
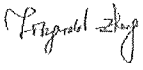
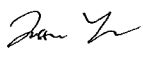




Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment	
Part 1: General requirements for basic safety and essential performance	
Report Reference No.....:	171201810SHA-001
Date of issue	2018-07-30
Total number of pages.....:	246 Pages
CB Testing Laboratory.....:	Intertek Testing Services Shanghai
Address	Building No.86, 1198 Qinzhou Road (North), 200233 Shanghai, China
Applicant's name.....:	GlobTek, Inc.
Address	186 Veterans Dr. Northvale, NJ 07647 USA
Test specification:	
Standard	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	CB Scheme
Non-standard test method.....:	
Test Report Form No.....:	IEC60601_1K
Test Report Form Originator	UL(US)
Master TRF	2015-11
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General disclaimer:	
<p>The test results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.</p>	

Test item description..... :	Medical Power Supply	
Trade Mark..... :	 GlobTek, Inc.	
Manufacturer	Same as applicant	
Model/Type reference..... :	GT*86100-**-W2** ((Refer to general product information for details.)	
Ratings..... :	Input: 100-240V~,50-60Hz,0.3A Output: 5-5.2VDC, Max.2A Max 10W	
Testing procedure and testing location:		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	
Testing location/ address		Intertek Testing Services Shanghai Building No.86, 1198 Qinzhou Road (North), 200233 Shanghai, China
<input type="checkbox"/>	Associated CB Testing Laboratory:	
Testing location/ address		
Tested by (name, function, signature)..... :		Fitzgerald Zhang (Engineer) 
Approved by (name, function, signature) .. :		Justin Yu (Mandated Reviewer) 
<input type="checkbox"/>	Testing procedure: CTF Stage 1:	
Testing location/ address		
Tested by (name, function, signature)..... :		
Approved by (name, function, signature) .. :		
<input type="checkbox"/>	Testing procedure: CTF Stage 2:	
Testing location/ address		
Tested by (name, function, signature)..... :		
Witnessed by (name, function, signature) .. :		
Approved by (name, function, signature) .. :		
<input type="checkbox"/>	Testing procedure: CTF Stage 3:	
<input type="checkbox"/>	Testing procedure: CTF Stage 4:	
Testing location/ address		
Tested by (name, function, signature)..... :		
Witnessed by (name, function, signature) .. :		

Approved by (name, function, signature) .. :		
Supervised by (name, function, signature) :		

List of Attachments (including a total number of pages in each attachment):	
<p>Photo of EUT: Page 146-158</p> <p>Circuit Diagram / Layout: Page 159-160</p> <p>National difference: Page 161-183</p> <p>Evaluation sheet for interchangeable plug portion: Page 184-246</p>	
Summary of testing	
Tests performed (name of test and test clause):	Testing location:
<p>4.11 Power Input</p> <p>5.7 Humidity Preconditioning</p> <p>5.9.2 Accessible Parts</p> <p>7.1.2 Legibility of Markings</p> <p>7.1.3 Durability of Markings</p> <p>8.4.3 Plug Voltage and/or Energy</p> <p>8.5.4 Working Voltage Measurement</p> <p>8.6.4 Earthing</p> <p>8.7.4 Leakage Current Test</p> <p>8.8.3 Dielectric Strength</p> <p>8.8.4.1 Ball Pressure Test</p> <p>8.9.4 Creepage & Clearance Measurements</p> <p>9.3 Surfaces, corners and edges</p> <p>11.1 Excessive Temperature</p> <p>13.2 Single Fault Conditions</p> <p>15.3.2 Push Test</p> <p>15.3.3 Impact Test</p> <p>15.3.4 Drop Test</p> <p>15.3.6 Moulding Stress Relief</p> <p>15.5.1.2 Transformer Short-Circuit</p> <p>15.5.1.3 Transformer Overload</p> <p>15.5.2 Transformer Dielectric Strength</p>	<p>Intertek Testing Services Shanghai</p> <p>Building No. 86, 1198 Qinzhou Road (North), 200233 Shanghai, China</p>
Summary of compliance with National Differences	

List of countries addressed:

Canada, USA, Switzerland, Korea, Japan

Group- and national differences for the CENELEC countries according to EN 60601-1:2006 + A11:2011 + A1:2013. The text of the International Standard IEC 60601-1:2005/A1:2012 was approved by CENELEC as a European Standard without any modification.

☒ The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012.

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.

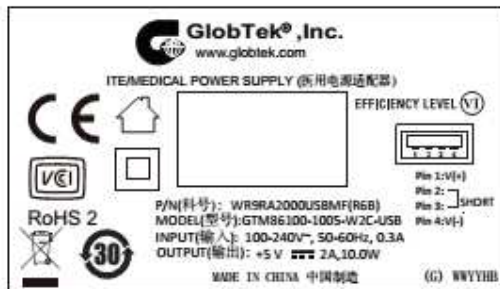
US without LED



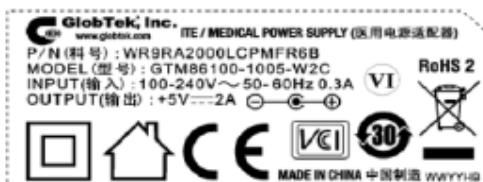
EU without LED



CN without LED



CN with LED



Note: The above markings are the minimum requirements required by the safety standard. For the final production samples, the additional markings which do not give rise to misunderstanding may be added.

Other models are with similar label as corresponding above models except different model name and output ratings.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use	Direct plug-in for power adapter model/Transportable.
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	Direct plug-in for power adapter model.
Accessories and detachable parts included.....	None
Other options include	None
Testing	
Date of receipt of test item(s)	2017-12-30
Dates tests performed	2017-12-30 to 2018-03-01
Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement.....	Pass (P)
- test object was not evaluated for the requirement	N/E (collateral standards only)
- test object does not meet the requirement.....	Fail (F)
Abbreviations used in the report:	
- normal condition	N.C.
- means of Operator protection	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection	MOPP

General remarks:

Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "J" of TRF for IEC for 60601-1 3rd edition with Amendment 1.
 "(See Attachment #)" refers to additional information appended to the report.
 "(See appended table)" refers to a table appended to the report.
 The tests 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 testing laboratory.
 List of test equipment must be kept on file and available for review.
 Additional test data and/or information provided in the attachments to this report.

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The test report only allows to be revised only within the report defined retention period unless standard or regulation was withdrawn or invalid.

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

Manufacturer's Declaration per sub-clause 4.2.5 of IEC 60601-1:2012	
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	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Not applicable
When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies).....	1. GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA 2. GlobTek (Suzhou) Co., Ltd Building 4, No. 76 JinLing East Road, Suzhou Industrial Park, Suzhou, 215021, JiangSu, China Sanqi Electronics Information Industry District, Jiashan Economy Development Zone, Jiashan Town, Jiaxing, Zhejiang 314100, P.R. 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 different models are corresponding to two structure types respectively.

All models have same PCB, but some non-critical components may be adjusted according different output voltage. The parameters of these components depend on output voltage.

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

The insulation construction of EUT is evaluated as 2MOPP in this report as customer's request.

Model Similarity:

GT*86100-**-W2**

The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety.

The 2nd "*" denotes the rated output wattage designation, which can be "01" to "10", with interval of 1

The 3rd "*" denotes the rated output voltage designation, which can be "05", "5.1", "5.2" or "05", "05.1", "05.2".

The 4th "*" designates type of plug and can be E for European plug, U for British plug, blank for North American /Japan plug/Taiwan plug, C for China plug, I for India plug, A for Australia plug, K for Korea plug.

The 5th "*" can be "-USB" or blank, -USB denote the power supplies use USB port, when it is blank, denote the power supplies use DC output wires.

Model list

Model	Output Voltage	Max. output current	Max. output power
GT*86100-**-W2**	5-5.2Vdc	2A	10W

Technical Considerations:

Transformers used in all models are with same construction. The turns of secondary winding may be added or reduced according different output voltage. All models have same PCB, but some non-critical components may be adjusted according different output voltage. The parameters of these components depend on output voltage.

The products are not intended to use in environment which altitude exceed 5000m.

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),

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

INSULATION DIAGRAM

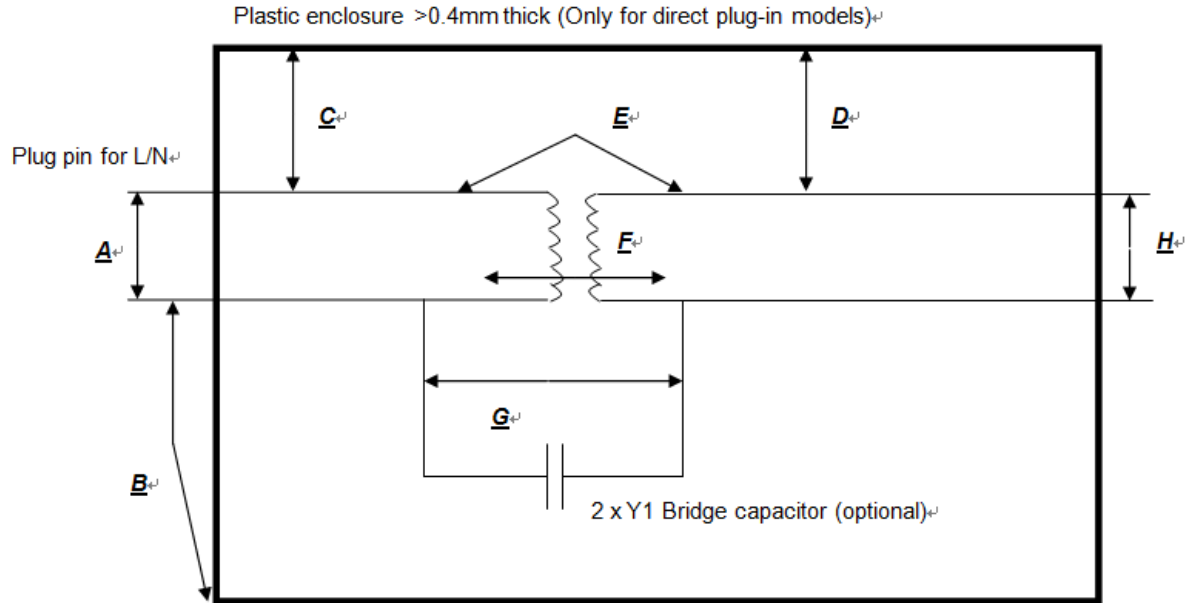


TABLE: INSULATION DIAGRAM									P
Pollution degree				2					—
Overvoltage category				II					—
Altitude				Up to 5000m, use multiple factor 1.29 for MOPP, multiple factor 1.48 for MOOP					—
Additional details on parts considered as applied parts				<input checked="" type="checkbox"/> None <input type="checkbox"/> Areas _____ (See Clause 4.6 for details)					—
Area	Number and type of Means of Protection: MOOP, MOPP	CTI	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			V _{rms}	V _{pk}					
Model: GTM86100-1005-W2E-USB									
A	1MOOP	IIIb	240	--	3.0	3.0	3.1	3.1	Mains opposite polarity
B	2MOPP	IIIb	240	--	8.0	6.5	8.2	8.2	Mains (plug pin) to enclosure (accessible position during normal use)
C	2MOPP	IIIb	240	--	--	--	--	--	Mains to external of

IEC 60601-1									
Clause	Requirement + Test				Result - Remark				Verdict
									enclosure (>0.4mm thick plastic enclosure, solid insulation)
D	2MOPP	IIIb	--	Max. 48	--	--	--	--	Secondary to external of enclosure (>0.4mm thick plastic enclosure, solid insulation)
E	2MOPP	IIIb	240	352	8.0	6.5	8.8	8.8	Mains to secondary on PCB
F	2MOPP	IIIb	240	352	8.0	6.5	16.3	16.3	Mains to secondary on transformer
G	2MOPP	IIIb	240	352	8.0	6.5	10.5	10.5	Mains to secondary on bridge capacitors, see 8.5.1.2 and 8.8.3
H	2MOPP	IIIb	--	Max. 48	--	--	--	--	Accessible part per 8.4.2c)
Model: GTM86100-1005-W2C									
A	1MOOP	IIIb	240	--	3.0	3.0	4.2	4.2	Mains opposite polarity
B	2MOPP	IIIb	240	--	8.0	6.5	8.1	8.1	Mains (plug pin) to enclosure (accessible position during normal use)
C	2MOPP	IIIb	240	--	--	--	--	--	Mains to external of enclosure (>0.4mm thick plastic enclosure, solid insulation)

IEC 60601-1									
Clause	Requirement + Test				Result - Remark				Verdict
D	2MOPP	IIIb	--	Max. 48	--	--	--	--	Secondary to external of enclosure (>0.4mm thick plastic enclosure, solid insulation)
E	2MOPP	IIIb	240	352	8.0	5.7	8.8	8.8	Mains to secondary on PCB
F	2MOPP	IIIb	240	352	8.0	5.7	19.1	19.1	Mains to secondary on transformer
G	2MOPP	IIIb	240	352	8.0	5.7	10.5	10.5	Mains to secondary on bridge capacitors, see 8.5.1.2 and 8.8.3
H	2MOPP	IIIb	--	Max. 48	--	--	--	--	Accessible part per 8.4.2c)
Supplementary Information:									

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	RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS		P
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007)	See Appended RM Results Table 4.2.2.	P
4.2.3	Evaluating RISK		P
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level		P
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN	RISK MANAGEMENT PLAN Document: GT-RMPLAN2018-002 (Version: A.0)	P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		P
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		P
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.		P
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.	No essential performance.	N/A
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		N/A
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		N/A
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE	See Appended Table 4.3	N/A
	- RISK CONTROL measures implemented		N/A
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		N/A
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE	5 years.	P
4.5	Alternative RISK CONTROL methods utilized:		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No alternative risk control method.	N/A
	Alternative means based scientific data or clinical opinion or comparative studies :		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 :	No such parts.	N/A
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	Assessment identified the APPLIED PART TYPE requirements :	No applied part.	N/A
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2 :		P
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested..... : (ISO 14971 Cl. 4.2-4.4)	GT-RM2018-002 Cl. 6.3.	P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically :	See appended Table 13.2 for simulated physical test.	P
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified.... :	All components and wiring used according to applicable rating.	P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS		P
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No components used outside their ratings.	N/A
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION... :	See Table 8.10 b.	N/A
	Components determined to be acceptable where used as a MEANS OF PROTECTION :	RMF Reference to specific RISKS:	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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 and selected appropriately	No component with high-integrity characteristics.	N/A
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:	See Table 8.10 b	N/A
4.10	Power supply		
4.10.1	ME EQUIPMENT is suitable for connection to indicated power source (select applicable)	Suitable for connection to a SUPPLY MAINS.	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:	Not hand-held equipment.	N/A
	- 250 V for HAND-HELD ME EQUIPMENT (V)	100-240Vac, single phase, less than 4KVA	P
	- 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V)	100-240Vac, single phase, less than 4KVA	N/A
	- 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
4.11	Power input		P
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%	See appended Table 4.11	P
5	GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT		P
5.1	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods	RM not provided: All the applicable tests were conducted.	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
5.3	Tests conducted within the environmental conditions specified in technical description	Rated input in amps: 0.3A.	P
	Temperature (°C), Relative Humidity (%)	0-40 °C, 15-95%RH.	—
	Atmospheric Pressure (kPa)	700-1060hPa.	—
5.5	a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V)	100-240V~	P
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)	50-60Hz	P
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current	85-264V~, 50-60Hz considered.	P
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered.....	Not for d.c. supply connection.	N/A
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions	No alternative accessory.	N/A
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	No separate power supply used.	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	Equipment subject to humidity preconditioning.	P
	ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time	T = 25 °C. Time – 48H.	—
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS.....		N/A
5.9.2	ACCESSIBLE PARTS		P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.9.2.1	Accessibility determined using standard test finger of Fig. 6	See Appended Table 5.9.2	P
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	No 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
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL	No such part.	N/A

