PAPER PRINTING CO LTD	Type FJ-03-3	Rated min 80℃ Suitable for use on the plastic enclosure	UL 969	UL MH19546
Alt.	FAN JA PAPER PRINTING CO LTD	Type FJ07	Rated min 80℃ Suitable for use on the plastic enclosure (PC or ABS)	UL 969	UL MH19546
Alt.	DONGGUAN XIANGQUAN PRINTING CO LTD	Type XQ004-B	Rated min 80℃ Suitable for use on the plastic enclosure	UL 969	UL MH47303
Alt.	E-LIN ADHESIVE LABEL CO LTD	Type EL-15	Rated min 80℃ Suitable for use on the plastic enclosure	UL 969	UL MH45549
Alt.	SHENZHEN CORWIN PRINTING CO LTD	CW-01	Rated min 80℃ Suitable for use on the plastic enclosure	UL 969	UL MH47077
Alt.	YUEN CHANG SPECIAL PRINTING (SHENZHEN) CO LTD	JL-08	Rated min 80℃ Suitable for use on the plastic enclosure (PC or ABS)	UL 969	UL MH29752
Alt.	GlobTek	---	Engraving or Silkscreen	---	---

Supplementary information:
1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

8.10.1	**RM RESULTS TABLE: Fixing of components**	**N/A**

8.10.2	**RM RESULTS TABLE: Fixing of wiring**	**N/A**

8.10.5	**RM RESULTS TABLE: Mechanical protection of wiring**	**N/A**

8.11.3.5	**TABLE: Cord anchorages**	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Cord under test	Mass of equipment (kg)	Pull (N)	Torque Nm)	Remarks
--	--	--	--	--
Supplementary information:				

8.11.3.6	TABLE: Cord guard			N/A
Cord under test		Test mass	Measured curvature	Remarks
--		--	--	--
Supplementary information:				

8.11.5	RM RESULTS TABLE: Mains fuses and over-current releases	N/A

9.2.1	RM RESULTS TABLE: HAZARDS associated with moving parts - General	N/A

9.2.2.2	TABLE: Measurement of gap “a” according to Table 20 (ISO 13852: 1996)			N/A
Part of body	Allowable adult gap[1], mm	Measured adult gap, mm	Allowable children gap[1], mm	Measured children gap, mm
Body	> 500	--	> 500	--
Head	> 300 or < 120	--	> 300 or < 60	--
Leg	> 180	--	> 180	--
Foot	> 120 or < 35	--	> 120 or < 25	--
Toes	> 50	--	> 50	--
Arm	> 120	--	> 120	--
Hand, wrist, fist	> 100	--	> 100	--
Finger	> 25 or < 8	--	> 25 or < 4	--
Supplementary information: [1] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.				

9.2.2.4.3	RM RESULTS TABLE: Movable guards	N/A

9.2.2.4.3	RM RESULTS TABLE: Movable guards	N/A

9.2.2.4.4	RM RESULTS TABLE: Protective measures	N/A

9.2.2.5 c)	RM RESULTS TABLE: Continuous activation	N/A

9.2.2.6	RM RESULTS TABLE: Speed of movement(s)	N/A

9.2.3.2	RM RESULTS TABLE: Over travel	N/A

9.2.4	RM RESULTS TABLE: Emergency stopping devices	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.2.5	**RM RESULTS TABLE: Release of patient**		**N/A**
9.3	**RM RESULTS TABLE: Hazards associated with surfaces, corners and edges**		**N/A**
9.4.2.1	**TABLE: Instability—overbalance in transport position**		**N/A**
9.4.2.2	**TABLE: Instability—overbalance excluding transport position**		**N/A**
9.4.2.3	**TABLE: Instability—overbalance from horizontal and vertical forces**		**N/A**
9.4.2.4.2	**TABLE: Castors and wheels – Force for propulsion**		**N/A**
9.4.2.4.3	**TABLE: Castors and wheels – Movement over a threshold**		**N/A**
9.4.2.4.3	**RM RESULTS TABLE: Movement over a threshold**		**N/A**
9.4.3.1	**TABLE: Instability from unwanted lateral movement (including sliding) in transport position**		**N/A**
9.4.3.2	**TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position**		**N/A**
9.4.4	**TABLE: Grips and other handling devices**		**N/A**
9.5.1	**RM RESULTS TABLE: Protective means**		**N/A**
9.6.1	**RM RESULTS TABLE: Acoustic energy - General**		**N/A**
9.6.2.2	**RM RESULTS TABLE: Infrasound and ultrasound energy**		**N/A**
9.7.2	**RM RESULTS TABLE: Pneumatic and hydraulic parts**		**N/A**
9.7.4	**RM RESULTS TABLE: Pressure rating of ME equipment parts**		**N/A**
9.7.5	**TABLE: Pressure vessels**		**N/A**
9.7.6	**RM RESULTS TABLE: Pressure-control device**		**N/A**
9.7.7	**RM RESULTS TABLE: Pressure-relief device**		**N/A**
9.8.1	**RM RESULTS TABLE: Hazards associated with support systems - General**		**N/A**
9.8.2	**RM RESULTS TABLE: Tensile safety factor**		**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

9.8.3.1	**RM RESULTS TABLE: Strength of patient or operator support or suspension systems - General**	**N/A**
9.8.3.2	**TABLE: PATIENT support/suspension system - Static forces**	**N/A**
9.8.3.2a, b	**RM RESULTS TABLE: Static forces due to loading from persons**	**N/A**
9.8.3.3	**TABLE: Support/Suspension System – Dynamic forces due to loading from persons**	**N/A**
9.8.4.1	**RM RESULTS TABLE: Systems with mechanical protective devices - General**	**N/A**
9.8.4.3	**RM RESULTS TABLE: Mechanical protective device for single activation**	**N/A**
9.8.5	**RM RESULTS TABLE: Systems without mechanical protective devices**	**N/A**
10.1.1	**TABLE: Measurement of X - radiation**	**N/A**
10.2	**RM RESULTS TABLE: Alpha, beta, gamma, neutron & other particle radiation**	**N/A**
10.3	**RM RESULTS TABLE: Microwave radiation**	**N/A**
10.5	**RM RESULTS TABLE: Other visible electromagnetic radiation**	**N/A**
10.6	**RM RESULTS TABLE: RISK associated with infrared radiation other than emitted by lasers and LEDS**	**N/A**
10.7	**RM RESULTS TABLE: RISK associated with ultraviolet radiation other than emitted by lasers and LEDS**	**N/A**

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**				**P**
Model No. ..... :	1	2	--	--	--
Test ambient (°C) ..... :	21.8	23.5	--	--	--
Test supply voltage/frequency (V/Hz)[4] ... :	See below	See below	--	--	--

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
Input: 264V~/60HZ					
1	1	C2 body	105	55.4	T marking on capacitor body

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
1	2	PCB near U1	130	59.0	--
1	3	CY1 body	125	51.9	Thermocouples are used, so the limit is to be reduced by 10°C.
1	4	T1 core	105	65.6	--
1	5	T1 bobbin	105	67.9	--
1	6	T1 winding	105	70.5	Thermocouples are used, so the limit is to be reduced by 10°C.
1	7	U2 body	100	49.7	--
1	8	C5	105	50.3	T marking on capacitor body
1	9	Enclosure	48	35.6	Table 23 used, enclosure is not intended to be touched for more than 1 min.
1	10	Internal secondary wire	70	41.5	8.10.7 c)
2	1	C2 body	105	63.1	T marking on capacitor body
2	2	PCB near U1	130	62.4	--
2	3	CY1 body	125	65.8	Thermocouples are used, so the limit is to be reduced by 10°C.
2	4	T1 core	105	75.8	--
2	5	T1 bobbin	105	72.7	--
2	6	T1 winding	105	78.4	Thermocouples are used, so the limit is to be reduced by 10°C.
2	7	U2 body	100	55.3	--
2	8	C5	105	72.0	T marking on

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
					capacitor body
2	9	Enclosure	48	40.3	Table 23 used, enclosure is not intended to be touched for more than 1 min.
2	10	Internal secondary wire	70	42.6	8.10.7 c)
Input: 90V~/60HZ					
1	1	C2 body	105	54.7	T marking on capacitor body
1	2	PCB near U1	130	55.0	--
1	3	CY1 body	125	48.4	Thermocouples are used, so the limit is to be reduced by 10°C.
1	4	T1 core	105	59.9	--
1	5	T1 bobbin	105	62.1	--
1	6	T1 winding	105	64.3	Thermocouples are used, so the limit is to be reduced by 10°C.
1	7	U2 body	100	45.4	--
1	8	C5	105	47.8	T marking on capacitor body
1	9	Enclosure	48	32.6	Table 23 used, enclosure is not intended to be touched for more than 1 min.
1	10	Internal secondary wire	70	40.5	8.10.7 c)
2	1	C2 body	105	55.2	T marking on capacitor body
2	2	PCB near U1	130	56.4	--
2	3	CY1 body	125	63.8	Thermocouples are used, so the limit is to be reduced by

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Model No.	Thermo-couple No.	Thermocouple location[3]	Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C)	Max measured temperature[2], (°C)	Remarks
					10°C.
2	4	T1 core	105	72.5	--
2	5	T1 bobbin	105	70.3	--
2	6	T1 winding	105	75.3	Thermocouples are used, so the limit is to be reduced by 10°C.
2	7	U2 body	100	53.3	--
2	8	C5	105	71.4	T marking on capacitor body
2	9	Enclosure	48	37.3	Table 23 used, enclosure is not intended to be touched for more than 1 min.
2	10	Internal secondary wire	70	43.2	8.10.7 c)

Supplementary information:

[1] Maximum allowable temperature on surfaces of test corner is 90 °C

[2] Max temperature determined in accordance with 11.1.3e)

[3] When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

[4] Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

[5] APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

[6] Model No.1 represents 48Vdc/0.125A output model; Model No.2 represents 3Vdc/2A output model;

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	**RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24)**	**N/A**

11.1.2.1	**RM RESULTS TABLE: Applied parts intended to supply heat to patient**	**N/A**

11.1.2.2	**RM RESULTS TABLE: Applied parts not intended to supply heat to patient**	**N/A**

11.1.3	**TABLE: Temperature of windings by change-of-resistance method**	**N/A**

Temperature T of winding:	t_1 (℃)	R_1 (Ω)	t_2 (℃)	R_2 (Ω)	T (°C)	Allowed T_{max} (°C)	Insulation class
--	--	--	--	--	--	--	--

Supplementary information:

--

11.1.3	**RM RESULTS TABLE: Measurements**	**N/A**

11.2.2.1	**RM RESULTS TABLE: Risk of fire in an oxygen rich environment**	**N/A**

11.2.2.1	**TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source**	**N/A**

11.3	**RM RESULTS TABLE: Constructional requirements for fire enclosures of ME equipment**	**N/A**

11.5	**RM RESULTS TABLE: ME equipment and ME systems intended for use in conjunction with flammable agents**	**N/A**

11.6.1	**TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances**	**N/A**

11.6.2	**RM RESULTS TABLE: Overflow in ME equipment**	**N/A**

11.6.3	**RM RESULTS TABLE: Spillage on ME equipment and ME system**	**N/A**

11.6.5	**RM RESULTS TABLE: Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**	**N/A**

11.6.6	**RM RESULTS TABLE: Cleaning and disinfection of ME equipment and ME systems**	**N/A**

11.6.7	**RM RESULTS TABLE: Sterilization of ME equipment and ME systems**	**N/A**

11.6.8	**RM RESULTS TABLE: Compatibility with substances used**	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

12.1	**RM RESULTS TABLE: Accuracy of controls and equipment**	**N/A**
12.3	**RM RESULTS TABLE: Alarm systems**	**N/A**
12.4.1	**RM RESULTS TABLE: Intentional exceeding of safety limits**	**N/A**
12.4.2	**RM RESULTS TABLE: Indication of parameters relevant to safety**	**N/A**
12.4.3	**RM RESULTS TABLE: Accidental selection of excessive output values**	**N/A**
12.4.4	**RM RESULTS TABLE: Incorrect output**	**N/A**
12.4.5.2	**RM RESULTS TABLE: Diagnostic X-ray equipment**	**N/A**
12.4.5.3	**RM RESULTS TABLE: Radiotherapy equipment**	**N/A**
12.4.5.4	**RM RESULTS TABLE: Other ME equipment producing diagnostic or therapeutic radiation**	**N/A**
12.4.6	**RM RESULTS TABLE: Diagnostic or therapeutic acoustic pressure**	**N/A**

13.1.2	**TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances**	**N/A**

Power dissipated less than (W) ..... :	**15**
Energy dissipated less than (J) .....:	**900**

Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks
--	--	--	--	--

Supplementary information:

--

13.2	**TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive**	**P**

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Clause 8.1:**	—	—
	C1 short circuit	RF1 Broken	No Hz
	D5 short circuit	RF1 Broken	No HZ
	D7 (sec.) short circuit	No output, circuit protected.	No HZ

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	C5 (Sec.) short circuit	No output, circuit protected.	NO HZ
	CS2 (Pri.) short circuit	No output, circuit protected.	NO HZ
	U2 (Sec.) short circuit	No output, circuit protected.	NO HZ
	U2 (Pri.) short circuit	No output, circuit protected.	NO HZ
	DZ1(Sec.) short circuit	No output, circuit protected.	NO HZ
	D6 (Sec.) short circuit	Fuse open	NO HZ
13.2.3	**Overheating of transformers per Clause 15.5:**	**—**	**—**
		See 15.5	NO HZ
13.2.4	**Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:**	**—**	**—**
		No thermostat used	**N/A**
13.2.5	**Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:**	**—**	**—**
		No temperature limiting device	**N/A**
13.2.7	**Impairment of cooling that could result in a HAZARD using test method of 11.1:**	**—**	**—**
	Single ventilation fans locked consecutively	**No fan used**	**N/A**
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	**No ventilation opening**	**N/A**
	Simulated blocking of filters	**No filter**	**N/A**
	Flow of a cooling agent interrupted	**No cooling agent used**	**N/A**
13.2.8	**Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:**	**—**	**—**
		No moving part	**N/A**
13.2.9	**Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10**	**—**	**—**
		No such motor	**N/A**
		No such motor	**N/A**
13.2.10	**Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:**	**—**	**—**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or at the upper limit of RATED voltage range for specified time:	**No motor**	**N/A**
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices	**No motor**	**N/A**
	Temperatures measured as specified in 11.1.3 d)	**No motor**	**N/A**
	Temperatures did not exceed limits of Table 26	**No motor**	**N/A**
13.2.12	**Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):**	**—**	**—**
	See clause 9 and clause 15.3	**To be checked on end product**	**N/A**
Supplementary information: [1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.			

13.2.6	**RM RESULTS TABLE: Leakage of liquid**	**N/A**
14.1	**RM RESULTS TABLE: Programmable electrical medical systems - General**	**N/A**
14.6.1	**RM RESULTS TABLE: Identification of known and foreseeable hazards**	**N/A**
14.6.2	**RM RESULTS TABLE: Risk control**	**N/A**
14.7	**RM RESULTS TABLE: Requirement specification**	**N/A**
14.8	**RM RESULTS TABLE: Architecture**	**N/A**
14.9	**RM RESULTS TABLE: Design and Implementation**	**N/A**
14.10	**RM RESULTS TABLE: Verification**	**N/A**
14.11	**RM RESULTS TABLE: PEMS validation**	**N/A**
14.13	**RM RESULTS TABLE: Connection of PEMS by NETWORK/DATA COUPLING to other equipment**	**N/A**
15.1	**RM RESULTS TABLE: Construction of ME equipment – Arrangements of controls and indicators of ME equipment**	**N/A**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.3	TABLE: Mechanical Strength tests [1)]		P
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No damage
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	N/A
15.3.4.1	Drop Test (hand-held)	Free fall height (m) = 1	No damage
15.3.4.2	Drop Test (portable)	Drop height (cm) =	N/A
15.3.5	Rough handling test	Travel speed (m/s) =	N/A
15.3.6	Mould Stress Relief	7 h in oven at temperature (℃) = 70	No damage

Supplementary information:

[1)] As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).

[2)] Although ME equipment installation and use type are not specified, mechanical strength tests including push test, 1 m height drop test and mould stress relief test are performed considering the usage for adapter model.

15.3.2	RM RESULTS TABLE: Push test	N/A
15.3.3	RM RESULTS TABLE: Impact test	N/A
15.3.4.2	RM RESULTS TABLE: Portable ME equipment	N/A
15.3.5	RM RESULTS TABLE: Rough handling test	N/A
15.4.1	RM RESULTS TABLE: Construction of connectors	N/A
15.4.2.1 a	RM RESULTS TABLE: THERMAL CUT-OUTS and OVER-CURRENT RELEASES	N/A
15.4.2.1 b	RM RESULTS TABLE: THERMAL CUT-OUTS with a safety function	N/A
15.4.2.1 c	RM RESULTS TABLE: Independent non-SELF-RESETTING THERMAL CUT-OUT	N/A
15.4.2.1 d	RM RESULTS TABLE: Loss of function of ME EQUIPMENT	N/A
15.4.2.1 h	RM RESULTS TABLE: ME EQUIPMENT with tubular heating elements	N/A
15.4.3.1	RM RESULTS TABLE: Housing	N/A
15.4.3.2	RM RESULTS TABLE: Connection	N/A
15.4.3.3	RM RESULTS TABLE: Protection against overcharging	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

15.4.3.4	**RM RESULTS TABLE: Lithium batteries**	**N/A**

15.4.3.5	**RM RESULTS TABLE: Excessive current and voltage protection**	**N/A**

15.4.4	**RM RESULTS TABLE: Indicators**	**N/A**

15.4.5	**RM RESULTS TABLE: Pre-set controls**	**N/A**

15.4.6	**TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests**	**N/A**

15.4.7.3 b	**RM RESULTS TABLE: Entry of liquids**	**N/A**

15.5.1.2	**TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION**	**P**

Primary voltage (most adverse value from 90 % to 110 % of rated voltage)(V)[1] .....:	**264Vac**	**—**
RATED input frequency (Hz).....:	**60Hz**	**—**

Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY (when protective device did not operate)(Min)	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)
XF00852	A	Fuse 1.0A	No	60min	140[2]	32.1	25
XF00857	A	Fuse 1.0A	No	60min	140[2]	31.1	25
XF00853	A	Fuse 1.0A	No	60min	140[2]	30.2	25
XF00862	A	Fuse 1.0A	No	60min	140[2]	32.2	25
XF00850	A	Fuse 1.0A	No	60min	140[2]	30.5	25

Supplementary information:

[1] Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

[2] Thermocouples are used, so the limit is to be reduced by10 ° C.