6	CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS		P
6.2	CLASS I ME EQUIPMENT, externally powered	Class II construction for power adapter model.	N/A
	CLASS II ME EQUIPMENT, externally powered	Class II construction for power adapter model.	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
	TYPE B APPLIED PART	No applied part.	N/A
	TYPE BF APPLIED PART		N/A
	TYPE CF APPLIED PART		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529	IP20	P
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
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		P
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IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	See appended Tables 7.1.3 and 8.10	P
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		P
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6, 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
	Single use item marked	No part intended for a single use.	N/A
7.2.2	ME EQUIPMENT marked with:		P
	– the name or trademark and contact information of the MANUFACTURER	See attached copy of Marking Plate.	P
	– a MODEL OR TYPE REFERENCE	See attached copy of Marking Plate.	P
	– a serial number or lot or batch identifier; and		P
	– the date of manufacture or use by date		P
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or		N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts: (ISO 14971 Cl. 4.2-4.4, 5, 6.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and		N/A
	– a MODEL OR TYPE REFERENCE		N/A
	Software forming part of a PEMS identified with a unique identifier	No PEMS.	N/A
7.2.3	Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted		N/A
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and	No such accessories.	N/A
	- with a MODEL or TYPE REFERENCE		N/A
	– a serial number or lot or batch identifier		N/A
	– the date of manufacture or use by date		N/A
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		N/A
7.2.5	ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following	Not receive power from other equipment.	N/A
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or		N/A
	– Table D.2, safety sign No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or		N/A
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.		N/A
7.2.6	Connection to the Supply Mains		P
	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	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 and type of current.....	Single phase, AC.	P
	Symbols 1-5, Table D.1 (used for same parameters	‘~’ is used.	P
	– RATED supply frequency or RATED frequency range in hertz	50-60Hz	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT	Symbol 9 is used for Class II adapter model.	P
7.2.7	RATED input in amps or volt-amps, (A, VA)	RATED input in amps: 0.3A	P
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)	No such range provided.	N/A
	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 $\pm 10\%$ of the mean value of specified range (A, VA, W)		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)		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)		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)		N/A
7.2.8	Output connectors		P
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), marking optional for ME EQUIPMENT or parts rated IPX0. ...	IP20	P
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols	No applied part.	N/A
	TYPE B APPLIED PARTS with symbol 19 of Table D.1		N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1		N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1		N/A



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Clause	Requirement + Test	Result - Remark	Verdict
	Proper symbol marked adjacent to or on connector for APPLIED PART		N/A
	Safety sign 2 of Table D.2 placed near relevant outlet.....		N/A
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use		N/A
7.2.11	ME EQUIPMENT 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		—
	Voltage (V) and Current (A) rating.....		—
	Operating speed (s) and Breaking capacity		—
7.2.13	Physiological effects – safety sign and warning statements	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	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.3)		
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	No such high voltage terminal device.	N/A
7.2.15	Requirements for cooling provisions marked...		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
	Permissible environmental conditions marked on outside of packaging	Component, to be determined as part of end product.	N/A
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK		N/A
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK.	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.3-6.4)		
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and :	No external pressure source.	N/A
	- the RATED flow rate also marked		N/A
7.2.19	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL:	No FE terminal.	N/A
7.2.20	Removable protective means 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
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms:	Not mobile me equipment.	N/A
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		P
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		N/A
7.3.2	Symbol 24 of Table D.1, or safety sign No.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 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:		N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK..... :		N/A
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD:		N/A
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified:	Specification adjacent to component.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Voltage (V) and Current (A) rating.....:	F1: T1A or T2A/250V RT1: 3.3ohm, 2W (For USB only)	—
	Operating speed(s), size & breaking capacity .:	See the table 8.10	—
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1	No Protective earth terminal.	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		N/A
7.3.6	Symbol 7 of Table D.1 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
	Terminals for supply connections are not marked, the RISK MANAGEMENT FILE includes an assessment of the RISKS resulting from misconnections.....: (ISO 14971 Cl. 4.3)	GT-RM2018-002 Cl. 6.3.	P
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	Marked on EUT.	P
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	Not permanently installed.	N/A
	Marking for connection to a 3-phase supply, 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 °C” or equivalent, marked at the point of supply connections	No such high temperature.	N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	Marking of controls and instruments		N/A
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 or	No power switch.	N/A
	– indicated by an adjacent indicator light, or		N/A
	– indicated by other unambiguous means		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, 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 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		N/A
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2, 6.3)	RMF Reference to specific RISKS: List of controls: (ISO14971 Cl. __)	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		N/A
	– or an indication of direction in which magnitude of the function changes		N/A
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009		N/A
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units		N/A
	ISO 80000-1 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	See Appended Tables 7.1.2 and 7.1.3.	N/A
7.5	Safety signs		N/A
	Safety sign with established meaning used		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	RMF Reference to specific RISK & Marking: Safety Sign Used: (ISO 14971 Cl. __)	N/A
	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 notices include appropriate precautions or instructions on how to reduce RISK(S)		N/A
	Safety signs including any supplementary text or symbols described in instructions for use		N/A
	- and in a language acceptable to the intended OPERATOR		N/A
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use.....:	See Appended Instruction for Use	P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable		N/A
7.7	Colours of the insulation of conductors		N/A
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		N/A
7.7.3	Green and yellow insulation identify only following conductors:		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”	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		N/A
7.8	Indicator lights and controls		N/A
7.8.1	Red indicator lights used only for Warning	No indicator light.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Yellow indicator lights used only for Caution		N/A
	Green indicator lights used only for Ready for use		N/A
	Other colours: Meaning other than red, yellow, or green (colour, meaning)		N/A
7.8.2	Red used only for emergency control		N/A
7.9	ACCOMPANYING DOCUMENTS		P
7.9.1	ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description	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
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		P
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to	 GlobTek, Inc.	P
	– MODEL OR TYPE REFERENCE	GT*86100-**-W2**	P
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT		N/A
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use		N/A
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended		N/A
7.9.2	Instructions for use include the required information		P
7.9.2.1	– use of ME EQUIPMENT as intended by the MANUFACTURER:	Power adapter.	P
	– frequently used functions,	Power supply only.	P
	– known contraindication(s) to use of ME EQUIPMENT		N/A
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient		N/A
	– name or trademark and address of the MANUFACTURER	 GlobTek, Inc.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– MODEL OR TYPE REFERENCE	GT*86100-**-W2**	P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:		N/A
	– the PATIENT is an intended OPERATOR		N/A
	– warning against servicing and maintenance while the ME EQUIPMENT is in use		N/A
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and		N/A
	–maintenance the PATIENT can perform		N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT		P
	Instructions for use are in a language acceptable to the intended operator	English.	P
7.9.2.2	Instructions for use include all warning and safety notices		P
	Warning statement for CLASS I ME EQUIPMENT included		N/A
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments		P
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference		P
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No multiple socket-outlet.	N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS		N/A
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions		N/A
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source		N/A
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries : (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	Specific RISKS: (ISO 14971 Cl. __)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time..... :	No battery.	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided :	No internal electrical power source.	N/A
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK :	Further evaluation is needed on end product level.	N/A
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE		P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to		N/A
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	No SIP/SOP.	N/A
	APPLIED PARTS specified	No applied parts.	N/A
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation		N/A
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device		N/A
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation		N/A
7.9.2.9	Information provided to operate ME EQUIPMENT		N/A
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use		N/A
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message		N/A
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT		P
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use		N/A
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	Further evaluation is needed on end product level.	N/A
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT		N/A
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application		N/A
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL		N/A
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	No accessories.	N/A
	Other equipment providing power to ME SYSTEM sufficiently described		N/A
7.9.2.15	Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use		N/A
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)		P
7.9.2.17	Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation		N/A
7.9.2.18	The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization		N/A
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization		N/A
7.9.2.19	The instructions for use contain a unique version identifier	Version A	P
7.9.3	Technical description		P

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use		P
	Technical description separable from instructions for use contains required information, as follows		P
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT		P
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and		P
	a unique version identifier: WR9MA2000LCPMFR6B Version A WR9RA2000LCPMFR6B Version A		P
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		N/A
7.9.3.2	The technical description contains the following required information		N/A
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT :		N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and		N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and		N/A
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component		N/A
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair		N/A
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description		P

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Clause	Requirement + Test	Result - Remark	Verdict

8	PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT		P
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		P
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION..... : (ISO 14971 Cl. 4.3)	GT-RM2018-002 Cl.6.3.	P
8.2	Requirements related to power sources		N/A
8.2.1	Connection to a separate power source		N/A
	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	Connect 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	Connection to an external d.c. power source		N/A
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source		N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset		N/A
8.3	Classification of APPLIED PARTS		N/A
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	No applied part.	N/A
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART		N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF		N/A
8.4	Limitation of voltage, current or energy		P
8.4.2	ACCESSIBLE PARTS and APPLIED PARTS		P

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT :	See appended Table 8.7	N/A
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT..... :	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.	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
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J)..... :	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 touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	No internal part is touchable for adapter model.	N/A
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL		N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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 sec after disconnecting the plug of ME EQUIPMENT or its parts (V)..... :	See appended Table 8.4.3	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, and manual discharging device specified in technical description		N/A
8.5	Separation of parts		P
8.5.1	MEANS OF PROTECTION (MOP)		P
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
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing 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
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		P
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test	See appended Table 8.8.3	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		N/A
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION	See appended Tables 8.8.3 and 8.10	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c. :	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 Total Working (V) and C Nominal (μF) :	Each 250V, 2200pF.	—
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		N/A
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:	The separation between primary and secondary was evaluated by MOPP.	N/A
	– dielectric strength test :	See appended Table 8.8.3	N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– limits of Tables 13 to 16 (inclusive); or		N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		N/A
	– or with requirements and tests of IEC 60950-1 for protective earthing :	See Attachment No. __	N/A
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION :	See appended Tables 8.8.3 and 8.10	N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION :	See appended Tables 8.8.3 and 8.10	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 Total Working (V) and C Nominal (μF) :		—
	Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were 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

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Clause	Requirement + Test	Result - Remark	Verdict
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION :	EUT is evaluated according to requirement of MOPP.	N/A
8.5.2	Separation of PATIENT CONNECTIONS		N/A
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE :	No patient connections.	N/A
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS:		N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4 :	See appended Table 8.7	N/A
	Dielectric strength test conducted per 8.8.3.... :	See appended Table 8.8.3	N/A
	CREEPAGE and CLEARANCES measured :	Refer to Insulation Diagram	N/A
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s		N/A
8.5.2.2	PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED :		N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and		N/A
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4 :	See appended Table 8.7	N/A
	Dielectric strength test conducted per 8.8.3.... :	See appended Table 8.8.3	N/A
	Relevant CREEPAGE and CLEARANCES measured	Refer to Insulation Diagram	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits : (ISO 14971 Cl. 4.2-4.4, 5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
8.5.2.3	A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		N/A
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT :		N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm		N/A
	– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1		N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,		N/A
	Test finger test (10 N) :	See appended Table 5.9.2	N/A
	Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces : (ISO 14971 Cl. 4.2-4.4, 5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __) See appended Table 5.9.2	N/A
8.5.4	WORKING VOLTAGE		P
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V) :	240Vac	
	– 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) :		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

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Clause	Requirement + Test	Result - Remark	Verdict
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	No patient connection.	N/A
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)..... :	No applied part.	N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No applied parts.	N/A
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) :	No motor.	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
8.5.5.1	Classification “DEFIBRILLATION-PROOF APPLIED PART” applied to one APPLIED PART in its entirety	No applied parts.	N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N/A
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator :	See appended Table 8.5.5.1a	N/A
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS..... :	See appended Table 8.5.5.1b	N/A
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load :	See appended Table 8.5.5.2	N/A
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		N/A
8.6.1	Requirements of 8.6.2 to 8.6.8 applied	No protective 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..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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,		N/A
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to proof of reliability: (ISO 14971 Cl. __)	N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop	See appended Table 8.6.4	N/A
	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	See appended Table 8.6.4 & Clause 8.7	N/A
8.6.5	Surface coatings		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact		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 connection.	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

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Clause	Requirement + Test	Result - Remark	Verdict
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		N/A
	–accidental disconnection avoided 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		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		N/A
8.6.9	Class II ME EQUIPMENT		P
	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		N/A
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.		N/A
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS		N/A
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		P
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)	Class II equipment.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz :	See appended Table 8.7	N/A
	c) TOUCH CURRENT did not exceed 100 μ A in NORMAL CONDITION and 500 μ A 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}) :	See appended Table 8.7	N/A
	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..... :	See appended Table 8.7	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
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION :	See appended Table 8.7	N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements :	See appended Table 8.7	P
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing		P

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Clause	Requirement + Test	Result - Remark	Verdict
	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		N/A
8.8.2	Distance through solid insulation or use of thin sheet material		P
	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		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..... :	See appended Table 8.8.3	P
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test..... :	See appended Table 8.8.3	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		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
	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		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

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Clause	Requirement + Test	Result - Remark	Verdict
	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	See appended Table 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		P
	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		P
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 design documentation examined	See appended Table 8.10	P
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	GT-RM2018-002 Cl. 8 EL4.	P
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :	See Attachment No.____	N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat..... :		P
	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 Fig 21 apparatus... :	See appended 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 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C)..... :	See appended Table 8.8.4.1	P

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Clause	Requirement + Test	Result - Remark	Verdict
	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		N/A
8.8.4.2	Resistance to environmental stress		P
	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		N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		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 \pm 70 kPa, with an effective capacity of at least 10 times volume of samples		N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C \pm 2 °C for 96h, and afterwards, left at room temperature for at least 16h		N/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive)	Refer to Insulation Diagram	P
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1	No applied parts.	N/A
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION , min CREEPAGE and CLEARANCES not applied	See appended Table 8.9.2	N/A
8.9.3	Spaces filled by insulating compound		N/A
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound		N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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 (cl. 8.8.3 at 1,6 x test voltage)..... :	See appended Table 8.9.3.2	N/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N/A
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N/A
	A winding of solvent-based enamelled 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 followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage	See appended Table 8.9.3.3	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 cl. 8.8.3 at 1.6 times the test voltage		N/A
8.9.4	Minimum spacing of grooves transverses to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree	Pollution degree: 2	P
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES	Refer to Insulation Diagram supplemental information for location and force used	P
8.10	Components and wiring		P
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely..... :	Securely fixed by additional means	P
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components	GT-RM2018-002 Cl. 8 EL3.	P
	(ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)		
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment..... :		P
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS		P