15.5.1.3	**TABLE: transformer overload test – conducted only when protective device under short-circuit test operated**	**P**

Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1] :	264V
RATED input frequency (Hz).....:	60Hz
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A).....:	See below
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A):	Not 60127-1 fuse

Winding tested	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

XF00852	A	Fuse 1.0A (OL current 0.203A)	140[2]	100.7	25
XF00857	A	Fuse 1.0A (OL current 0.201A)	140[2]	98.8	25
XF00853	A	Fuse 1.0A (OL current 0.197A)	140[2]	97.2	25
XF00862	A	Fuse 1.0A (OL current 0.192A)	140[2]	96.1	25
XF00850	A	Fuse 1.0A (OL current 0.189A)	140[2]	95.9	25

Supplementary information:
[1] Loads on other windings between no load and their NORMAL USE load.
Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32.
Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.
- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.
[2] Thermocouples are used, so the limit is to be reduced by 10 °C.

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				P
Transformer Model/Type/ Part No	**Test voltage applied between**	**Test voltage, (V)**	**Test frequency (Hz)**	**Breakdown Yes/No**	**Deterioration Yes/No**
All models	Primary & secondary windings	4000	50	No	No
All models	Secondary winding & core	4000	50	No	No
All models	1 of 2 layers insulation tape	4000	50	No	No
All models	Primary winding	1200	300	No	No

Supplementary information: Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details

16.1	RM RESULTS TABLE: General requirements for ME Systems	N/A

16.6.1	TABLE: Leakage currents in ME system _ Touch current measurements	N/A

16.9.1	RM RESULTS TABLE: Connection terminals and connectors	N/A

17	RM RESULTS TABLE: Electromagnetic compatibility of ME equipment and ME systems	N/A

SP	TABLE: Additional or special tests conducted	N/A
Clause and Name of Test	**Test type and condition**	**Observed results**
Supplementary information:		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1
US NATIONAL DIFFERENCES
Medical electrical equipment, Part 1: General Requirements

Differences according to.....: US National standard ANSI/AAMI ES60601-1: 2005 / A2:2010
Attachment Form No. .....: US_ND_IEC60601_1G
Attachment Originator .....: Underwriters Laboratories Inc.
Master Attachment .....: 2011-04

Copyright © 2011 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.

	US NATIONAL DIFFERENCES		
4.8 b	Replacement: where there was no relevant IEC/ISO standard, the relevant US ANSI standard applied		P
	- when no relevant US ANSI standard existed, the requirements of this standard applied		P
4.10.2	Replacement: Rated voltage not exceeding 250V dc or single phase ac. or 600V poly-phase ac for ME EQUIPMENT and ME SYSTEMS up to 4kVA		P
	Rated voltage not exceeding 600 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
6.6	Addition: To comply with NFPA 70, X-Ray systems are classified as long time operation (> 5 min) or momentary operation (< 5 sec)	Not X-ray system	N/A
7.2.11	Addition: To comply with NFPA 70, X-Ray systems are marked as long time operation or momentary operation	Not X-ray system	N/A
7.2.21	New Sub-clause: **Colors of medical gas cylinders**		
	To comply with NFPA 99: Cylinders containing medical gases and their connection points are colored in accordance with the requirements of NFPA 99	No medical gas	N/A
8.2	Addition: All FIXED ME EQUIPMENT & PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT	Direct plug-in	N/A
8.6.1	Addition: To comply with NFPA 99, the enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850Vdc MAINS VOLTAGE, or containing voltages up to 50 V peak and enclosed in protectively earthed enclosure as well as connections to X-ray tubes and other high voltage components that include high voltage shielded cables are PROTECTIVELY EARTHED.	Not X-ray system	N/A
	To comply with NFPA 99, non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized are PROTECTIVELY EARTHED	Not X-ray system	N/A
8.7.3 d	EARTH LEAKAGE CURRENT values are not higher than the stated values	Class II	N/A
	5 mA in NORMAL CONDITION	Class II	N/A
	10 mA in SINGLE FAULT CONDITION	Class II	N/A
8.11	Addition prior to the first paragraph:		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) To comply with the NEC, add the following requirements to this clause:		
	Addition: PERMANENTLY CONNECTED ME EQUIPMENT provided with field wiring provision in accordance with NEC	Not permanently connected, direct plug-in	N/A
	Installation of connecting cords between EQUIPMENT parts comply with NEC	Direct plug-in	N/A
	Cable used as external interconnection between units		
	1) Exposed to abuse: Type SJT, SJTO, SJO, ST, SO, STO, or equivalent, or similar multiple-conductor appliance-wiring material,	No such cable.	N/A
	2) Not exposed to abuse: The cable was as in item 1) above, or	No such cable.	N/A
	i) Type SPT-2, SP-2, or SPE-2, or equivalent	No such cable.	N/A
	ii) Type SVr, SVRO, SVE, or equivalent or similar multiple-conductor appliance wiring material,	No such cable.	N/A
	iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more,	No such cable.	N/A
	- enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more	No such cable.	N/A
	Receptacles provided as part of ME EQUIPMENT and ME SYSTEMS for use in the patient care areas of pediatric wards, rooms, or areas are Listed tamper resistant	No such cable.	N/A
	- or employ a Listed tamper resistant cover in accordance with NEC	No such cable.	N/A
	Addition at the end of the clause: b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked	No such plug.	N/A
8.11.3.2	Addition: The flexible cord is a type acceptable for the particular application,	No such cord.	N/A
	- and it is acceptable for use at a voltage not less than the rated voltage of the appliance	No such cord.	N/A
	- and has an ampacity as in NEC, not less than the current rating of the appliance	No such cord.	N/A
8.11.3.3	Addition: To comply with NFPA 99, for X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug is 2X the maximum input current of the equipment	Not X-ray equipment.	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT IEC 60601-1 3rd edition CA - CANADIAN NATIONAL DIFFERENCES to CAN/CSA-C22.2 No. 60601-1:08	
Differences according to.....:	Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08
Attachment Form No. .....:	CA_ND_IEC60601_1G
Attachment Originator .....:	CSA International
Master Attachment .....:	2010-12
Copyright © 2010 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.	

CA - Canadian National Differences as per CAN/CSA-C22.2 No. 60601-1:08			
1	**Scope, object and related documents**		---
1.1	**Scope**		---
	This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32.		P
	NOTE 1A: *In the IEC 60601 standards series adopted for use in Canada, the Canadian-particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.*		---
1.3	**Collateral standards**		---
	Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard.		P
	NOTE 1: *When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards.*		---
1.4	**Particular standards**		---
	A requirement of a Canadian-particular safety standard takes precedence over this standard.		P
3	**Terminology and definitions**		---
3.41	**HIGH VOLTAGE**		---
	any voltage above 750 V, 1 050 V peak, as defined in the *Canadian Electrical Code (CEC), Part I*	Noted, but no such HV in EUT	N/A