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Clause	Requirement + Test	Result - Remark	Verdict
8.10.3	Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken	See appended Table 5.9.2	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
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 the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3		N/A
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3		N/A
8.10.5	Mechanical protection of wiring		N/A
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges	No moving parts.	N/A
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS		N/A
8.10.6	Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead	No guiding roller.	N/A
8.10.7	a) Insulating sleeve adequately secured.....	See appended Table 8.10	P
	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		P
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C.....	See appended Table 8.10	P
8.11	MAINS PARTS, components and layout		P
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles	See appended Table 8.10	P

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Clause	Requirement + Test	Result - Remark	Verdict
	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
	PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position		N/A
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		P
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description	See appended Table 8.10	P
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV.....	See appended Table 8.10	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		N/A
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N/A
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH.....	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		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 applied		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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)... :	See appended Table 8.10	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 °C touchable by the cord in NORMAL USE :	See appended Table 8.10	N/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 :		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..... :	See appended Table 8.10	N/A
8.11.3.5	Cord anchorage		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage		N/A
	b) Cord anchorage of POWER SUPPLY CORD is an 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		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components		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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		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..... :	See appended Table 8.11.3.5	N/A
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests		N/A
	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 protected against excessive bending at inlet opening of equipment		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 D² gram attached to the free end of cord (g) :	See appended Table 8.11.3.6	N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, 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..... :	See appended Table 8.11.3.6	N/A
8.11.4	MAINS TERMINAL DEVICES		N/A
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection	No mains terminal device.	N/A
	Terminals alone are not used to keep conductors in position		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Screws and nuts clamping external conductors do not serve to secure any other component		N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection		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 after fastening and loosening a conductor of largest cross-sectional area 10 times		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		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		N/A
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		P
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection . :	See appended Table 8.10	P
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT :		P
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not permanently installed.	N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART		N/A
	Protective devices have adequate breaking capacity to interrupt the max. fault current :	See appended Table 8.10	N/A
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Justification for omission of fuses or OVER-CURRENT RELEASES documented :	See Attachment No.____	N/A
8.11.6	Internal wiring of the MAINS PART		N/A
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable :	No such internal wire.	N/A
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient :	See appended Table 8.10 for details	N/A

9	PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS		P
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level :	No moving part.	N/A
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and		N/A
	RISK CONTROLS implemented :		
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
	All RISKS associated with moving parts have been reduced to an acceptable level		N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	No trapping zone.	N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE OF ME EQUIPMENT OR ME SYSTEM		N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20	See appended Table 9.2.2.2	N/A
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008	See appended Table 9.2.2.2	N/A
9.2.2.4	GUARDS and other RISK CONTROL measures		N/A
9.2.2.4.1	A TRAPPING ZONE do not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK	See appended Table 15.3	N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N/A
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	– absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with any applicable tests		N/A
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement and		N/A
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or		N/A
	ME EQUIPMENT IS SINGLE FAULT SAFE		N/A
9.2.2.5	Continuous activation		N/A
	Continuous activation used as a RISK CONTROL, complies with the following		N/A
	a) movement was in OPERATOR's field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR		N/A
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- the continuous activation system is SINGLE FAULT SAFE		N/A
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement		N/A
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
9.2.3	Other MECHANICAL HAZARDS associated with moving parts		N/A
9.2.3.1	Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated		N/A
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or		N/A
	- activation does not result in an unacceptable RISK		N/A
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented.....:		N/A
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse.....:	See appended Table 9.2.3.2	N/A
9.2.4	Emergency stopping devices		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power		N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A
	RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD		N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping		N/A
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N/A
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented		N/A
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered	No rough surface / sharp edge.	P
9.4	Instability HAZARDS		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.4.1	ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE	Direct plug-in type.	N/A
9.4.2	Instability – overbalance		N/A
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested..... :	See appended Table 9.4.2.1	N/A
9.4.2.2	Instability excluding transport		N/A
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE, ... :	See appended Table 9.4.2.2	N/A
	A warning provided when overbalance occurred during 10° inclined plane test		N/A
9.4.2.3	Instability from horizontal and vertical forces		N/A
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it		N/A
	Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK		N/A
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)	See appended Table 9.4.2.3	N/A
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping		N/A
	ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning :		N/A
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b)..... :	See appended Table 9.4.2.3	N/A
9.4.2.4	Castors and wheels		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE		N/A
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT did not exceed 200 N :	See appended Table 9.4.2.4.2	N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold :	See appended Table 9.4.2.4.3	N/A
9.4.3	Instability from unwanted lateral movement (including sliding)		N/A
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements		N/A
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1	See appended Table 9.4.3.1	N/A
9.4.3.2	Instability excluding transport		N/A
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test	See appended Table 9.4.3.2	N/A
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test	See appended Table 9.4.3.2	N/A
9.4.4	Grips and other handling devices		N/A
	a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method		N/A
	Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS		N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood loading test	See appended Table 9.4.4	N/A
9.5	Expelled parts HAZARD		N/A
9.5.1	Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE (ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)	No expelled parts.	N/A
	All identified RISKS associated with expelled parts mitigated to an acceptable level		N/A
9.5.2	Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965	See appended Table 8.10	N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		N/A
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and	Component, to be determined as part of end product.	N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and (ISO 14971 Cl. 4.2-44, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
	All identified RISKS mitigated to an acceptable level		N/A
9.6.2	Acoustic energy		N/A
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE		N/A
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA)..... :		—
	- 83 dBA (when halving the cumulative exposure time) (dBA)..... :		—
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB)..... :		—
9.6.2.2	RISK MANAGEMENT FILE examined : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
9.6.3	Hand-transmitted vibration		N/A
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values		N/A
	– 2.5 m/s ² for a cumulative time of 8 h during a 24 h period (m/s ²) :		N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s ²)..... :		N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE : (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity		N/A
9.7.3	Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:		N/A
	a) RATED maximum supply pressure from an external source		N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly		N/A
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device		N/A
9.7.4	Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests.....:		N/A
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was more than 50 kPa, and product of pressure and volume was more than 200 kPa:	See appended Table 9.7.5	N/A
9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE ..:		N/A
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests.....:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A
	c) Could be adjusted or rendered inoperative without a TOOL		N/A
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
	RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device : (ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
9.8	HAZARDS associated with support systems		N/A
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK ...:	See appended Table 8.10	N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N/A
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES		N/A
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials		N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to		N/A
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest		N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing .. :		N/A
	RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system .. : (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	All identified RISKS are mitigated to an acceptable level		N/A
	When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK..... :	See appended Table 8.10	N/A
	Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results : (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)	RMF Reference to specific RISK: (ISO 14971 Cl. __)	N/A
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications		N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS		N/A
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS		N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance:	See copy of Marking Label	N/A
9.8.3.2	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m² on a foot rest temporarily supporting a standing PATIENT or OPERATOR:		N/A
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests:	See appended Tables 8.10 and 9.8.3.2	N/A
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK		N/A
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test.....:	See appended Tables 8.10 and 9.8.3.2	N/A
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test	See appended Table 9.8.3.3	N/A
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided for the support system		N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	– Designed based on TOTAL LOAD		N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel produced an unacceptable RISK		N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests	See appended Table 8.10	N/A
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE		N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced		N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE :		N/A
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal		N/A
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.		N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE		N/A
	– Compliance confirmed by examination and following test	See appended Table 8.10	N/A
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT		N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function		N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N/A
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system..... : (ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A

10	PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS		N/A
10.1	X-Radiation		N/A
10.1.1	The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT	See Table 10.1.1 No X-radiation.	N/A
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE		N/A
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or		N/A
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
10.3	The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2		N/A
	Microwave radiation is propagated intentionally		N/A
10.4	Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A

11	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS		P
11.1	Excessive temperatures in ME EQUIPMENT		P
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and :	See appended Table 11.1.1	P
	Surfaces of test corner did not exceed 90 °C		P
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	No thermal cut-out	N/A
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	GT-RM2018-002 CL.6.3.	P
11.1.2	Temperature of APPLIED PARTS		N/A
11.1.2.1	APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply :	No applied parts.	N/A
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use		N/A
11.1.2.2	APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION :		N/A
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:		N/A
	Maximum Temperature :		—

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Clause	Requirement + Test	Result - Remark	Verdict
	Conditions for safe contact, e.g. duration or condition of the PATIENT :		—
	Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	APPLIED PARTS surface temperature of equal to or less than 41°C		N/A
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted..... :	RMF Reference to specific RISKS:	N/A
	Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	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 : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See appended Table 11.1.3d and RMF Reference to specific RISKS: (ISO 14971 Cl. __)	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..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE..... :	RMF Reference to specific RISKS:	N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No alternative method.	N/A
11.2	Fire prevention		P
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3		P

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Clause	Requirement + Test	Result - Remark	Verdict
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of..... :	See appended Table 8.10	N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions		N/A
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively :	See appended Table 11.2.2.1	N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three..... :		N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3	See appended Tables 4.11, 11.1.1, 11.2.2.1 and 13.2	N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%).....		N/A
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE.....	See Attachment No. ____	N/A
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases	See Attachment No. ____	N/A
11.2.2.2	RISK of ignition did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT		N/A
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks		N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		N/A
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2)..... :		N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3)..... :		N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) :		N/A
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a) :		N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas..... :		N/A
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		P
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2..... :		P
	Constructional requirements were met, or		P
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	GT-RM2018-002 CL.6.3.	P
	Justification, when requirement not met :	Specific requirement that is not met:____ Justification:____	N/A
	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
	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		P
	b) Fire ENCLOSURE met following:		P

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Clause	Requirement + Test	Result - Remark	Verdict
	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 $\leq 2 \times 2$ 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 are made of appropriate metal or of non-metallic materials	See appended Table 8.10	P
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G		N/A
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		N/A
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	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		N/A
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT..... :	See Appended Table 11.6.1	N/A
11.6.2	Overflow in ME EQUIPMENT		N/A
	ME EQUIPMENT incorporates a reservoir or liquid storage that did not wet any MEANS OF PROTECTION, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	See Appended Table 11.6.1	N/A
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.		N/A
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM		N/A
	ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See appended Tables 11.6.1; 8.7, 8.8.3 and RMF Reference to specific RISK: (ISO 14971 Cl. __)	N/A
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill :		N/A
11.6.5	Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :	See Appended Table 11.6.1	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 the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION...:	See appended Tables 8.7 8.8.3	N/A
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use :	See Appended Tables 11.6.1, 8.7, and 8.8.3	N/A
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER :		N/A
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests..... :	See appended Tables 8.7 8.8.3, and 11.6.1	N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	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		N/A
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A

12	ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS		N/A
12.1	RISKS associated with accuracy of controls and instruments stated : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING :	See Report based on IEC 60601-1-6	N/A
12.3	MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. :	See Report based on IEC 60601-1-8	N/A
12.4	Protection against hazardous output		N/A
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
12.4.2	- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
12.4.4	RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
12.4.5	Diagnostic or therapeutic radiation		N/A
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3..... :	See IEC 60601-1-3 Report	N/A
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
12.4.5.4	RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
12.4.6	RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A

13	HAZARDOUS SITUATIONS AND FAULT CONDITIONS		P
13.1	Specific HAZARDOUS SITUATIONS		P
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		P
	– 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		N/A
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 :	See appended Table 11.1.1	P
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23..... :	See appended Table 11.1.1	P
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C 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
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	See appended Table 13.1.2	P
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed :	See appended Table 8.7	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed	See appended Table 8.7	P
13. 2	SINGLE FAULT CONDITIONS		P
13.2.1	During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination		P
	ME EQUIPMENT complied with 13.2.2 -13.2.12	See appended Table 13.2	P
	RISK MANAGEMENT FILE includes and assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	GT-RM2018-002 6.3 & 6.4.	P
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:		N/A
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment 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, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C 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		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No heating elements provided.	N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests		N/A
	a 3) other ME EQUIPMENT with heating elements met test		N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part		N/A
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself		N/A
	b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V) :		N/A
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N/A
	2) When more than one control provided, they were disabled in turn		N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N/A
13.2.13.3	ME EQUIPMENT with motors		N/A
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	No motors provided in power supply.	N/A
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Motor met running overload protection test of this clause when:		N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) :		N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N/A
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification)..... :		N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		N/A
13.2.13.4	ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION		N/A
	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 $\leq 5^{\circ}\text{C}$ 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)..... :		—