4	**General requirements**		---
4.8	**Components of ME EQUIPMENT**		---
	a) the applicable safety requirements of a relevant CSA, IEC, or ISO standard; or		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	NOTE 1: *For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.*		---
	b) where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied		P
	NOTE 2: *If there are neither requirements in this standard nor in a CSA, IEC, or ISO standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.*		---
4.10.2	**SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS**		----
	and shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1:		P
7	**ME EQUIPMENT identification, marking and documents**		---
7.7.1 to 7.7.5	and shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1		P
	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the *Canadian Electrical Code (CEC), Part I*, CSA C22.2 No. 21, and CSA C22.2 No. 49……..:	Class II	N/A
8	**Protection against electrical HAZARDS from ME EQUIPMENT**		---
8.7.3	**Allowable values**		---
	Allowable values shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1.		P
8.11.3	**POWER SUPPLY CORDS**		---
8.11.3.2	**Types**		---
	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be		---
	i) If molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21……..…:	No power cord	N/A
	ii) Hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or……..:	No power cord	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	iii) Class II equipment having fuses on the line side/sides and neutral and may use a non-polarized attachment plug or a polarized attachment plug — CSA configuration type 1-15P shall be required and shall meet all applicable requirements in CSA C22.2 No. 21 and CSA C22.2 No. 42. Where a polarized attachment plug is used, the POWER SUPPLY CORD shall be connected to the wiring of the EQUIPMENT on the ungrounded side of the line when any of the following devices are used in the primary circuit:……:	No power cord	N/A
	1- the centre contact of an Edison base lampholder;	No power cord	N/A
	2- a single pole switch;	No power cord	N/A
	3- an automatic control with a marked off position;	No power cord	N/A
	4- a solitary fuse/fuse holder; or	No power cord	N/A
	5- any other single pole overcurrent protective device	No power cord	N/A
	b) Detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type that		---
	i) can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety HAZARD to a PATIENT or OPERATOR;	No power cord	N/A
	ii) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and	No power cord	N/A
	iii) has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable POWER SUPPLY CORD which could create a HAZARDOUS SITUATION	No power cord	N/A
	c) A detachable POWER SUPPLY CORD shall		---
	i) comply with the applicable requirements of CSA C22.2 No. 21; and……:	No power cord	N/A
	ii) not be smaller than No.18 AWG, and the mechanical serviceability shall be not less than…….:	No power cord	N/A
	1) Type SJ or equivalent for mobile or exposed to abuse ME EQUIPMENT; and……....:	No power cord	N/A
	2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature)……..:	No power cord	N/A
	NOTE 1A: *See CSA C22.2 No. 49 for requirements on the cord types mentioned in Sub-item 2).*		---
	d) Power supply cords shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable……..:	No power cord	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Connecting cords between equipment parts shall meet the requirements of the *Canadian Electrical Code, Part I*, as applicable……..:	No power cord	N/A
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		---
	Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1……:	See the table 8.10.	P
9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**		---
9.7.5	**Pressure vessels**		---
	Pressure vessels shall comply with the requirements of CSA B51, as applicable……..:	No pressure vessel	N/A
9.7.7	**Pressure-relief device**		---
	A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements……:	No pressure relief device	N/A
15	**Construction of ME EQUIPMENT**		---
15.4.1	**Construction of connectors**		---
	A) The point of connection of gas cylinders to EQUIPMENT shall be gas specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on EQUIPMENT shall be		---
	i) gas specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1 380 kPa (200 psi); or……:	No gas connection	N/A
	ii) DISS type complying with CGA V-5 for pressures 1 380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359……..:	No gas connection	N/A
	NOTE 1A: *Users of this standard should consult the CSA Z305 series of standards, CAN/CSA-Z9170-1, CAN/CSA-Z9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke-type valve connections; and ISO 32 for colour coding.*		---
15.4.8	**Internal wiring of ME EQUIPMENT**		---
	Internal wiring of ME EQUIPMENT shall be in accordance with the *Canadian Electrical Code (CEC), Part I,* CSA C22.1……:	No such wire.	N/A
16	**ME SYSTEMS**		---
16.1	**General requirements for the ME SYSTEMS**		---
	An ME SYSTEM shall provide		---

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and	Not medical system	N/A
	- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA, IEC, or ISO safety standards	Not medical system	N/A
	Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with CSA, IEC, or ISO safety standards that are relevant to that equipment.	Not medical system	N/A
16.9.2.1	**MULTIPLE SOCKET OUTLET**		---
	c) The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements…….:	No MSO	N/A
	- The separating transformer shall comply with the requirements of CAN/CSA-E61558-2-1 with a rated output not exceeding		---
	- 1 kVA for single-phase transformers; and	No MSO	N/A
	- 5 kVA for polyphase transformers The separating transformer shall also have a degree of protection not exceeding IPX4.	No MSO	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	National standard reference: SN EN 60601-1:2006		
4	Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7, Mercury - Annex 1.7 of SR 814.81 applies for mercury. Switches containing mercury such as thermostats, relays and level controllers are not allowed. Ordinance on chemical hazardous risk reduction SR 814.81, Annex 2.15 Batteries Annex 2.15 of SR 814.81 applies for batteries containing cadmium and mercury. Note: Ordinance relating to environmentally hazardous substances, SR 814.013 of 1986-06-09 is not longer in force and superseded by SR 814.81 of 2009-02-01 (ChemRRV).	No such component.	N/A
4	Supply cords of portable electrical appliances having a rated current not exceeding 10 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: - SEV 6533-2:2009 Plug type 11, L + N, 250V 10A - SEV 6534-2:2009 Plug type 12, L + N + PE, 250V 10A - SEV 6532-2:2009 Plug type 15, 3L + N + PE, 250/400V 10A Supply cords of portable electrical appliances having a rated current not exceeding 16 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: - SEV 5933-2:2009 Plug type 21 L + N, 250 V, 16A - SEV 5934-2:2009 Plug type 23 L + N + PE, 250 V, 16A - SEV 5932-2:2009 Plug type 25 3L + N + PE, 250/400V 16A NOTE 16 A plugs are not often used in Swiss domestic installation system. See TRF template regulatory requirements Switzerland on IECEE Website R.R. TRF templates.	No supply cord.	N/A

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix no. 1 Equipment combined with two-pole plug (Class II)

Supplementary tests on plug portion according to EN 50075:1990

1.	**Dimensions (Clause 7 of EN 50075)**	
	Plugs shall comply with standard size. (Standard sheet 1)	P
2.	**Protection Against Electric Shock (Clause 8 of EN 50075)**	
2.1	Live parts of plugs with the exception of the bare metal parts of the pins, shall not be accessible. (Clause 8.1 of EN 50075)	P
2.2	It shall not be possible to make connection between a pin of a plug and a live socket contact of a socket-outlet while the other pin is an accessible. (Clause 8.2 of EN 50075)	P
2.3	External parts of plugs, with the exception of pins, shall be of insulating material. (Clause 8.3 of EN 50075)	P
3.	**Construction (Clause 9 of EN 50075)**	
3.1	The plug cannot be opened by hand or by using a general purpose tool. (Clause 9.1 of EN 50075)	P
3.2	Pins of plugs shall be solid and shall have adequate mechanical strength. (Clause 9.3 of EN 50075)	P
3.3	Pins of plugs shall be locked against rotation and adequately fixed into the body of the plug. (Clause 9.4 of EN 50075)	P
3.4	Plugs shall be provided with soldered, crimped or equally effective permanent connection. (Clause 9.5 of EN 50075)	P
3.5	Plug shall be shaped in such a way and made of such a material that they can easily be withdrawn by hand from a socket-outlet. (by gripping the medical power supply's enclosure, Clause 9.6 of EN 50075)	P
4.	**Resistance to Humidity (Clause 10 of EN 50075)**	N/A
	The integrated pins were tested together with the medical power supply. (See test report for medical power supply)	
5.	**Insulation Resistance and Electric Strength (Clause 11 of EN 50075)**	N/A
	(See test report for medical power supply)	
6.	**Mechanical Strength (Clause 13 of EN 50075)**	
	Plug shall have adequate mechanical strength to withstand the stresses imposed during use.	P
6.1	The plugs are pressed between two flat surfaces with a force of 150N for 5min. 15min after removal of the force, the plug shall not show such deformation as would result in undue alteration of the dimensions which ensure safety. (Clause 13.1 of EN 50075)	P

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict
6.2	The plug is tested in a tumbling barrel. (Clause 13.2 of EN 50075, fall number is shown in test report for medical power supply) After the test, the plug shall show no damage within the meaning of this standard, in particular: --- No part shall become detached or loosened. --- The pin shall not turn when a torque of 0.4Nm is applied. Note: A section of the pin is square constructed for preventing the rotation.		P
6.3	The pins is held in a suitable clamp in such a position that the straight part of a steel wire (D=1+-0.02mm, U-shaped) rests on the plug pin. The plug is caused to move backwards and forwards, so that the wire rubs along the pin. The number of the movements is 20 000, and the rate of the operation is 25 movements per min. (Clause 13.3 of EN 50075)		P
	After the test, the pin show no damage which may effect safety or impair the further use of the plug, in particular, the insulating sleeve shall not have punctured or rucked up.		P
6.4	A pull force of 40N is applied for 60s on each pin in turn in the direction of the longitudinal axis of the pin. The pull is applied 60min after the plug has been placed in a heating cabinet of 70°C. After the plug cooling down to ambient temperature, any pin shall not have displaced in the body of the plug more than 1mm. (Clause 13.4 of EN 50075)		P
7.	**Resistance to Heat and to Ageing (Clause 14 of EN 50075)**		P
8.	**Current-carrying Parts and Connections (Clause 15 of EN 50075)**		
8.1	Connection, electrical and mechanical, shall withstand the mechanical stresses occurring in normal use, and electrical connections shall be designed that contact pressure is not transmitted through insulating material. (Clause 15.1 & 15.2 of EN 50075)		P
8.2	Current-carrying parts shall be of copper or an alloy containing at least 58% of copper. (Clause 15.3 of EN 50075)		P
9.	**Creepage Distance, Clearances, and Distances Through Insulation (Clause 16 of EN 50075)**		P
10.	**Resistance of Insulating Material to Abnormal Heat and to fire (Clause 17 of EN 50075)**		P

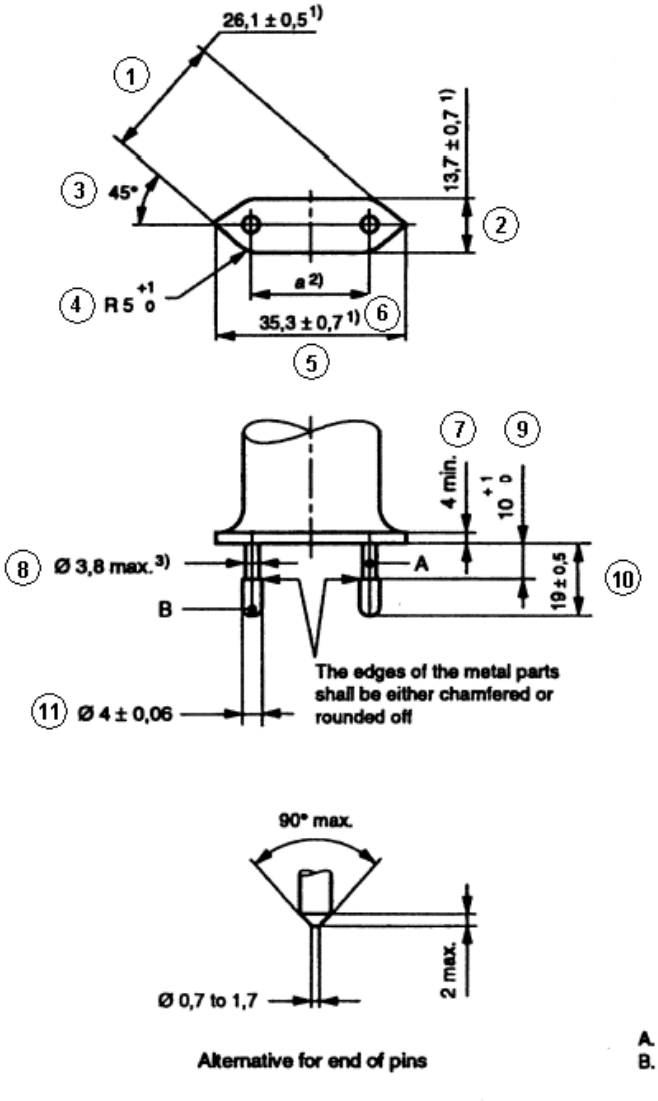
IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 2: Dimensions of integral plug

	DIMENSIONS Checked by means of measurement according to EN50075 Standard sheet 1		P
Position	Requirement (mm)	Measured (mm)	Verdict
1	25,6 – 26,6	25,84	P
2	13 – 14,4	13,98	P
3	45°	45°	P
4	R5 – 6	R5,4	P
5	34,6 – 36	35,09	P
6	18-19,2 in the plane of the engagement face	18,15	P
	17-18 at the ends of the pins	17,55	P
7	4min	-	N/A
8	ϕ3,8max	ϕ3,42	P
9	10-11	10,05	P
10	18,5 – 19,5	19,12	P
11	ϕ3,94 - ϕ4,06	ϕ3,98	P
	Dimensions of position 1, 2 and 3 shall not be exceeded within a distance of 18mm from the engagement face of the plug	19,15	P
	The edges of the metal parts shall be either chamfered or rounded off	Rounded off	P

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

EN50075: 1990 Standard sheet 1



Alternative for end of pins

A. Insulating collar
B. Metal pin

Dimensions in millimetres

1) These dimensions shall not be exceeded within a distance of 18 mm from the engagement face of the plug.

2) Dimension *a* is:

18 mm to 19,2 mm in the plane of the engagement face;

17 mm to 18 mm at the ends of the pins.

3) This dimension may be increased to 4 mm within a distance of 4 mm from the engagement face of the plug.

Pin ends shall be rounded, or conical as shown in detail sketch.

The sketches are not intended to govern design except as regards the dimensions shown.

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 3: Photo for plug portion according to EN 50075:1990

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 4 Equipment's combined with Australian plug.

The Australian plug was tested according to Annex J of AS/NZS 3112:2011+A1:2012:

Clause	Requirement – Test	Remark	Verdict
2.2	PLUG PINS		P
2.2.1	MATERIAL FOR PINS: - Copper alloy containing at least 58% copper for parts made from cold rolled sheet		P
2.2.2	ASSEMBLY OF PINS - Assembled in factory and non-rewirable		P
2.2.3	FORM OF PIN		P
2.2.4*	INSULATION OF PLUG PINS - live parts of insulated pins plug are not exposed when plug is partially or fully engaged with the associated socket.		P
2.3	INSULATING MATERIALS		P
2.3.1	GENERAL		P
2.3.2	PLUG BODY - Consisting of PBT which has properties not inferior to those specified in AS 3121 for insulating mouldings having a temperature class of 80°C		P
2.3.3	PLUG COVER - Consisting of PVC which has properties not inferior to those specified in AS 3121 for insulating mouldings having a temperature class of 60°C		P
2.8	RATINGS AND DIMENSIONS OF LOW VOLTAGE PLUGS - Comply with Figure 2.1 (c), rated 10A 250V~. - Distance between live pin and edge of plug moulding more than 9 mm		P
2.9	INTERNAL CONNECTIONS -No earthing connection		N/A
2.10	ARRANGEMENT OF EARTHING CONNECTIONS -No earthing connection		N/A
2.12	MARKING (No marking is applicable for the integral plug portion. See markings for transformer)		N/A
2.12.6	CONFIGURATION OF PLUGS - Figure 2.1 (c), the pin configuration is neutral and active in a clockwise direction		P
2.13	TESTS ON PLUGS		P
2.13.3	HIGH VOLTAGE TEST		P
2.13.7	TUMBLING BARREL TEST		P
2.13.8	TEMPERATURE RISE TEST		P
2.13.9	SECUREMENT OF PLUG		P

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Clause	Requirement – Test	Remark	Verdict
2.13.9.1	MOVEMENT OF PINS		P
2.13.9.2	FIXING OF PINS		P
2.13.13	ADDITIONAL TESTS ON THE INSULATION MATERIAL OF INSULATED PIN PLUGS		P

INSULATING MATERIALS TEST IN ACCORDANCE WITH AS/NZS 3121: 2002			
7.1	General		P
7.2	Resistance to heat test The moulding shall be placed in an oven and maintained for 6 h at the temperature appropriate to its class (see Clause 5) plus 10℃. The temperature of the oven during this period shall not vary by more than ± 5℃. The moulding shall show no physical or chemical change likely to impair the safety of the equipment of which it forms a part.		P
7.3	Water absorption test The complete moulding shall be immersed in water at 20 ℃ ± 5℃ for 48 h. The moulding shall not swe ll, delaminate, warp or show any physical change to a degree that would be liable to impair the safety of the equipment of which it forms a part.		P
7.4	Resistance to white spirit test Sample shall be immersed in white spirit at room temperature for 2 min. The moulding shall not blister, warp or show any physical or chemical change to a degree that would be liable to impair the safety of the equipment of which it forms a part.		P

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 5 Photos of Australian plug portion

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 6: Equipment's combined with NEMA 5-15 plug portion.