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Clause	Requirement + Test	Result - Remark	Verdict
14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		N/A
14.1	Requirements in 14.2 to 14.12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or	No Such Parts/ PESS relied upon for Basic Safety or Essential Performance.	N/A
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK..... :		N/A
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)	RMF Reference to specific RISKS: ISO 14971 Cl. __)	N/A
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		N/A
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 6204:2006 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS		N/A
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304 :	Software Class: __	N/A
	Software development process applied according to Clause 5 of IEC 62304..... :		N/A
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 :		N/A
	Software development process Configuration Management applied according to Clause 8 of IEC 62304..... :		N/A
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304 :		N/A
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process :		N/A
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan		N/A
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		N/A
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N/A
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained		N/A
14.6	RISK MANAGEMENT PROCESS		N/A
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS.....:		N/A
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems.....: (ISO 14971 Cl. 4.3)	RMF Reference to specific HAZARDS: (ISO 14971 Cl. __)	N/A
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2.:		N/A
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure.....: (ISO 14971 Cl. 6.1)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem: (ISO 14971 Cl. 6.3)	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems: (ISO 14971 Cl. 6.3)	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	N/A
14.9	Design is broken up into sub systems and descriptive data on design environment documented :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures..... : (ISO 14971 Cl. 6.3)	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	N/A
	– milestone(s) when VERIFICATION is to be performed for each function		N/A
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		N/A
	– selection and utilization of VERIFICATION tools		N/A
	– coverage criteria for VERIFICATION		N/A
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented		N/A
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE:		N/A
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented		N/A
	The person with overall responsibility for PEMS VALIDATION is independent		N/A
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)	RMF Reference to specific RISK CONTROLS: (ISO 14971 Cl. __)	N/A
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		N/A
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304..... :	Software Class: __	N/A
	Software Process for Software changes applied according to Clause 5 of IEC 62304..... :		N/A
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304..... :		N/A
	Configuration management of software changes applied per Clause 8 of IEC 62304 :		N/A
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304 :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
14.13	For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following :		N/A
	a) Purpose of the PEMS connection to an IT-NETWORK		N/A
	b) required characteristics of the IT-NETWORK		N/A
	c) required configuration of the IT-NETWORK		N/A
	d) technical specifications of the network connection, including security specifications		N/A
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK		N/A
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)	RMF Reference to specific hazardous situations: (ISO 14971 Cl. __)	N/A
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		N/A
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties		N/A
	– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS		N/A
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis		N/A
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment		N/A
15	CONSTRUCTION OF ME EQUIPMENT		P
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS..... :	See Attached IEC 60601-1-6	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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		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		P
15.3.1	Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		P
15.3.2	Push test conducted :	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.3	Impact test conducted :	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.4	Drop test		
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested :	See Appended Table 15.3 Not hand-held ME equipment.	N/A
	No unacceptable RISK resulted		N/A
15.3.4.2	Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test :	See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.5	MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests..... :	See Appended Table 15.3 Not mobile ME equipment.	N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.6	Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Mould-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°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C..... :		P
	No damage resulting in an unacceptable RISK		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		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		N/A
15.4	ME EQUIPMENT components and general assembly		N/A
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists,..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions,..... :	See attachment No. __	N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection	See attachment No. __	N/A
15.4.2	Temperature and overload control devices		N/A
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION..... : (ISO 14971 Cl. 4.2-4.4, 5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT		N/A
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE : (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests		N/A
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17		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 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 operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	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
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating		N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating : (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS		N/A
15.4.3	Batteries		N/A
15.4.3.1	Battery housings provided with ventilation.... : (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Battery compartments designed to prevent accidental short circuiting		N/A
15.4.3.2	Means provided to prevent incorrect connection of polarity		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries : (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
15.4.3.3	Overcharging of battery prevented by virtue of design		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries..... : (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
15.4.3.4	Primary lithium batteries comply with IEC 80086-4		N/A
	Secondary lithium batteries comply with IEC 62133		N/A
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire		N/A
	Protective device has adequate breaking capacity		N/A
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented		N/A
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPs provided, or		N/A
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION		N/A
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for		N/A
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,		N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters : (ISO 14971 Cl. 4.2-4.4)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists		N/A
	Colours of indicator lights complied with 7.8.1		N/A
	Charging mode visibly indicated		N/A
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
15.4.6	Actuating parts of controls of ME EQUIPMENT		N/A
15.4.6.1	a) Actuating parts cannot be pulled off or loosened during NORMAL USE		N/A
	b) Controls secured so that the indication of any scale always corresponds to the position of the control		N/A
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values per Table 30 applied knobs did not rotate :	See appended Table 15.4.6	N/A
	Tests conducted with no unacceptable RISK . :	See appended Table 15.4.6	N/A
15.4.6.2	Stops on rotating/ movable parts of controls are of adequate mechanical strength :	See appended Table 15.4.6	N/A
	Torque values in Table 30 applied :	See appended Table 15.4.6	N/A
	No unexpected change of the controlled parameter when tested :	See appended Table 15.4.6	N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N/A
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1		N/A
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage :		N/A
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	a) Foot-operated control device is at least rated IPX1	See appended Table 11.6.1 IP Code = __	N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.....	See appended Table 11.6.1 IP Code = __	N/A
15.4.8	Aluminium wires less than 16 mm² in cross-sectional area are not used		N/A
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed		N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport		N/A
	A pressure-release device operating during NORMAL USE is provided		N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		P
15.5.1	Overheating		P
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating..... :	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 conducted 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		P
15.5.1.3	Multiple overload tests conducted on windings	See appended Table 15.5.1.3	P
15.5.2	Transformers operating at a frequency above 1kHz tested according to clause 8.8.3..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Transformer windings provided with adequate insulation		P
	Dielectric strength tests were conducted :	See appended Table 15.5.2	P
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with :	See appended Table 8.10	P
	- Means provided to prevent displacement of end turns		P
	- protective earth screens with a single turn have insulated overlap		P
	- Exit of wires from internal windings of toroid transformers protected with double sleeving		P
	- insulation between primary and secondary windings complies with 8.8.2		P
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		P

16	ME SYSTEMS		N/A
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	Component power supply; compliance determined in the end product.	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM..... : (ISO 14971 Cl. 4.2-4.4, 5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered		N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard		N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards		N/A
	– tests performed in NORMAL CONDITION, except as specified		N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM		N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated		N/A
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards		N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM		N/A
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		N/A
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		N/A
	c) the required information is provided:		N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		N/A
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard		N/A
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM		N/A
	– additional safety measures to be applied during installation of ME SYSTEM		N/A
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT		N/A
	– additional measures to be applied during preventive maintenance		N/A
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor		N/A
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM		N/A
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(s) used with ME SYSTEM		N/A
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM		N/A
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer		N/A
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET		N/A
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage		N/A
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT		N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		N/A
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		N/A
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard		N/A
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements		N/A
	Transient currents restricted to allowable levels for the specified IPS or UPS :		N/A
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified		N/A
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed		N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION		N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :		N/A
16.6	LEAKAGE CURRENTS		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION did not exceed 100 μ A..... :	See appended Table 16.6.1	N/A
	TOUCH CURRENT did not exceed 500 μ A in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR..... :	See appended Table 16.6.1	N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA..... :		N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values :	See appended Tables 8.7 8.7.4.7 and 16.6.1	N/A
16.7	ME SYSTEM complied with applicable requirements of Clause 9..... :	See applicable appended Tables in section 9	N/A
16.8	Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE		N/A
16.9	ME SYSTEM connections and wiring		N/A
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result :		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
	– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results		N/A
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16.9.2	MAINS PARTS, components and layout		N/A
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or		N/A
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N/A
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and		N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to		N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N/A
	– CREEPAGE and CLEARANCES complied with 8.9		N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets		N/A
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:		N/A
	– ENCLOSURE complied with 8.4.2 d)		N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable		N/A
	– RATINGS of components are not in conflict with conditions of use	See appended Table 8.10	N/A
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL		N/A
	– POWER SUPPLY CORD complied with 8.11.3		N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:		N/A
	– Separating transformer complied with this standard or IEC 61558-2-1,	See appended Table 8.10	N/A
	– Separating transformer is CLASS I		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Degree of protection against ingress of water specified as in IEC 60529		N/A
	– Separating transformer assembly marked according to 7.2 and 7.3		N/A
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083		N/A
16.9.2.2	The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED did not exceed 200 mΩ		N/A
	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part		N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL		N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage		N/A

17	ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS		N/E
	RISKS associated confirmed by review..... :		N/E
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS :		N/E
	RISK MANAGEMENT FILE includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the EQUIPMENT or SYSTEM..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/E
	– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems	See IEC 60601-1-2 Report	N/E

ANNEX G	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES		N/A
G.2	Locations and basic requirements		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5		N/A
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH		N/A
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE		N/A
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5		N/A
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6		N/A
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7		N/A
G.3	Marking, ACCOMPANYING DOCUMENTS		
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1)..... :	See copies of Marking Labels	N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A
	When above marking not possible, relevant information included in instructions for use... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1)..... :	See copies of Marking Labels	N/A
	Marking is as large as possible for the particular case		N/A
	When above marking not possible, the relevant information included in instructions for use... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.3	The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts		N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts		N/A
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		
G.4.1	a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION		N/A
	b) Connections protected against accidental disconnection		N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,		N/A
G.4.2	Construction details		
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL		N/A
	b) ENCLOSURE complies with..... :	See appended Table 8.10	N/A
	– no openings on top covers of ENCLOSURE,		N/A
	– openings in side-covers prevented penetration of a solid cylindrical test rod		N/A
	– openings in base plates prevented penetration of a solid cylindrical test		N/A
	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION		N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures		N/A
	– Use of antistatic materials with a limited electrical resistance :	See appended Table 8.10	N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor		N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882..... :		N/A
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5		N/A
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components		
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5..... :		N/A
G.5.2	Temperature limits :	See appended Tables 11.1.1 and 11.2.2.1	N/A
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1 :	$U_{max} = __ V$ $U_{zR} = __ V$ $I_{zR} = __ A$	N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ... :	$U_{max} = __ V$ $U_c = __ V$ $C_{max} = __ \mu F$	N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 :	$I_{max} = __ A$ $I_{zR} = __ A$ $U_{zR} = __ V$	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24 V$ as in Fig G.3 :	$I_{max} = __ A$ $I_{zL} = __ A$ $L_{max} = __ mH$	N/A
	– Combinations of currents and corresponding voltages within the limitations $I_{zR}.U_{zR} \leq 50 W$ extrapolated from Fig G.1		N/A
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2 mJ$ extrapolated from Fig G.2		N/A
	No extrapolation made for voltages above 242V		N/A
	U_{max} determined using actual resistance R		N/A
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3 mJ$ extrapolated from Fig G.3		N/A
	No extrapolation made for inductances larger than 900 mH		N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open		N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max} , either as d.c. or a.c. peak values in case of a complicated circuit... :		N/A
	Temperature measurements made according to 11.1, and U_{max} , I_{max} , R , L_{max} , and C_{max} determined with application of Figs G.1-G.3 .. :	See appended Table 11.1.1	N/A
	Alternatively, compliance was verified by examination of design data		N/A
G.5.4	External ventilation with internal overpressure		
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR removed by ventilation before EQUIPMENT energized,		N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)		N/A
	Overpressure maintained at the site of potential ignition		N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE		N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N/A
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa)		N/A
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C		N/A
G.5.5	ENCLOSURES with restricted breathing		
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		N/A
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h :	See appended Table 8.10	N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained		N/A
	Cords are fitted with adequate anchorages to limit stresses as determined by test		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C) :		N/A
	Steady state operating temperature of ENCLOSURE also measured (°C) :		N/A
G.6	CATEGORY APG ME EQUIPMENT, parts and components thereof		
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION		N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test		N/A
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :		N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..... :		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or	See Tables 11.1.1, 11.2.2.1 and 13.2	N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:	See Tables 11.1.1 and 13.2	N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 :	$U_{max} = __\text{V}$ $U_{zR} = __\text{V}$ $I_{zR} = __\text{A}$	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Measured $U_{\max} \leq U_{zC}$ with C_{\max} as in Fig. G.5... :	$U_{\max} = __V$ $U_c = __V$ $C_{\max} = __\mu F$	N/A
	Measured $I_{\max} \leq I_{zR}$ with U_{zR} as in Fig G.4 :	$I_{\max} = __A$ $I_{zR} = __A$ $U_{zR} = __V$	N/A
	Measured $I_{\max} \leq I_{zL}$ with L_{\max} and a $U_{\max} \leq 24 V$ as in Fig G.6 :	$I_{\max} = __A$ $I_{zL} = __A$ $L_{\max} = __mH$	N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A
	– U_{\max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N/A
	– I_{\max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N/A
	– C_{\max} and L_{\max} are values occurring in relevant circuit		N/A
	– U_{\max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{\max} and I_{\max} , either as d.c. or a.c. peak values in case of a complicated circuit :		N/A
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components		N/A
	- requirement not applied to transformers complying with this standard		N/A
	- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N/A
	Temperature measurements made in accordance with 11.1 :	See Table 11.1.1	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- or U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6 :	$U_{max} = __ V$ $I_{max} = __ A$ $R = __ \Omega$ $L_{max} = __ mH$ $C_{max} = __ \mu F$	N/A
	Alternatively, compliance verified by comparison with design data :		N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1 :	See appended Table 8.10	N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N/A
G.7	Test apparatus for flammable mixtures according to this Clause and Fig G.7		N/A

ANNEX L	INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION		N/A
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex		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		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		N/A
	Temperature (°C) :		N/A
	Humidity (%) :		N/A
L.3.1	Dielectric strength		
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:		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		

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Clause	Requirement + Test	Result - Remark	Verdict
	Sample subjected to flexibility and adherence		N/A
	Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown		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
	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		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)..... :		N/A
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm²)..... :		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		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/mm²) :		N/A
L.4	Tests during manufacture		
L.4.1	Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3..... :	See attached manufacturer's routine testing verification	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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:		N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See manufacturer's routine testing verification	N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) :	See manufacturer's routine testing verification	N/A
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)..... :	See manufacturer's routine testing verification	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 :	See manufacturer's routine testing verification	N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION :	See manufacturer's routine testing verification	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
3.1	Risk management procedure GTQPR05000 A2.CL.5.0	—	Risk Management Process (excluding production and post-production)	P
3.2	Risk management procedure GTQPR05000 A2.CL.5.0	—	Adequate Resources	P
3.2	Risk management procedure GTQPR05000 A2.CL.5.0	—	Assignment of qualified personnel	P
3.2	Risk management procedure GTQPR05000 A2.CL.5.0	—	Policy for determining criteria for risk acceptability	P
3.3	—	Risk management Report GT-RM2018-002 CL.2.0	Qualification of personnel	P
3.4a	—	Risk management plan GT-RMPLAN2018-002	Scope of risk management activities/identification and description of device/ applicable life-cycles	P
3.4b	—	Risk management plan GT-RMPLAN2018-002	Assignment of responsibilities and authorities	P
3.4c	—	Risk management plan GT-RMPLAN2018-002	Requirement for review of risk management activities	P
3.4d	—	Risk management plan GT-RMPLAN2018-002	Criteria for risk acceptability	P
3.4e	—	Risk management plan GT-RMPLAN2018-002	verification activities	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
3.5	—	Risk management plan GT-RMPLAN2018-002	RMF	P
4.1	—	Risk management procedure GTQPR05000 A2.CL.5.0	Documents produced during clause 4.2 and 4.4 shall include: -Identification/description of the device -Identification of the persons involved in the risk analysis -Scope and date of the risk analysis	P
4.2	—	Risk Management Report GT-RM2018-002 CL.6.1	Identification of characteristics	P
4.3	—	Risk Management Report GT-RM2018-002 CL.6.2	Hazard identification	P
4.4	—	Risk Management Report GT-RM2018-002 CL.6.4	Risk estimation	P
5	—	Risk Management Report GT-RM2018-002 CL.7	Risk evaluation	P
6.2	—	Risk Management Report GT-RM2018-002 CL.8.1	Risk control options	P
6.3	—	Risk Management Report GT-RM2018-002 CL.8.1	Implementation/effectiveness of risk control	P
6.4	—	Risk Management Report GT-RM2018-002 CL.8.2	Residual risk evaluation	P
6.5	—	GT-RM2018-002 CL.8.3	Risk/Benefit analysis	P
6.6a	—	Risk Management Report GT-RM2018-002 CL.8.1	Introduction of new risks due to risk control	P

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Clause	Requirement + Test		Result - Remark	Verdict
4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
6.6b	—	Risk Management Report GT-RM2018-002 CL.8.2	Estimation of previously risk due to risk control	P
6.7	—	Risk Management Report GT-RM2018-002 CL.8.1	Completeness of risk control	P
7	—	Risk Management Report GT-RM2018-002 CL.10	Overall residual risk evaluation	P
8	—	GT-RM2018-002 A2	Risk management report	P
Supplementary Information: Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.				

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Clause	Requirement + Test	Result - Remark	Verdict

4.3	TABLE: ESSENTIAL PERFORMANCE		N/A
List of ESSENTIAL PERFORMANCE functions	MANUFACTURER’S document number reference or reference from this standard or collateral or particular standard(s)	Remarks	
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.			

4.11	TABLE: Power Input					p
Operating Conditions / Ratings		Voltage (V)	Frequency (Hz)	Current (A)	Power (VA)	Power factor (cos ϕ)
Model: GTM86100-1005-W2E-USB						
Normal condition		85	50	0.248	21.1	<0.9
Normal condition		85	60	0.262	22.3	<0.9
Normal condition		100	50	0.227	22.7	<0.9
Normal condition		100	60	0.243	24.3	<0.9
Normal condition		240	50	0.126	30.2	<0.9
Normal condition		240	60	0.133	31.9	<0.9
Normal condition		264	50	0.120	31.7	<0.9
Normal condition		264	60	0.125	33.0	<0.9
Model: GTM86100-1005.2-W2E-USB						
Normal condition		85	50	0.247	21.0	<0.9
Normal condition		85	60	0.251	21.3	<0.9
Normal condition		100	50	0.229	22.9	<0.9
Normal condition		100	60	0.231	23.1	<0.9
Normal condition		240	50	0.126	30.2	<0.9
Normal condition		240	60	0.128	30.7	<0.9
Normal condition		264	50	0.118	31.2	<0.9
Normal condition		264	60	0.120	31.7	<0.9
Model: GTM86100-1005-W2C						
Normal condition		85	50	0.244	20.7	<0.9
Normal condition		85	60	0.244	20.7	<0.9
Normal condition		100	50	0.220	22.0	<0.9
Normal condition		100	60	0.222	22.2	<0.9
Normal condition		240	50	0.122	29.3	<0.9
Normal condition		240	60	0.120	28.8	<0.9
Normal condition		264	50	0.116	30.6	<0.9

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

4.11	TABLE: Power Input					p
Operating Conditions / Ratings		Voltage (V)	Frequency (Hz)	Current (A)	Power (VA)	Power factor (cos ϕ)
Normal condition		264	60	0.114	30.1	<0.9
Model: GTM86100-1005.2-W2C						
Normal condition		85	50	0.243	20.1	<0.9
Normal condition		85	60	0.246	20.9	<0.9
Normal condition		100	50	0.219	21.9	<0.9
Normal condition		100	60	0.225	22.5	<0.9
Normal condition		240	50	0.123	29.5	<0.9
Normal condition		240	60	0.122	29.3	<0.9
Normal condition		264	50	0.114	30.1	<0.9
Normal condition		264	60	0.116	42.2	<0.9
Supplementary Information:						

5.9.2	TABLE: Determination of ACCESSIBLE parts		P
Location	Determination method (NOTE1)	Comments	
Enclosure	Test finger, test hook	Can't insert	
Supplementary information:			
1) NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.			

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Clause	Requirement + Test	Result - Remark	Verdict

7.1.2	TABLE: Legibility of Marking		P
Markings tested		Ambient Illuminance (lx)	Remarks
Outside Markings (Clause 7.2)		100-1500	Readable
Inside Markings (Clause 7.3)		100-1500	Readable
Controls & Instruments (Clause 7.4)		100-1500	Readable
Safety Signs (Clause 7.5)		100-1500	Readable
Symbols (Clause 7.6)		100-1500	Readable
Supplementary information: Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance 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 or if not defined 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	PET		
Ink/other printing material or process	Heat transfer print		
Material (composition) of Warning Label	PET		
Ink/other printing material or process	Heat transfer print		
Other	--		
Marking Label Tested:		Remarks	
Marking plate		Clearly legible and not work loose or become curled at the edges.	
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 soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.			

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					P
Test supply voltage/frequency (V/Hz) ¹⁾						264V/50Hz
Location From/To	Measured values					Remarks
	Vrms	Vpk or Vdc	Peak-to-peak ripple ²⁾	Power W/VA	Energy (J)	
Transformer, primary to secondary	Max. 412Vrms	--	--	--	--	GTM86100-1005-W2E-USB
Transformer, primary to secondary	Max. 420Vrms	--	--	--	--	GTM86100-1005-W2C
Supplementary Information:						
¹⁾ The input supply voltage to the ME EQUIPMENT was 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						

8.4.3	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	<1	<1	<1	<1	<1	<1	<1	<1	<1	<1
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	--	--	--	--	--	--	--	--	--	--
Plug pin 1 and enclosure	--	--	--	--	--	--	--	--	--	--
Plug pin 2 and enclosure	--	--	--	--	--	--	--	--	--	--

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Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

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:			

8.5.5.1a	TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies				N/A
Test Condition: Figs. 9 & 10	Measurement made on accessible part	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
Supplementary information:					

8.5.5.1b	TABLE: defibrillation-proof applied parts – verification of recovery time				N/A
Applied part with test voltage	Test voltage polarity	Recovery time from documents (s)	Measured recovery time (s)	Remarks	
Supplementary information:					

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Clause	Requirement + Test	Result - Remark	Verdict

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
Test Voltage applied to		Measured Energy E1 (mJ)	Measured Energy E2 (mJ)	Energy E1 as % of E2 (%)
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth				
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth				
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth				
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth				
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 Ω with ME Equipment connected; E2= Measured energy delivered to 100 Ω without ME equipment connected.				

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 (m Ω)	Maximum allowable impedance (m Ω)
Supplementary information: PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 m Ω ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 m Ω ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 m Ω ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 m Ω					

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Clause	Requirement + Test	Result - Remark	Verdict

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
N/A				
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 μA NC; 500 μA SFC
Measured with a frequency-weighted device	—	—	—	—
NC, S1=1, S5=N	264	60	3.7	Before humidity
NC, S1=1, S5=R	264	60	3.3	Before humidity
SFC, S1=0, S5=N	264	60	3.8	Before humidity
SFC, S1=0, S5=R	264	60	3.5	Before humidity
NC, S1=1, S5=N	264	60	3.7	After humidity
NC, S1=1, S5=R	264	60	3.4	After humidity
SFC, S1=0, S5=N	264	60	3.9	After humidity
SFC, S1=0, S5=R	264	60	3.6	After humidity
Measured with a non-frequency-weighted device	—	—	—	—
NC, S1=1, S5=N	264	60	10.7	Before humidity
NC, S1=1, S5=R	264	60	10.3	Before humidity
SFC, S1=0, S5=N	264	60	10.8	Before humidity
SFC, S1=0, S5=R	264	60	10.5	Before humidity
NC, S1=1, S5=N	264	60	10.7	After humidity
NC, S1=1, S5=R	264	60	10.4	After humidity
SFC, S1=0, S5=N	264	60	10.9	After humidity
SFC, S1=0, S5=R	264	60	10.6	After humidity
Fig. 15 - Patient Leakage Current (P)	—	—	—	Maximum allowed values: Type B or BF AP: 10 μA NC; 50 μA SFC (d.c. current); 100 μA NC; 500 μA SFC (a.c.) Type CF AP: 10 μA NC; 50 μA SFC (d.c. or a.c. current)
N/A				
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 μA Type CF AP: 50 μA
N/A				
Fig. 17 - Patient leakage current with	—	—	—	Maximum allowed values:

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Clause	Requirement + Test		Result - Remark	Verdict
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
external voltage on Signal Input/Output part (SIP/SOP)				Type B or BF AP: 10 μA NC; 50 μA SFC(d.c. current); 100 μA NC; 500 μA SFC (a.c.) ; Type CF AP: 10 μA NC; 50 μA SFC (d.c. or a.c. current)
N/A				
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 μA Type CF: N/A
N/A				
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 μA NC; 50 μA SFC (d.c. current); 100 μA NC; 500 μA SFC (a.c.) ; Type CF AP: 10 μA NC; 50 μA SFC (d.c. or a.c. current)
N/A				
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 μA NC; 100μA SFC (d.c. current); 500 μA NC; 1000 μA SFC (a.c.); Type CF AP: 50 μA NC; 100 μA SFC (d.c. or a.c. current)
N/A				
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 μA NC; 100μA SFC (d.c. current); 500 μA NC; 1000 μA SFC (a.c.); Type CF AP: 50 μA NC; 100 μA SFC (d.c. or a.c. current)
N/A				
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 μA Type CF: 100 μA
N/A				
Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 μA Type CF: N/A
N/A				
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
N/A				
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;				

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Clause	Requirement + Test	Result - Remark	Verdict

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
<p>Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7</p> <p>Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.</p> <p>Note 5: 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).</p>				
ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device			A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition	

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Clause	Requirement + Test	Result - Remark	Verdict

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 (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s ¹⁾	Dielectric breakdown after 1 minute Yes/No ²⁾
		PEAK WORKING VOLTAGE (U) V _{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
A	1MOOP	340	--	1500	No breakdown
B	2 MOPP	340	--	4000	No breakdown
C	2 MOPP	340	--	4000	No breakdown
D	2 MOPP	--	Max. 48	1000	No breakdown
E	2 MOPP	352	--	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		125	1.3
Bobin of transformer		125	1.0
Supplementary information:			

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

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: ¹⁾ Note: 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
Part Test	8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7	Dielectric test voltage	Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No	Crack or voids in the insulating compound: Yes/No
	68 h at $T1 \pm 2\text{ }^{\circ}\text{C} = \text{ }^{\circ}\text{C}^{\text{1)}$			
	1 h at $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$			
	2 h at $0\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$			
	1 or more h at $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$			
Supplementary information: ¹⁾ T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.				

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Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.3	Table: Thermal cycling tests on one sample of cemented joint with other insulating parts (see 8.9.3.3)			N/A
Part tested	Sample	Each test duration and temperature	Dielectric test voltage	Dielectric strength test Breakdown: Yes/No
	1	10 Cycles conducted of the following:		
		1 - 68 h at $T1 \pm 2\text{ }^{\circ}\text{C} = \text{ ______ }^{\circ}\text{C}^1$		
		2 - 1 h at $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$		
		3 - 2 h at $0\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$		
		4 - 1 or more h at $25\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$		
	2	Humidity Conditioning per 5.7		
	3	Humidity Conditioning per 5.7		
Supplementary information:				
1) T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C 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

8.10	TABLE: List of critical components				
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity ¹⁾
Enclosure (all parts)	SABIC JAPAN L L C	SE1X	PPE+PS, Min. V-1, Min. thickness: 1.5mm, 105°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	SABIC JAPAN L L C	SE100	PPHOX, Min. V-1, Min. thickness: 1.5mm, 80°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	SABIC JAPAN L L C	940	PC, Min. V-0, Min. thickness: 1.5mm, 120°C	IEC 60601-1UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	SABIC JAPAN L L C	CX7211	PC/ABS, Min. V-1, Min. thickness: 1.5mm, 90°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	SABIC JAPAN L L C	C2950	PC/ABS, Min. V-0, Min. thickness: 1.5mm, 75°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	SABIC JAPAN L L C	925U	PC, Min. V-0, Min. thickness: 1.5mm, 115°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	SABIC JAPAN L L C	945	PC, Min. V-0, Min. thickness: 1.5mm, 120°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	SABIC JAPAN L L C	CH6410	PC/ABS, V-0, Min. thickness: 1.5mm, 100°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	SABIC JAPAN L L C	EXCY0098	PC/ABS, V-0, Min. thickness: 1.5mm, 100°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	ASAHI KASEI CORPORATION	540V	m-PPE, V-1, Min. thickness: 1.5mm, 100°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance E82268
-Alt. use	COVESTRO DEUTSCHLAND	FR6005	PC, Min. V-0, Min. thickness:	IEC 60601-1	Tested with appliance

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Clause	Requirement + Test		Result - Remark		Verdict
	AG [PC RESINS]		1.5mm, 105°C	UL 94 UL 746 A/B/C/D	UL E41613
-Alt. use	COVESTRO DEUTSCHLAND AG [PC RESINS]	6485	PC, Min. V-0, Min. thickness: 1.5mm, 115°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E41613
-Alt. use	IDEMITSU KOSAN CO LTD	AZ2201	PC, Min. V-0, Min. thickness: 1.5mm, 125°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E48268
European plug	GlobTek	EU	2.5A, 250VAC	EN 50075	TÜV Rheinland (J 2156136)
Australia plug	GlobTek	AU	10A, 250VAC	AS/NZS 3112	Intertek test report: 180501604SHA- 001
America plug	GlobTek	US	15A, 125VAC	UL 498	Intertek test report: 171001667SHA- 001
Plug holder	SABIC Japan L L C	SE1X	PPE+PS, Min. V-1, Min. thickness: 1.5mm, 105°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	SABIC JAPAN L L C	945	PC, Min. V-0, Min. thickness: 1.5mm, 120°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E207780
-Alt. use	NAN YA PLASTICS CORP PLASTICS 3RD DIV	6410G5	PA66, V-0, 130°C	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E130155
PCB	Shenzhen Wuzhu Tech Co Ltd	WZ-4	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E170968
-Alt. use	WALEX ELECTRONIC(WU XI)CO LTD	T2, T2A, T2B, T4	Min. V-0, 130° C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E154355
-Alt. use	DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1, 2V0, FR4	Min. V-0, 130° C	Applicable parts of IEC 60601-1, UL94,	Tested with appliance UL E243157

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Clause	Requirement + Test		Result - Remark		Verdict
				UL 796	
-Alt. use	Huizhou Shunjia Electronics Co Ltd	SJ-B	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E320884
-Alt. use	Cheerful Electronics(HK)Ltd	02,03,03A	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E199724
-Alt. use	Dongguan Daysun Electronic Co Ltd	DS2	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E251754
-Alt. use	Suzhou City Yilihua Electronics Co Ltd	YLH-1	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E251781
-Alt. use	DAFENG AREX ELECTRONICS TECHNOLOGY CO LTD	02V0, 04V0, 03V0	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E186016
-Alt. use	BRITE PLUS ELECTRONICS(SUZHOU)CO LTD	DKV0-3A, DGV0-3A	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E177671
-Alt. use	KUOTIANG ENT LTD	C-2, C-2A	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E227299
-Alt. use	SHENZHEN TONGCHUANXIN ELECTRONICS CO LTD	TCX	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E250336
-Alt. use	PACIFIC WIN INDUSTRIAL LTD	PW-02, PW-03	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E228070
-Alt. use	YUANMAN PRINTED CIRCUIT CO LTD	1V0	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E74757
-Alt. use	SUZHOU XINKE ELECTRONICS	XK-2, XK-3	Min. V-0, 130°C	Applicable	Tested with