Section	Key	Comment
FORWARD		
Introduction		
1		**Scope**
1.1-1.4	G	The device under evaluation is an integral plug for medical power supply GTM43033-*** whose input rated 100-240V~, 50-60Hz, 0.3A. The plug is evaluated according to rated input.
2		**Glossary**
2.1-2.38	G	Noted.
3		**Components**
3.1-3.4	G	Noted
4		**Units of Measurement**
4.1	G	Noted
5		**Reference**
5.1	G	Noted
CONSTRUCTION		
		ALL DEVICES
6		**General**
6.1	√	According to declared reasonable condition, 100-240VAC, 50-60Hz, has been considered in all following test.
6.2	√	Plug for AC use only
7		**Configurations**
7.1	√	1-15P plug applied.
8		**Insulating Materials**
8.1		General
8.1.1	√	All parts that act as the electrical insulation or enclosure are made of plastic material. See 8.2.1
8.1.2	N/A	Vulcanized fiber is not provided
8.2		Flammability
8.2.1	√	The insulating material required HB or more. For detailed parts, see report of end product)
8.3		Electrical properties
8.3.1	√	Exception No. 1: No information according to above table info. The insulating material has a CTI 3 (Required 3), so it need NOT comply with Comparative Tracking Index Test, Section 55.
8.3.2	√	Exception No. 2: The insulating material has a HWI 3, (required HWI value is 4 when material class is V-0). According to 8.1.2 (UL746D) and reasonable usage, reasonable arcing occurs in normal use. We are of the opinion that it need NOT comply with Glow Wire Test, see Section 56. Exception No. 3: The insulating material has a HAI 2. (required HWI value is 4 when material class is V-0. or check if the thickness), since no arcing in normal use, so it need not comply with High-Current Arc Resistance to Ignition Test, Section 57.
8.4		Thermal properties
8.4.1	√	All the RTI rating of the insulating materials are higher than 80 degree (C)
8.5		Vulcanized fiber

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Section	Key	Comment
8.5.1	N/A	No Vulcanized fiber is provided
8.5.2	N/A	No Vulcanized fiber is provided
8.6		Sealing compounds
8.6.1-8.6.2	N/A	Sealing compound is not provided, no need to comply with relevant requirement involved in ASTM 28.
8.7		Fuse enclosures
8.7.1-8.7.2	N/A	Fuse is not provided
9		**Enclosure**
9.1		General
9.1.1	√	Live parts of plug parts are protected against exposure to contact by persons when fully assembled using all essential parts. Exception no. 2: for fixed wiring.
9.1.2-9.1.3	N/A	No accessible dead-metal parts
9.1.4	√	The probe shown in Figure 9.1 is used to judge the accessibility of a live or dead-metal part. The applied force is not more than 13.3N.
9.1.5-9.1.7	N/A	No such separable part
9.2		Male faces and wire terminations
9.2.1	N/A	Not a 15 or 20A attachment plug or current tap
9.2.2	N/A	There is no exposed live part.
9.2.3	N/A	No such parts
9.2.4-9.2.5	√	Probe not access to live parts. The cover is securely fixed for all acceptable wiring.
9.2.6	√	The face plate is secure with the back part.
10		**Current-carrying Parts**
10.1		General
10.1.1	√	Iron or steel is not used for current-carrying parts.
10.1.2	√	The current-carrying parts are not able to be turned by means of general tools due to the appliance shroud mounted on Evaluated appliance.
10.1.3	N/A	No such uninsulated live parts except for female contact of connector
10.2		Contacts (applying to the connector)
10.2.1	N/A	Female contacts of the connector cannot be touched by the probe. Others parts are covered by exception no. 3
11		**Grounding and Dead Metal Parts**
11.1-11.10	N/A	No grounding parts
12		**Terminals**
12.1-12.4		No terminals for end user
13		**Cord Entry and Strain Relief**
13.1-13.5	N/A	Flexible cord part are considered in the end appliances.
14		**Spacings**
14.1	√	The spacing through air between uninsulated live parts of opposite polarity and between uninsulated live parts and exposed external surface is measured more than 2mm (required 3/36 inch, 1,2mm) for a device rated 250V or less.
14.2	N/A	No such isolated dead-metal part
15		**Assembly**
15.1		General
15.1.1	√	Pre-wired in factory

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Section	Key	Comment
15.1.2	√	Electrical contact is reliably maintained at any point
15.1.3	√	Live parts is protected against exposure to persons
15.1.4	N/A	Not multiple outlet device
15.1.5	N/A	Female contacts of the connector can be mated with the inlet in right way without exposure of the blades
15.2		Grounding and polarization
15.2.1-15.2.4	N/A	No grounding
15.3		Mating and interchangeability
15.3.1	√	The electrical continuity is automatically established.
15.3.2-15.3.6	√	1-15P receptacles ensuring.
15.4		Fuseholders
15.4.1-15.4.8	N/A	Fuseholder is not provided
15.5		Switches
15.5.1	N/A	The switch is provided between coupler 1 and coupler 2. but it is a information
ATTACHMENT PLUGS AND INLETS (for plug only)		
16		**Insulating material**
16.1	√	The enclosure is measured min. 2.1 mm.
17		**Enclosure**
17.1		General
17.1.1	N/A	Not a general use plug.
17.1.2	√	Measured 44 mm.
17.1.3	N/A	Not a 50A plug
17.2		Grip
17.2.1	N/A	See section 69
17.3		Face size
17.3.1	√	Larger than figure 17.1
18		**Current carrying parts**
18.1	N/A	Not a folded-over plug.
18.2	√	Dimensional requirements fulfilled.
19		**Grounding and dead metal parts**
19.1-19.4	N/A	No grounding or dead metal parts.
20		**Terminals and leads**
20.1-20.5	N/A	All the assembly are pre-wired in factory
21		**Assembly**
21.1	√	The blades are held securely in place
21.2	N/A	Not a inlet
21.3-21.4	N/A	The device under evaluate is a plug part not inlet or surface mounting.
21.5	N/A	Not for radio antenna or ground.
22		**Weatherproof type**
22.1-22.2	N/A	Not weatherproof type
23-26	N/A	**CONNECTORS**
27-37	N/A	**RECEPTACLES**
		SELF-CONTAINED RECEPTACLES FOR USE WITHOUT A SEPARATE OUTLET BOX

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Section	Key	Comment
38-44	N/A	**These sections are applicable for self-contained receptacles.**
		CURRENT TAPS
45	N/A	**The section is applicable for current taps only**
		FLATIRON AND APPLIANCE PLUGS
46-53	N/A	**These sections are applicable for flatiron and appliance plugs.**
PERFORMANCE		
		GENERAL
54		**Representative Devices**
54.1-54.7	G	Noted.
		ALL DEVICES
55		**Comparative Tracking Index Test**
55.1	N/A	Refer to Exception No. 2 of 8.3.2. Not main tests but the test is considered
56		**Glow Wire Test**
56.1-56.2	N/A	Refer to Exception No. 2 of 8.3.2, Not main tests but the test is considered
57		**High-Current Arc Resistance to Ignition Test**
57.1-57.6	G	Refer to Exception No. 3 of 8.3.2
58		**Mold Stress Relief**
58.1-58.2	T	All devices are placed in air oven maintained at a 80oC for 7 hours. After 58.2, there is not any warpage, shrinkage or other distortion.
58.3	T	Refer to data sheet. Repeat dielectric voltage-withstand test as described in section 60. Not required to be subjected to the humidity conditioning described in 60.1.2.
59		**Moisture Absorption Resistance**
59.1-59.2	T	Refer to data sheet
60		**Dielectric Withstand Test**
60.1-60.2	T	Refer to data sheet
61		**Accelerated Aging Tests**
61.1		General
61.1.1	G	Exception to 8.4.1 for other material is not applicable for the devices under evaluation
61.2		Rubber, EPDM, and TEE compounds
61.2.1-61.2.4	N/A	Not a rubber , EPDM, and TEE compounds
61.3		PVC compounds and copolymers
61.3.1-61.3.2	G	See 61.1.1 shown as above
62		**Insulation Resistance Test**
62.1-62.6	T	Refer to data sheet
63		**Conductor Secureness Test**
63.1-63.2	N/A	No wire leads provided.
64		**Tightening Torque Test**
64.1-64.2	N/A	Not provide any wire-binding screw
	N/A	ATTACHMENT PLUGS
65		**General**
65.1	G	Noted.
66		**Security of blades test**

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

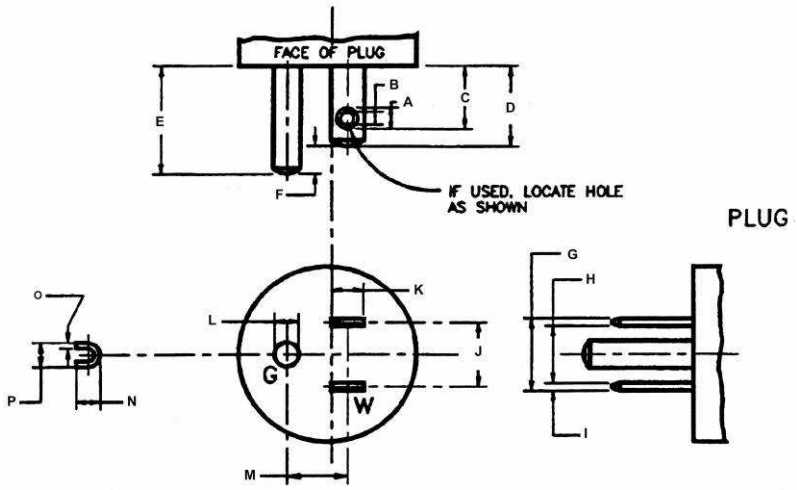
Section	Key	Comment
66.1-66.2	T	Refer to data sheet
67		**Secureness of cover test**
67.1-67.2	T	Refer to data sheet
68		**Crushing test**
68.1-68.2	T	Refer to data sheet
69		**Attachment plug grip test**
69.1-69.9	T	Refer to data sheet
70		**Integrity of assembly test**
70.1-70.2	N/A	Cord part shall be considered in the end appliance.
71		**Self-hinge Flexing test**
71.1-71.3	N/A	Not self-hinge type
72		**Terminal temperature test**
72.1-72.4	N/A	No terminal for end user.
73		**Fuse-holder temperature test**
73.1-73.8	N/A	No fuse-holder applied.
74-79	N/A	**Pin type terminal**
80-85	N/A	**INLET (applying for inlet)**
86-103	N/A	**CONNECTORS**
104-150	N/A	**RECEPTACLES**
		CURRENT-TAPS
		All devices
151-152	N/A	**These sections are for current-taps**
		Flatiron and appliance plugs.
153-161	N/A	**These sections are applicable for flatiron and appliance plugs.**
RATINGS		
162		**Details**
162.1	G	According to exception no. 2, rating is not required. The special-use device is not intended to ship out solely. (Note: plug is mounted in evaluated appliance).
162.2	√	Rating of 1A 120V~ is evaluated
162.3	√	0.5HP rated.
162.4-162.7	N/A	Not have the specified devices
MARKINGS AND INSTRUCTIONS		
163		**General**
163.1-163.2	G	The location of the catalog number is not prohibited from appearing according to exceptions of table 163.1 and 163.2
164		**Identification and marking of terminals**
164	G	No any grounding parts and terminals
SUPPLEMENT SA		**(reserved for future use)**
SUPPLEMENT SB		ENCLOSURE TYPES FOR ENVIRONMENTAL PROTECTION
SB1-SB7	N/A	The requirements of SB don't apply to the device under evaluation for it's intended for indoor use only (refer to SB1.1)
SUPPLEMENT SC		**MARINE SHORE POWER INLETS**