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Clause	Requirement + Test		Result - Remark		Verdict
	CO LTD			parts of IEC 60601-1, UL94, UL 796	appliance UL E231590
-Alt. use	KUNSHAN CITY HUA SHENG CIRCUIT BOARD CO LTD	HS-S	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E229877
-Alt. use	JIANGSU DIFEIDA ELECTRONICS CO LTD	DFD-1	Min. V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E213009
-Alt. use	SHANGHAI H-FAST ELECTRONIC CO LTD	211001, 411001	Min.V-0, 130°C	Applicable parts of IEC 60601-1, UL94, UL 796	Tested with appliance UL E337862
Current fuse (F1)	LITTELFUSE WICKMANN WERKE	392	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 126983 UL E67006
-Alt. use	Ever Island Electric Co., Ltd. & Walter Electric	2010 series	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40018781 UL E220181
-Alt. use	Shenzhen Lanson Electronics Co. Ltd.	SMT	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40012592 UL E221465
-Alt. use	Conquer Electronics Co., Ltd.	MST	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40017157 UL E82636
-Alt. use	Cooper Bussmann LLC	SS-5	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40015513 UL E19180
-Alt. use	Bel Fuse Ltd.	RST-Serie(s)	T1A or 2A, 250V	IEC 60127-1 IEC 60127-3	VDE 40011144

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
			sub-miniature fuse	UL 248-1 UL 248-14	UL E20624
-Alt. use	SMART ELECTRONICS INC	SPT	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40014285 UL E238986
-Alt. use	SUNNY EAST ENTERPRISE CO LTD	TSP series	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40027173 UL E133774
-Alt. use	Conquer Electronics Co., Ltd.	PTU	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40017157 UL E82636
-Alt. use	Littelfuse Inc	877	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40023242 UL E10480
-Alt. use	NIPPON SEISEN CABLE LTD	SLT	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40013103 UL E120786
-Alt. use	Walter Electronic Co. Ltd.	ICP	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40012824 UL E56092
-Alt. use	XC ELECTRONICS (SHENZHEN) CORP LTD	5TE	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40029550 UL E249609
-Alt. use	XC ELECTRONICS (SHENZHEN) CORP LTD	4T series	T1A or 2A, 250V sub-miniature fuse	IEC 60127-1 IEC 60127-3 UL 248-1 UL 248-14	VDE 40029295 UL E249609
Resistor Fuse(RT1) (For Model: GT*86100-**-W2*-USB	Anhui Changsheng Electronics Co., Ltd	RXF21-2W	3.3ohm,2W	IEC 60065:2015; IEC 60065:2014	VDE40024768

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Clause	Requirement + Test	Result - Remark	Verdict

only)					
-Alt. use	Shenzhen Great Electronics Co. Ltd.	RXF	3.3ohm,2W	IEC 60065:2015; IEC 60065:2014	VDE 40026608
-Alt. use	Shenzhen Kayocota Electronics Co., Ltd	FRKNP	3.3ohm,2W	IEC 60065:2015; IEC 60065:2014	VDE 40043957
-Alt. use	Jiang Su Xin Yang Electronic Element Co.,Ltd	RF10	3.3ohm,2W	IEC 60065:2015; IEC 60065:2014	Tested with appliance
-Alt. use	TZAI YUAN Enterprise Co., Ltd	KNF	3.3ohm,2W	IEC 60065:2015; IEC 60065:2014	VDE 40035589
-Alt. use	ChienTung Electronics Co.,Ltd	FKN	3.3ohm,2W	IEC 60065:2015; IEC 60065:2014	Tested with appliance
-Alt. use	HuaSheng Electronics Co.,Ltd	FKN	3.3ohm,2W	IEC 60065:2015; IEC 60065:2014	Tested with appliance
Y capacitor (CY1, CY2) (Optional)	TDK-EPC Corporation, Capacitors Group Circuit Devices Business Group	CD	Y1, AC250V, max 2200pF, 25/085/21/B	IEC 60384-14 UL 60384-14 UL 1414	VDE 40029780 UL E37861
-Alt. use	Murata Mfg. Co., Ltd.	KX	Y1, AC250V, max 2200pF, 25/125/21/B	IEC 60384-14 UL 60384-14 UL 1414	VDE 40002831 UL E37921
-Alt. use	Success Electronics Co., Ltd.	SE	Y1, AC250V, max 2200pF, 30/125/56/C	IEC 60384-14 UL 60384-14 UL 1414	VDE 40037211 UL E114280
-Alt. use	Success Electronics Co., Ltd.	SB	Y1, AC250V, max 2200pF, 30/125/56/C	IEC 60384-14 UL 60384-14 UL 1414	VDE 40037221 UL E114280
-Alt. use	JYA-NAY Co., Ltd.	JN	Y1, AC250V, max 2200pF, 30/125/56/C	IEC 60384-14 UL 60384-14 UL 1414	VDE 40001831 UL E201384
-Alt. use	WELSON INDUSTRIAL CO LT D	WD	Y1, AC250V, max 2200pF, 30/125/56/C	IEC 60384-14 UL 60384-14 UL 1414	VDE 40016157 UL E104572
-Alt. use	SAMWHA	SD	Y1, AC250V,	IEC 60384-14	VDE 40015804

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Clause	Requirement + Test		Result - Remark		Verdict
	CAPACITOR CO LTD		max 2200pF, 30/125/56/C	UL 60384-14 UL 1414	UL E97754
-Alt. use	NAN JING YUYUE ELECTRONICS CO LTD	CT7	Y1, AC250V, max 2200pF, 30/125/56/C	IEC 60384-14 UL 60384-14 UL 1414	VDE 40008010 UL E237728
-Alt. use	YINAN DON'S ELECTRONIC COMPONENT CO LTD	CT81	Y1, AC250V, max 2200pF, 30/125/56/C	IEC 60384-14 UL 60384-14 UL 1414	VDE 135256 UL E145038
-Alt. use	JYH CHUNG ELECTRONICS CO LTD	JD	Y1, AC400V, max 2200pF, 30/125/56/C	IEC 60384-14 UL 60384-14 UL 1414	VDE 137027 UL E187963
-Alt. use	JYH CHUNG ELECTRONICS CO LTD.	JY	Y2, AC300V, max 2200pF, 30/125/56/C	IEC 60384-14 UL 60384-14 UL 1414	VDE 137027 UL E187963
Transformer (T1)	GlobTek / Dee Van Enterprise Co., Ltd./ BOAM/HAOPUW EI	90E10PFX0-xxxx for Model: GT*86100-**-W2*-USB only; 90E10PF02-xxxx for Model: GT*86100-**-W2* only ("xxxx" to denote the part number, can be any alphanumeric character for marketing purposes only.	Class B, with critical component listed below	IEC 60601-1	Tested with appliance
-Insulation system used in T1	GlobTek	GTX-130-TM	Class B	IEC 60601-1	UL E243347
-Alt. use	Haopuwei	GTX-130-TM	Class B	IEC 60601-1	UL E315275
-Alt. use	Haopuwei	ZT-130	Class B	IEC 60601-1	UL E315275
-Alt. use	BOAM	BOAM-01	Class B	IEC 60601-1	UL E252329
-Alt. use	BOAM	B01	Class B	IEC 60601-1	UL E252329
-Alt. use	Dee Van	YCI-130	Class B	IEC 60601-1	UL E159480
-Bobbin	HITACHI CHEMICAL CO LTD	CP-J-8800	V-0, 150°C, thickness 0,45 mm min.	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E42956

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
- Alt. use	SUMITOMO BAKELITE CO LTD	PM-9820	V-0, 150°C, thickness 0,45 mm min.	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E41429
- Alt. use	SUMITOMO BAKELITE CO LTD	PM-9630	V-0, 150°C, thickness 0,45 mm min.	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E41429
- Alt. use	CHANG CHUN PLASTICS CO LTD	T375J	V-0, 140°C, thickness 0,74 mm min.	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E59481
- Alt. use	CHANG CHUN PLASTICS CO LTD	T373J	V-0, 150°C, thickness 0,45 mm min.	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E59481
- Alt. use	CHANG CHUN PLASTICS CO LTD	T375HF	V-0, 150°C, thickness 0,45 mm min.	IEC 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E59481
- Magnet wire	HUIZHOU GOLDEN OCEAN MAGNET WIRE FACTORY	UEW-X	130°C	IEC 60601-1 UL1446	Tested with appliance UL E225143
-Alt. use	SHENZHEN DAYANG INDUSTRY CO LTD	UEW	130°C	IEC 60601-1 UL1446	Tested with appliance UL E176101
-Alt. use	WA TAI ELECTROTECHNI CAL MATERIALS FACTORY LTD	UEW	130°C	IEC 60601-1 UL1446	Tested with appliance UL E243939
-Alt. use	FENG CHING METAL CORP	UEW	130°C	IEC 60601-1 UL1446	Tested with appliance UL E172395
-Alt. use	TAI-I COPPER (GUANZHOU) CO LTD	UEW	130°C	IEC 60601-1 UL1446	Tested with appliance UL E234896
-Triple- insulated wire (Secondary)	Furukawa Electric Co., Ltd.	TEX-E	Class B, reinforced insulation	IEC 60601-1 UL 2353	VDE 006735 UL E206440
- Alt. use	SUZHOU YUSHENG ELECTRONIC CO LTD	TIW-B, TWE-3	Class B, reinforced insulation	IEC 60601-1 UL 2353	VDE 40033527 UL E332529

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Clause	Requirement + Test	Result - Remark	Verdict

- Alt. use	DAH JIN TECHNOLOGY CO LTD	TLW-B	Class B, reinforced insulation	IEC 60601-1 UL 2353	VDE 40019324 UL E236542
- Alt. use	Furukawa Electric Co., Ltd.	TEX-E	Class B, reinforced insulation	IEC 60601-1 UL 2353	VDE 006735 UL E206440
- Alt. use	COSMOLINK CO. Ltd.	TIW-M	Class B, reinforced insulation	IEC 60601-1 UL 2353	VDE 138053 UL E213764
- Alt. use	YOUNG CHANG SILICONE CO LTD	STW-B	Class B, reinforced insulation	IEC 60601-1 UL 2353	VDE 40013359 UL E303298
- Alt. use	Great Leoflon Industrial Co., Ltd.	TRW (B) Serie(s)	Class B, reinforced insulation	IEC 60601-1 UL 2353	VDE 136581 UL E211989
- Alt. use	E&B TECHNOLOGY CO LTD	E&B-B-X.XX	Reinforced insulation, Class B	IEC 60601-1 UL 2353	VDE 40023473 UL E315265
- Alt. use	DONGGUAN KOSHEN INSULATOR CO LTD	TIW-B	Reinforced insulation, Class B	IEC 60601-1 UL 2353	Tested with appliance UL E365580
-Insulating tape	SYMBIO INC	35660/35661/35660Y	Min.130°C	IEC 60601-1 UL 510	Tested with appliance UL E50292
- Alt. use	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1, 1350T-1	Min.130°C	IEC 60601-1 UL 510	Tested with appliance UL E17385
- Alt. use	BONDTEC PACIFIC CO LTD	370S	Min.130°C	IEC 60601-1 UL 510	Tested with appliance UL E175868
- Alt. use	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ, CT, WF	Min.130°C	IEC 60601-1 UL 510	Tested with appliance UL E165111
- Alt. use	JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A	Min.130°C	IEC 60601-1 UL 510	Tested with appliance UL E246950
- Alt. use	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	Min.130°C	IEC 60601-1 UL 510	Tested with appliance UL E246820

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
-PTFE tubing	GREAT HOLDING INDUSTRIAL CO LTD	TFT / TFS	Min. 300V, 200°C	IEC 60601-1	Tested with appliance UL E156256
-Alt. use	SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD	WF	600V, 200°C	IEC 60601-1	Tested with appliance UL E203950
-Alt. use	CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-TT-T / CB-TT-S	Min. 300V, 200°C	IEC 60601-1	Tested with appliance UL E180908
-Alt. use	ZEUS	TFE-TW-300 or TFE-SW-600	Min.150V, 200°C	IEC 60601-1	Tested with appliance UL E64007
Varistor MOV1 (Optional)(For Model: GT*86100-**-W2* only)	CENTRA SCIENCE CORP	CNR-10D431-561K	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	IEC 61051-2 IEC 60950-1	VDE40008220 UL E316325
-Alt. use	CENTRA SCIENCE CORP	CNR-14D431-561K	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	IEC 61051-2 IEC 60950-1	VDE40008220 UL E316325
-Alt. use	Uppermost Electronic Industries Co Ltd	V10K300, V10K320, V10K350, V10K385, V14K300, V14K320, V14K350, V14K385	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	IEC 61051-2 IEC 60950-1	VDE 010108
-Alt. use	Jya-Nay Co Ltd	10D431-561K, 14D431-4561K	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	IEC 61051-2 IEC 60950-1	VDE 40023949
-Alt. use	Joyin Co Ltd	JVR10N431-56, JVR14N431-561K	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	IEC 61051-2 IEC 60950-1	VDE 005937
-Alt. use	Panasonic Corporation	10DK431-561U, 14DK431-561U	Min. 300Vac, min. 385Vdc,	IEC 61051-2 IEC 60950-1	VDE 005912

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
			fulfilled 6kV/3kA pulse test.		
-Alt. use	Thinking Electronic Industrial Co Ltd	TVR10431-561, TVR14431-561	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	IEC 61051-2 IEC 60950-1	VDE 005944
-Alt. use	Guangdong Fenghua Advanced Technology Holding Co Ltd. Xianhua New Sensitive Components Branch	FNR-10K431-561, FNR-14K431- 561	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	IEC 61051-2 IEC 60950-1	VDE 40008242
-Alt. use	Brightking (Shenzhen)Co Ltd	10D431-561K, 14D431-561K	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	EC 61051-2 IEC 60950-1	VDE 40027827
-Alt. use	Littelfuse Inc	V300-V385LA10P, V385LA20AP, V10E300P-385P, V14E300P-385P	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	EC 61051-2 IEC 60950-1	VDE 116895
-Alt. use	Guangxi New Future Information Industry Co Ltd	10D431-561K, 14D431-561K	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	IEC 61051-2 IEC 60950-1	VDE 40030322
-Alt. use	Walsin Technology Corp	VZ10D456K, VZ14D456K	Min.300Vac, Min.385Vdc	IEC 61051-2 IEC 60950-1	VDE 005932
-Alt. use	Success Electronics Co Ltd	SVR10D431K~56 1K SVR14D431K~56 1K	Min. 300Vac, min. 385Vdc, fulfilled 6kV/3kA pulse test.	IEC 609501 IEC 609501 Annex Q IEC 610512	VDE 123677
-Alt. use	Shantou Hongzhi Electronics Ltd	10D471K	Min310Vac, Min510Vdc	IEC 61051-1, IEC 61051-2, IEC 60950-1 2nd Annex Q	VDE 40037512
-Alt. use	BestBright Electronics Co.,Ltd.	10D471K	Min300Vac, Min470Vdc	IEC 61051-1, IEC 61051-2, IEC 60950-1 2nd Annex Q	VDE40027827

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Clause	Requirement + Test	Result - Remark	Verdict

-Alt. use	CeNtRa Science(Holdings)Ltd	10D471K	Min300Vac, Min470Vdc	IEC 61051-1, IEC 61051-2, IEC 60950-1 2nd Annex Q	VDE 40008220
-Alt. use	Huizhou Songlong Xindian Electronic Technology Co.,LTD	10D471K	Min300Vac, Min470Vdc	IEC 61051-1, IEC 61051-2, IEC 60950-1 2nd Annex Q	VDE40040037

Supplementary information:

1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

8.10 b	TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS				N/A
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity ¹⁾
Supplementary information: 1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

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Clause	Requirement + Test	Result - Remark	Verdict

8.11.3.5	TABLE: Cord anchorages				N/A
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:					

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.					

9.2.3.2	TABLE: Over-travel End Stop Test		N/A
ME EQUIPMENT end stop		Test Condition (cycles, load, speed)	Remarks
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

9.4.2.1	TABLE: Instability—overbalance in transport position		N/A
ME EQUIPMENT preparation	Test Condition (transport position)	Remarks	
Supplementary information:			

9.4.2.2	TABLE: Instability—overbalance excluding transport position		N/A
ME EQUIPMENT preparation	Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)	Remarks	
Supplementary information:			

9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces		N/A
ME EQUIPMENT preparation	Test Condition (force used, direction of force, weight of equipment, location of force)	Remarks	
Supplementary information:			

9.4.2.4.2	TABLE: Castors and wheels – Force for propulsion		N/A
ME EQUIPMENT preparation	Test Condition (force location and height)	Remarks	
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

9.4.2.4.3	TABLE: Castors and wheels – Movement over a threshold		N/A
ME EQUIPMENT preparation	Test Condition (speed of movement)	Remarks	
Supplementary information:			

9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position		N/A
ME EQUIPMENT Preparation	Test Condition (transport position, working load, locking device(s), caster position)	Remarks	
Supplementary information:			

9.4.3.2	TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position		N/A
ME EQUIPMENT Preparation	Test Condition (working load, locking device(s), caster position, force, force location, force direction)	Remarks	
Supplementary information:			

9.4.4	TABLE: Grips and other handling devices		N/A
Clause and Name of Test	Test Condition	Remarks	
Supplementary information:			

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Clause	Requirement + Test	Result - Remark	Verdict

9.7.5	TABLE: Pressure vessels					N/A
Hydraulic, Pneumatic or Suitable Media and Test Pressure	Vessel Burst	Permanent Deformation	Leaks	Vessel fluid substance	Remarks	
Supplementary Information:						

9.8.3.2	TABLE: PATIENT support/suspension system - Static forces				N/A
ME EQUIPMENT part or area	Position	Load	Area	Remarks	
Supplementary Information:					

9.8.3.3	TABLE: Support/Suspension System – Dynamic forces due to loading from persons				N/A
ME EQUIPMENT part or area	Position	Safe Working Load	Area	Remarks	
Supplementary Information:					

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Clause	Requirement + Test	Result - Remark	Verdict

10.1.1	TABLE: Measurement of X - radiation		N/A
Maximum allowable radiation pA/kg (μSv/h) (mR/h)		36 (5 μSv/h) (0.5 mR/h)	
Surface area under test Surface no./ Description¹⁾		Measured Radiation, pA/kg (μSv/h) (mR/h)	Remarks
1/ /			
2/ /			
3/ /			
4/ /			
5/ /			
6/ /			
7/ /			
8/ /			
9/ /			
10/ /			
Supplementary information: ¹⁾ Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access			

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

11.1.1		TABLE: Excessive temperatures in ME EQUIPMENT					P	
Model No.:		GTM86100-1005-W2E-USB	GTM86100-1005-W2E-USB	GTM86100-1005-W2C	GTM86100-1005-W2C			
Test ambient (°C)		40.0	40.0	40.0	40.0			
Test supply voltage/frequency (V/Hz) ⁴⁾ ..:		85V/60Hz	264V/60Hz	85V/60Hz	264V/60Hz			
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	
GTM86100-1005-W2E-USB 85V/60HZ								
	1	Enclosure Inside near Inlet Blade	125		64.3			
	2	PWB near Rectifier Bridge (BD1)	130		91.3			
	3	Choke (LF) Coil	120		87.2			
	4	Capacitor (C1) body near Transformer	105		85.5			
	5	Capacitor (C2) body near Transformer	105		89.3			
	6	Transformer (T1) Primary Winding	120		103.0			
	7	Transformer (T1) Secondary Winding	120		106.2			
	8	Transformer (T1) Core	Ref.		103.8			
	9	CY1 body near Transformer	125		98.9			
	10	CY2 body near Transformer	125		85.0			
	11	Capacitor (C7)	105		81.0			
	12	Capacitor (C8)	105		76.9			
	13	Enclosure Inside near Transformer (T1) Top	125		97.9			
	14	Enclosure Outside near Transformer (T1) Top	85		73.9			
	15	Output Cord	85		67.7			
	16	Ambient	--		40			
GTM86100-1005-W2E-USB 264V/60HZ								
	1	Enclosure Inside near Inlet Blade	125		57.9			

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Clause	Requirement + Test		Result - Remark		Verdict
	2	PWB near Rectifier Bridge (BD1)	130	80.5	
	3	Choke (LF) Coil	120	78.0	
	4	Capacitor (C1) body near Transformer	105	76.9	
	5	Capacitor (C2) body near Transformer	105	81.4	
	6	Transformer (T1) Primary Winding	120	94.6	
	7	Transformer (T1) Secondary Winding	120	102.4	
	8	Transformer (T1) Core	Ref.	99.7	
	9	CY1 body near Transformer	125	94.3	
	10	CY2 body near Transformer	125	81.0	
	11	Capacitor (C7)	105	78.5	
	12	Capacitor (C8)	105	75.8	
	13	Enclosure Inside near Transformer (T1) Top	125	92.8	
	14	Enclosure Outside near Transformer (T1) Top	71	67.8	
	15	Output Cord	85	71.8	
	16	Ambient	--	40	
GTM86100-1005-W2C 85V/60HZ					
	1	Enclosure Inside near Inlet Blade	125	64.7	
	2	PWB near Rectifier Bridge (BD1)	130	87.8	
	3	Choke (LF) Coil	120	99.1	
	4	Capacitor (C1) body near Transformer	105	84.3	
	5	Capacitor (C2) body near Transformer	105	91.5	
	6	Transformer (T1) Primary Winding	120	91.2	
	7	Transformer (T1) Secondary Winding	120	92.1	
	8	Transformer (T1) Core	Ref.	92.0	
	9	CY1 body near Transformer	125	80.7	
	10	CY2 body near Transformer	125	69.0	

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Clause	Requirement + Test		Result - Remark		Verdict
	11	Capacitor (C7)	105	80.1	
	12	Capacitor (C8)	105	67.2	
	13	Enclosure Inside near Transformer (T1) Top	125	61.9	
	14	Enclosure Outside near Transformer (T1) Top	71	61.1	
	15	Output Cord	85	59.2	
	16	Ambient	--	40	
GTM86100-1005-W2C 264V/60HZ					
	1	Enclosure Inside near Inlet Blade	125	53.9	
	2	PWB near Rectifier Bridge (BD1)	130	64.6	
	3	Choke (LF) Coil	120	68.4	
	4	Capacitor (C1) body near Transformer	105	66.3	
	5	Capacitor (C2) body near Transformer	105	79.8	
	6	Transformer (T1) Primary Winding	120	86.2	
	7	Transformer (T1) Secondary Winding	120	91.4	
	8	Transformer (T1) Core	Ref.	86.5	
	9	CY1 body near Transformer	125	76.3	
	10	CY2 body near Transformer	125	67.3	
	11	Capacitor (C7)	105	79.3	
	12	Capacitor (C8)	105	66.4	
	13	Enclosure Inside near Transformer (T1) Top	125	62.5	
	14	Enclosure Outside near Transformer (T1) Top	71	59.2	
	15	Output Cord	85	58.1	
	16	Ambient	--	40	

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

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.

Information from Risk Management, as applicable:

11.1.3d	TABLE: Temperature of windings by change-of-resistance method							N/A
Temperature T of winding:	t ₁ (°C)	R ₁ (Ω)	t ₂ (°C)	R ₂ (Ω)	T (°C)	Allowed T _{max} (°C)	Insulation class	
Supplementary information:								

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

11.2.2.1	TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source		N/A
Areas where sparking might cause ignition:		Remarks	
1.			
2.			
3.			
4.			
5.			
6.			
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):		Remarks	
1.			
2.			
3.			
4.			
5.			
6.			
Test parameters selected representing worst case conditions for ME EQUIPMENT:		Remarks	
Oxygen concentration (%)			
Fuel.....			
Current (A).....			
Voltage (V).....			
Capacitance (μF)			
Inductance or resistance (h or Ω)			
No. of trials (300 Min)			
Sparks resulted in ignition (Yes/No) :			
Supplementary information: Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur. Information from Risk Management, as applicable:			

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

11.6.1	TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances		N/A
Clause / Test Name	Test Condition	Part under test	Remarks
Supplementary information:			
Information from Risk Management, as applicable:			

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:				

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

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 Cl. 8.1:	—	—
	GTM86100-1005-W2E-USB		
	C1 short-circuited	Fuse opened immediately no hazard	No
	C2 short-circuited	Fuse opened immediately no hazard	No
	R6 short-circuited	Unit work normally no hazard	No
	R3 short-circuited	Unit shutdown immediately recoverable no hazard	No
	D5 short-circuited	Unit work normally no hazard	No
	D6 short-circuited	Unit shutdown immediately recoverable no hazard	No
	R4 short-circuited	Fuse opened immediately no hazard	No
	R11 short-circuited	Unit shutdown immediately recoverable no hazard	No
	R13 short-circuited	Unit work normally no hazard	No
	R16 short-circuited	Unit shutdown immediately recoverable no hazard	No
	D8 short-circuited	Unit shutdown immediately recoverable no hazard	No
	C9 short-circuited	Unit work normally no hazard	No
	GTM86100-1005-W2C		
	C1 short-circuited	Fuse opened immediately no hazard	No
	C2 short-circuited	Fuse opened immediately no hazard	No
	R6 short-circuited	Unit work normally no hazard	No
	R3 short-circuited	Unit shutdown immediately recoverable no hazard	No
	D1 short-circuited	Unit work normally no hazard	No

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	R8 short-circuited	Fuse opened immediately no hazard	No
	R9 short-circuited	Unit shutdown immediately recoverable no hazard	No
	R12 short-circuited	Unit shutdown immediately recoverable no hazard	No
13.2.3	Overheating of transformers per Clause 15.5:	—	—
		See 15.5	No
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 thermostats 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	N/A
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
		No liquid	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:	—	—

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
		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:	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT started from COLD CONDITION at RATED voltage or 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
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
		Component, to be determined as part of end product.	N/A
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 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. Information from Risk Management, as applicable:			

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	No damage.	
15.3.4.1	Drop Test (hand-held)	Free fall height (m) =	N/A	
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5	No damage.	
15.3.5	Rough handling test	Travel speed (m/s) =	N/A	
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 90	No damage.	

Supplementary information: ¹⁾ As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows or state N/A in Remarks field).

15.4.6	TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests				N/A
Rotating control under test	Gripping diameter “d” of control knob (mm) ¹⁾	Torque from Table 30 (Nm)	Axial force applied (N)	Unacceptable RISK occurred Yes/No	Remarks

Supplementary information: ¹⁾ Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

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

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⁾ ... :				264	—		
RATED input frequency (Hz) :				60	—		
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 (°C)	Maximum winding temp measured (°C)	Ambient (°C)
90E10PFX 0-xxxx for Model: GT*86100-**-W2*-USB only; 90E10PF0 2-xxxx for Model: GT*86100-**-W2* only ("xxxx" to denote the part number, can be any alphanumeric character for marketing purposes only.	B	Fuse 1A	No	10 min	165 ²⁾	88	24
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 by 10 °C.							

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

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⁾					264
RATED input frequency (Hz)					60
Test current just below minimum current that would activate protective device and 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 (°C)	Maximum winding temp measured (°C)	Ambient (°C)
90E10PFX0-xxxx for Model: GT*86100-**-W2*-USB only; 90E10PF02-xxxx for Model: GT*86100-**-W2* only (“xxxx” to denote the part number, can be any alphanumeric character for marketing purposes only.	B	Fuse 1A (OL current 2.34)	165 ²	84	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 by10 °C.					

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				N/A
Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No

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Clause	Requirement + Test		Result - Remark		Verdict
	Primary & secondary windings				
	Secondary winding & core				
	Primary winding				
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					

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS				N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (μA)	Measured TOUCH CURRENT in NORMAL CONDITION (μA)	Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (μA)	Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (μA)	
	100		500		
	100		500		
	100		500		
	100		500		
	100		500		
Supplementary information:					

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

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Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT Photo of EUT

Photo 1: External view of EUT (GTM86100-1005-W2E-USB)

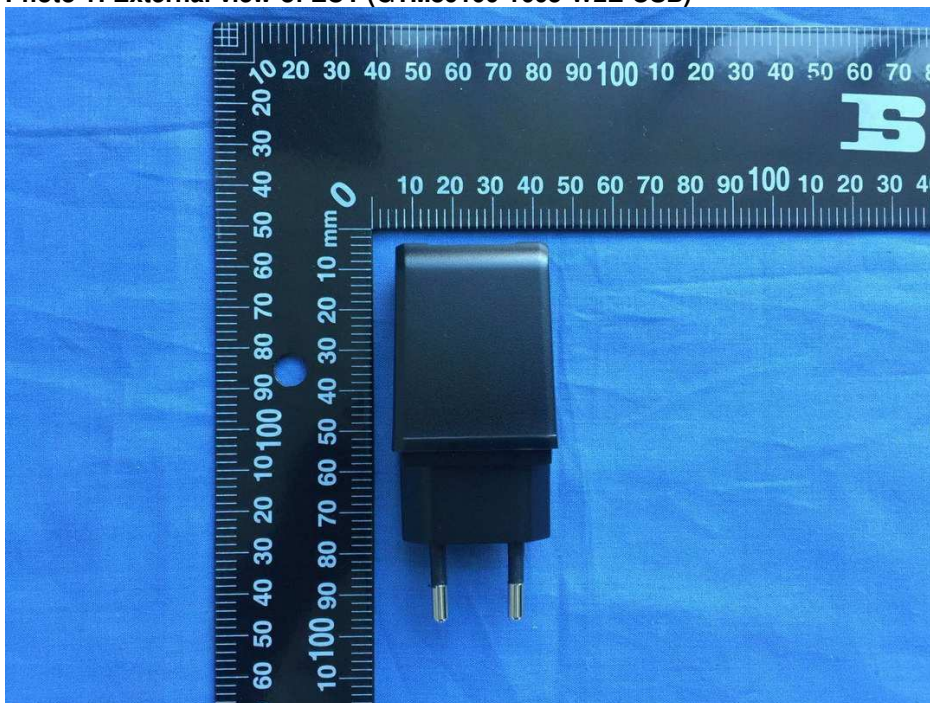


Photo 2: External view of EUT (GTM86100-1005-W2E-USB)



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Clause	Requirement + Test	Result - Remark	Verdict

Photo 3: External view of EUT (GTM86100-1005-W2E-USB)

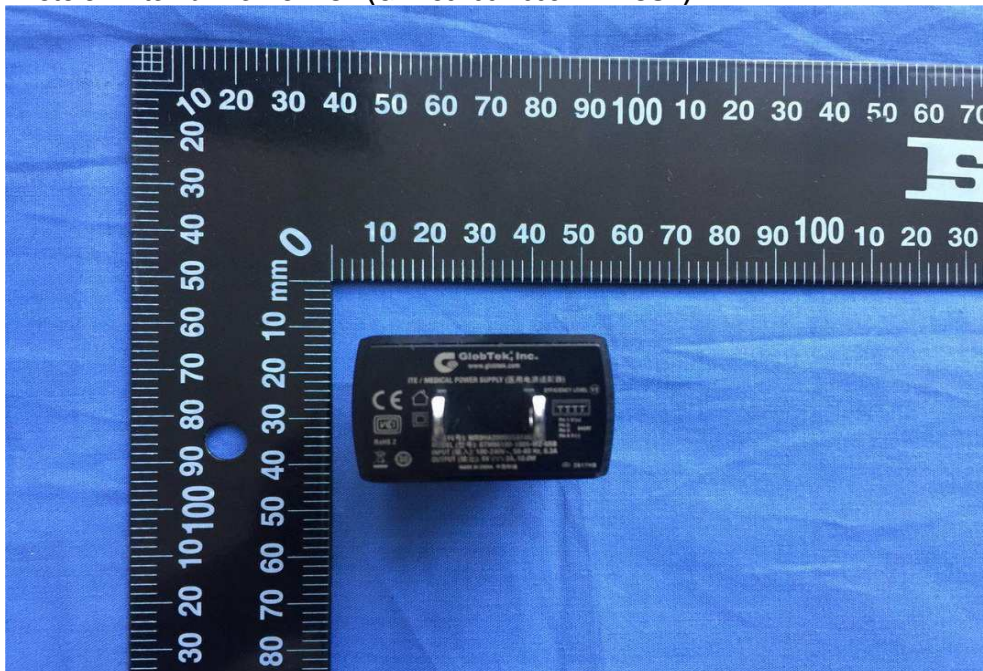
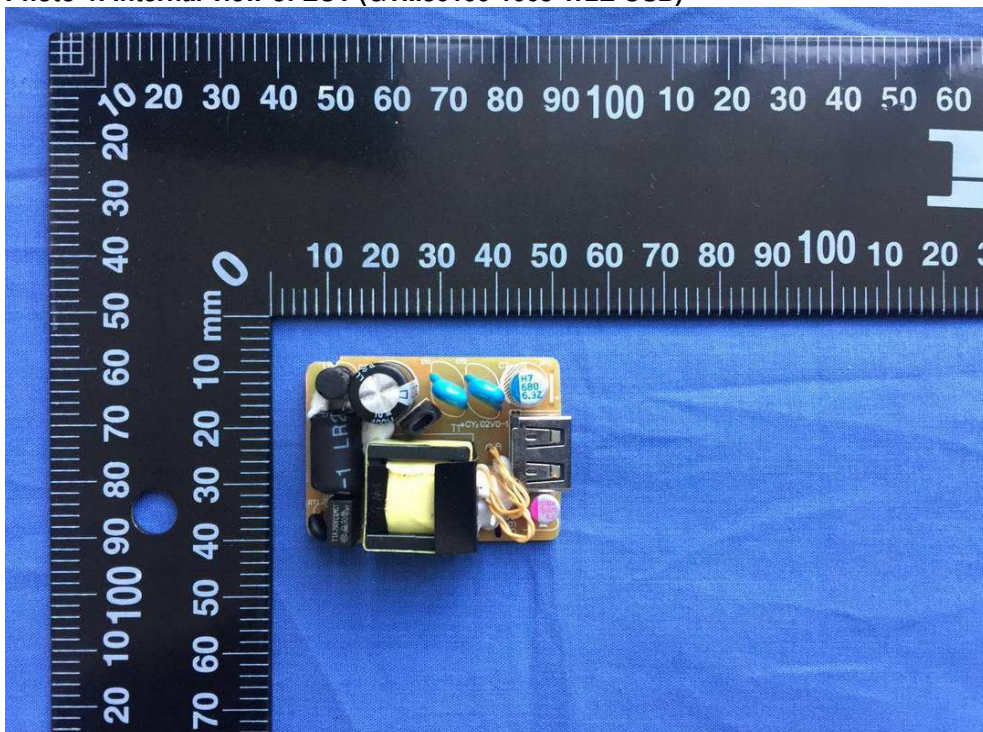


Photo 4: Internal view of EUT (GTM86100-1005-W2E-USB)



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Clause	Requirement + Test	Result - Remark	Verdict

Photo 5: Internal view of EUT (GTM86100-1005-W2E-USB)

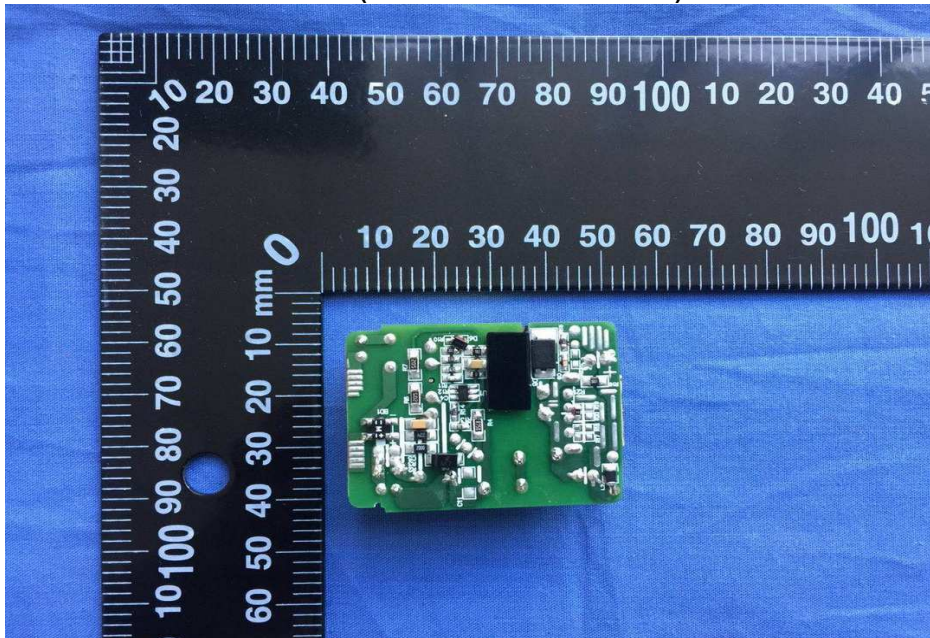
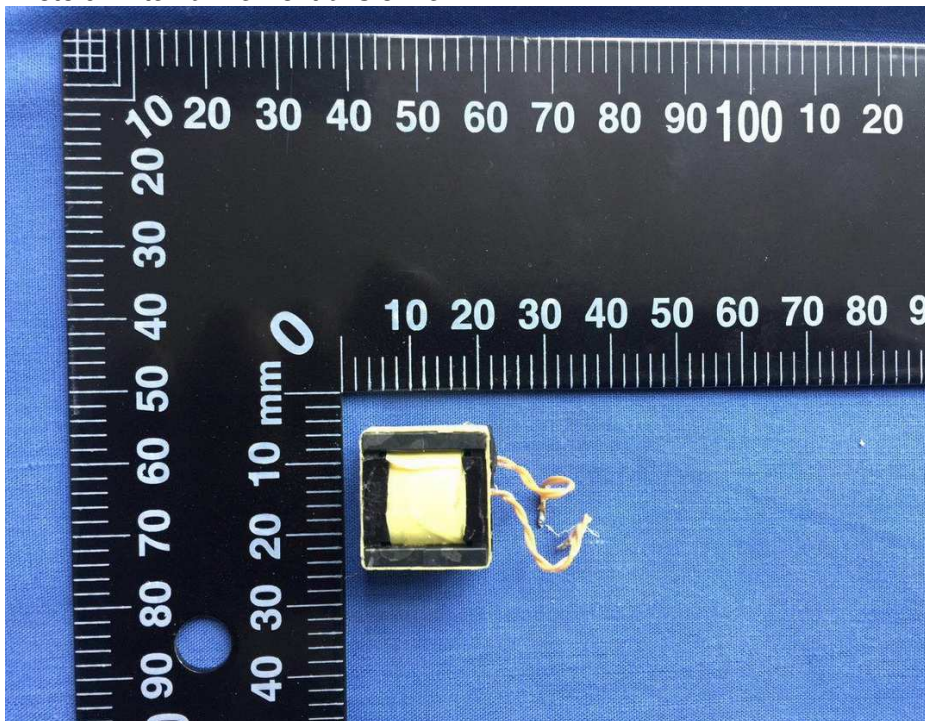


Photo 6: External view of transformer



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Clause	Requirement + Test	Result - Remark	Verdict

Photo 7: External view of transformer

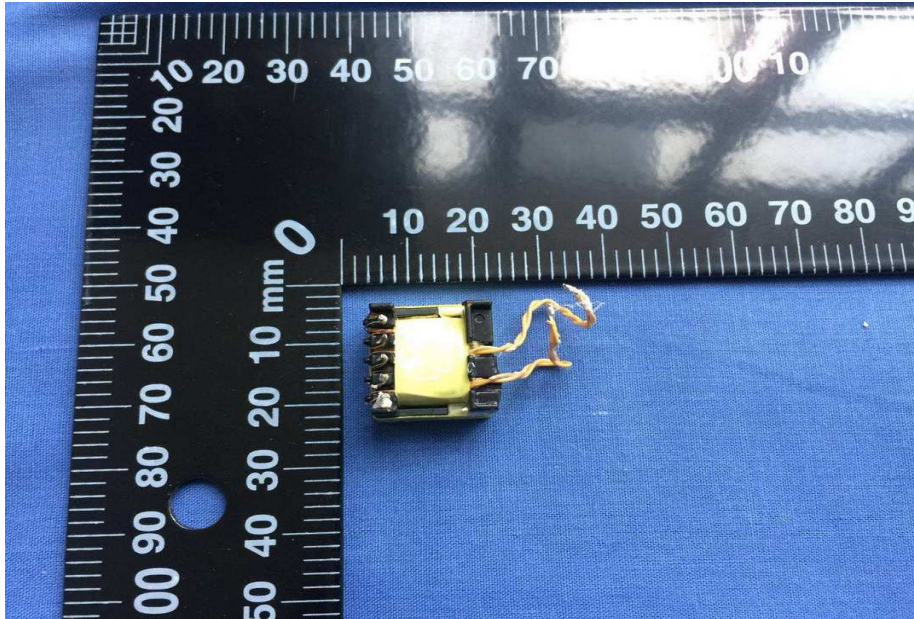
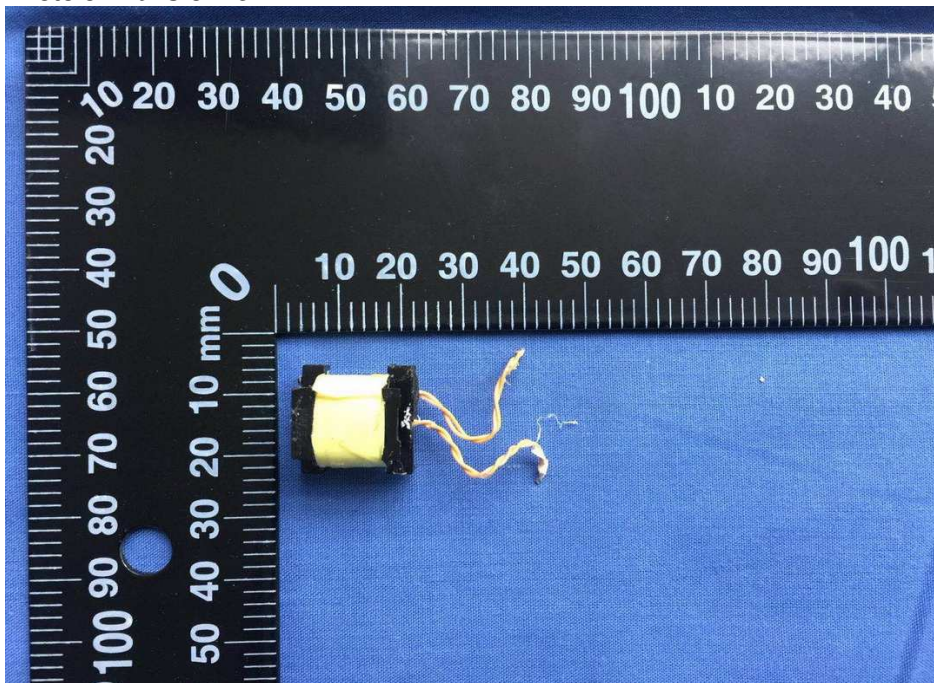


Photo 8: Transformer



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Clause	Requirement + Test	Result - Remark	Verdict

Photo 9: Primary winding view of mains transformer

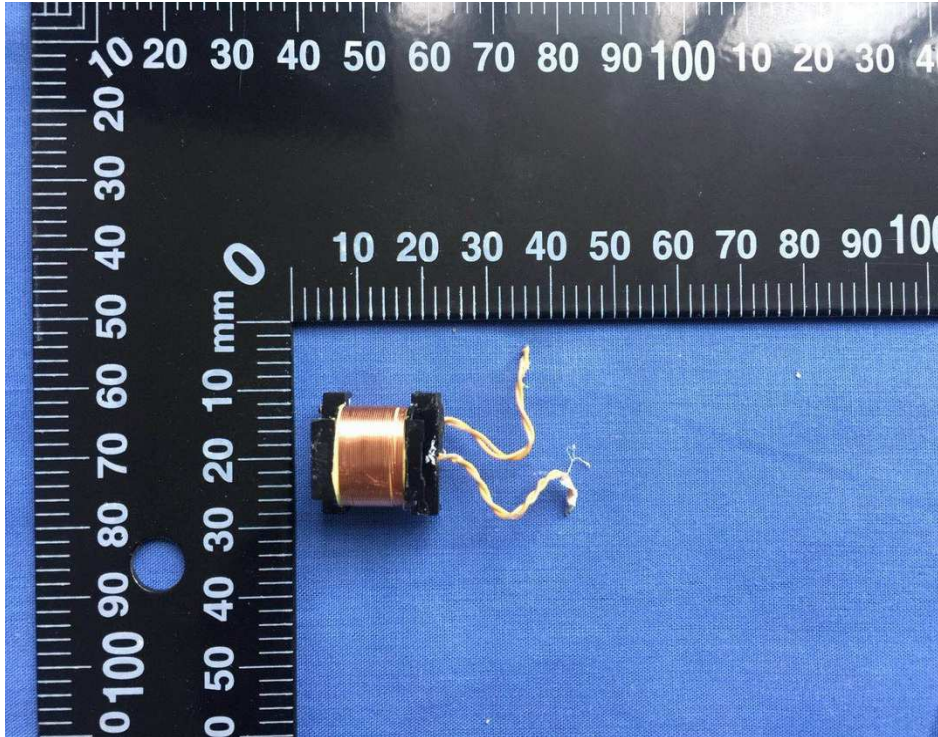