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Section	Key	Comment
SC1-SC12	N/A	These sections are for marine shore power inlets
SUPPLEMENT SD		**HOSPITAL GRADE DEVICES**
SD1-SD30	N/A	These sections are for hospital grade devices

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 7: Dimensions of NEMA 5-15 plug portion



Symbol	Requirement inch (mm)	Measured (mm)	Symbol	Requirement inch(mm)	Measured (mm)
A	0.125 (3.18)	3.17	I	0.065 (1.65) ≥ I ≥ 0.055 (1.40)	1.48
B	0.156 (3.96)	3.88	J	0.505 (12.82) ≥ I ≥ 0.495 (12.57)	12.76
C	0.546 (13.76) ≥ C ≥ 0.537 (13.00)	13.03	K	0.260 (6.60) ≥ K ≥ 0.240 (6.10)	6.28
D	(18.24) ≥ D ≥ 0.625 (15.88)	17.10	L	0.190 (4.82) ≥ L ≥ 0.184 (4.67)	N/A
E	E ≤ 0.843 (21.41)	N/A	M	0.473 (12.01) ≥ M ≥ 0.463 (11.76)	N/A
F	F ≥ 0.125 (3.18)	N/A	N	0.190 (4.82) ≥ N ≥ 0.184 (4.67)	N/A
G	G ≤ 0.575 (14.60)	14.24	O	O ≥ 0.038[1)] (0.96)	N/A
				O ≥ 0.027[1)] (0.68)	N/A
H	H ≥ 0.425 (10.80)	11.23	P	0.190 (4.82) ≥ P ≥ 0.184 (4.67)	N/A
Perimeter faces to the plug blades shall not be less than 7.9 mm from any point of either blade					12.39

1) 0.038[1)] (0.96) min is used on U shape, and 0.027[1)] (0.68) is used on tubular shape.

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 8: Photos for NEMA 5-15 plug portion.

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Equipment combined with BS-plug
Supplementary tests on plug portion according to BS1363: Part 3 + Amd 9543 + Amd 14225 + Amd 14540 + Amd 17437 + Amd A4

Clause	Requirement - Test	Result-Remark	Verdict
12.1	Dimensions (Checked according to figure 4)	See appendix no. 1 & 2	P
12.2	Outline of plug shall not exceed the dimension shown in Figure 4 for a distance of not less than 6.35 mm from the engagement surface	8.90 mm	P
	Pin disposition, length and body outline shall be checked by use of the gauge shown in Figure 5		P
12.3	L/N pin was more than 9.5 mm from the periphery of the plug measured along the engagement surface	9.60 mm	P
12.7	The base and cover of rewirable plugs shall be adaptor plugs having the cover fixed by screws shall be firmly secured to each other. It shall not be possible to remove the cover unless the adaptor is completely withdrawn from the socket-outlet. Fixing screws shall be captive. The test is carried out using apparatus similar to that shown in Figure 6		N/A
12.9	After the temperature rise test (clause 16). Use test probe 11 of BS EN 61032:1998 is applied a force 30 -5/0 N. During and after the test, it was not possible to touch the live parts.		P
12.11	Adaptor plug pins shall be constructed of brass, except for sleeves of pins as specified in 12.18		P
	All exposed surfaces of the adaptor plug pins shall be smooth and free from burrs or sharp edges and other irregularities which could cause damage or excessive wear to corresponding socket contacts or shutters.		P
	Those surfaces of the non-solid adaptor plug pins which are visible when the adaptor is correctly assembled shall be free of apertures.		P
	All seams and joints of non-solid adaptor plug pins shall be closed over their entire length.		P
	For solid pins, conformity shall be checked by 12.11.4.1.		P
	For non-solid pins, compliance shall be checked by 12.11.4.2.		N/A

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Clause	Requirement - Test	Result-Remark	Verdict
	Adaptors with non-solid pins shall not cause excessive wear to socket contacts or shutters of socket-outlets in accordance with BS 1363-2:1995.		N/A
	Adaptor plug pins shall have adequate mechanical strength to ensure that they cannot be distorted by twisting. Apply a torque 1N.m ± 10% for 60 +5/0 S. After each pin has been separately twisted, the plug was fit the gauge in fig. 5. Repeated with opposite direction.		P
12.13	Adaptors shall be so designed that when fully assembled the pins are adequately retained in position such that there is no likelihood of them becoming detached from the adaptor during normal use.		P
	Each pin is subjected for 60 +5/0 S to a pull of 100 -2/0 N without jerks in the direction of the major axis. The plug is mounted using the steel plate shown in fig.7. The apparatus is placed within an oven and the pull is applied at least 1 h after the plug body has attained the test temperature of 70℃ ± 5℃ while maintained at this temperature. After the test, the plug pin shall fit into the gauge and comply with 12.2.1.		P
12.14	The degree of flexibility of mounting of the plug pins or the angular movement of the pins in the base shall be not greater than 3°30'. See fig. 8.		P
	Test procedure refers to standard. During each test, the declination from the horizontal measured on the scale shall not exceed 3°30' and comply with 12.2.1.		P
12.18	Live and neutral adaptor plug pins shall be fitted with insulating sleeves. See fig.4. Sleeves shall not be fitted to any earthing adaptor plug pin.		P
12.19.3	Abrasion test – 10 000 times in each direction (20 000 movements) at a rate of 25 movements to 30 movements per min. (fig. 9). After the test, the sleeve shall show no damage and also shall not have been penetrated or creased, satisfy the tests in 12.19.2.		P

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Clause	Requirement - Test	Result-Remark	Verdict
13.10	The total mass of the equipment with all specified connectors shall not exceed 800 g. The torque exerted on a socket shall not exceed 0.7 N·m. The test apparatus as Figure 37	Compliance with the main standard	N/A
	Additional: Products with torque exceeding 0.25Nm do not comply with the main standard hence full compliance with the main standard cannot be claimed		N/A
Additional test for ISODs according to BS1363: Part 1 + Amd 9541 + Amd 14539 + Amd 17435 + Amd A4			
12.9.1	All exposed surfaces of plug pins shall be smooth and free from burrs or sharp edges and other irregularities which could cause damage or excessive wear to corresponding socket contacts or shutters.		P
12.9.4	Apply a force of 1100 -10/0N at a rate not exceeding 10 mm/min. After this test the plug should fit the gauge to fig. 5.		P
	Apply a force of 400 +10/0N at a rate 10 ± 2 mm/min. Deflection shall not exceed 1.5 mm. After this test the plug should fit the gauge to fig. 5.		P
12.9.6	ISODs shall have adequate mechanical strength to ensure that they cannot be distorted by twisting. Apply a torque 1N.m ± 10% for 60 +5/0 S. After each pin has been separately twisted, the plug shall fit the gauge in fig. 5. Repeated with opposite direction.		P

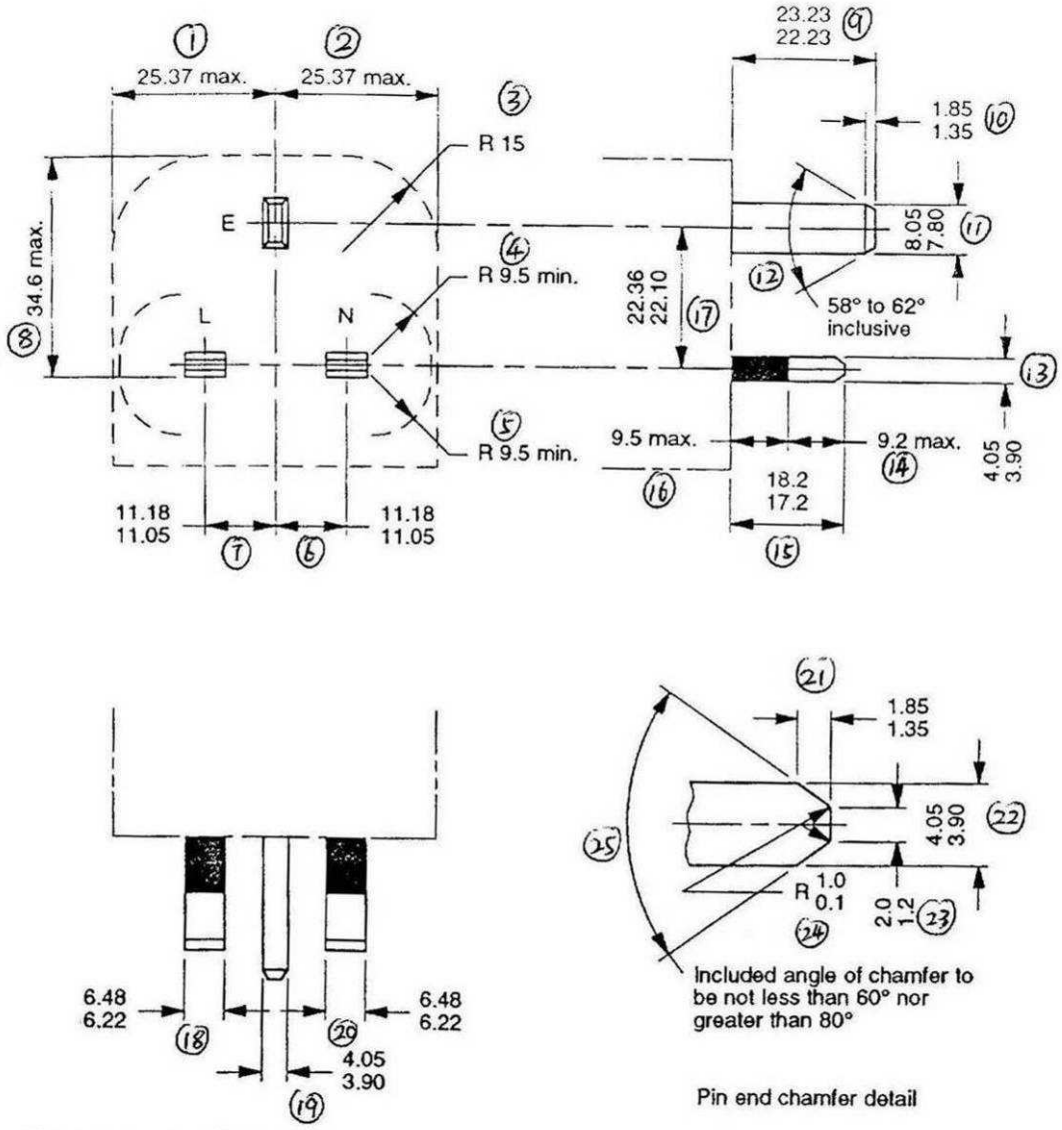
IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 9

	Dimensions Checked by means of measurement according to BS1363-3 Fig. 4 (see appendix no. 2)		
Position	Requirement (mm)	Measured (mm)	Verdict
1.	25,37max	24.02	P
2.	25,37max	24.02	P
3.	R15min	Measured by guage	P
4.	R9,5min	9.60	P
5.	R9,5min	9.60	P
6.	11,05-11,18	11.12	P
7.	11,05-11,18	11.12	P
8.	34,6max	30.50	P
9.	22,23-23,23	22.60	P
10.	1,35-1,85	1.55	P
11.	7,80-8,05	8.03	P
12.	58^{o}-62^{o} inclusive	60^{o}	P
13.	3,90-4,05	3.99	P
14.	9,2max	8.88	P
15.	17,2-18,2	18.05	P
16.	9,5max	9.17	P
17.	22,10-22,36	22.21	P
18.	6,22-6,48	6.26	P
19.	3,90-4,05	4.03	P
20.	6,22-6,48	6.26	P
21.	1,35-1,85	1.81	P
22.	3,90-4,05	3.98	P
23.	1,2-2,0	1.24	P
24.	R0,1-R1,0	R0.55	P
25.	60^{o}-80^{o} inclusive	68^{o}	P
Outline of the plug not exceed the dimension shown in figure 4 at least 6,35mm from the engagement surface		8.90	P

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 10: BS1363-3 Fig 4



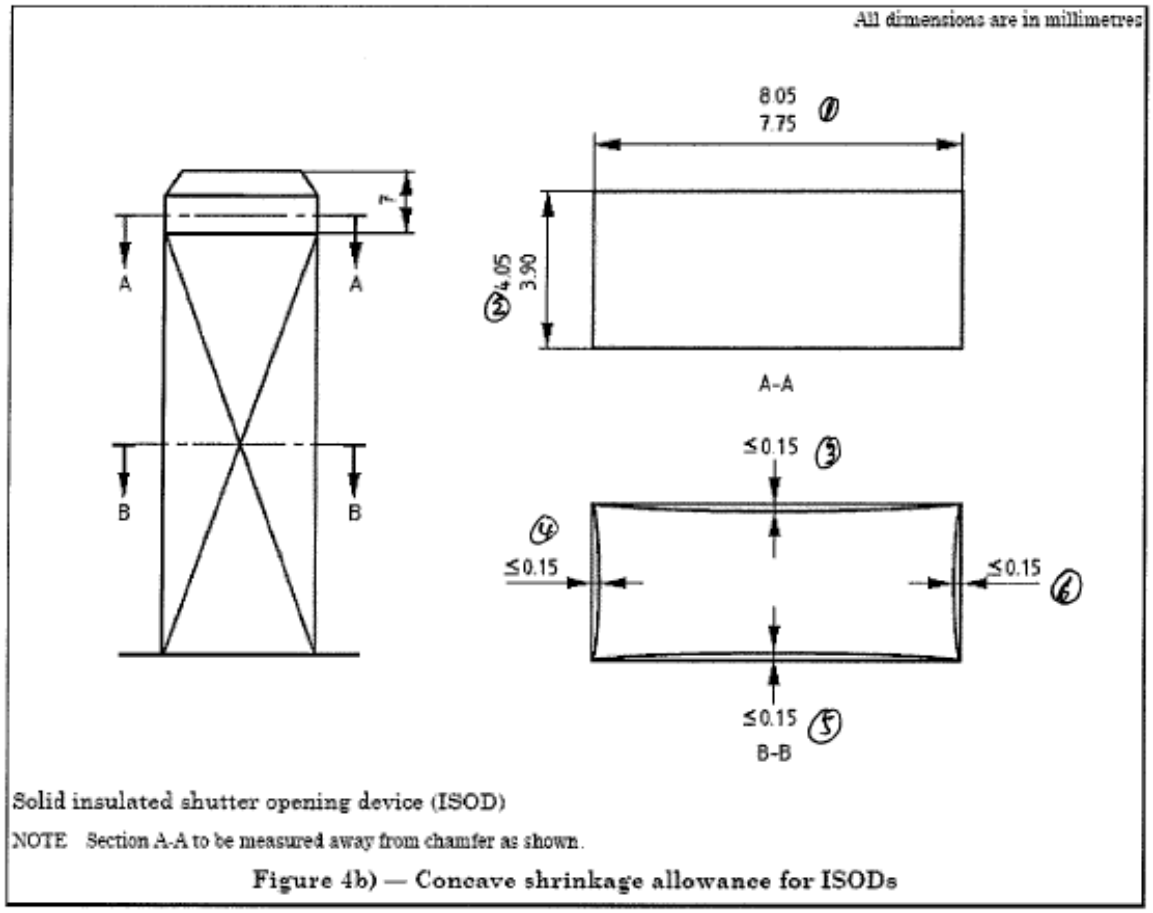
All dimensions are in millimetres.

Figure 4. Dimensions and disposition of pins (see clause 12)

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 11: Concave shrinkable allowance for ISODs

	Dimensions Checked by means of measurement according to BS1363-1 Fig. 4b		
Position	Requirement (mm)	Measured (mm)	Verdict
1.	7,75-8,05	8.03	P
2.	3,90-4,05	3.99	P
3.	≤ 0,15	0.01	P
4.	≤ 0,15	0.01	P
5.	≤ 0,15	0.01	P
6.	≤ 0,15	0.01	P



Solid insulated shutter opening device (ISOD)

NOTE Section A-A to be measured away from chamfer as shown.

Figure 4b) — Concave shrinkage allowance for ISODs

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 12: Photo for BS1363 plug

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict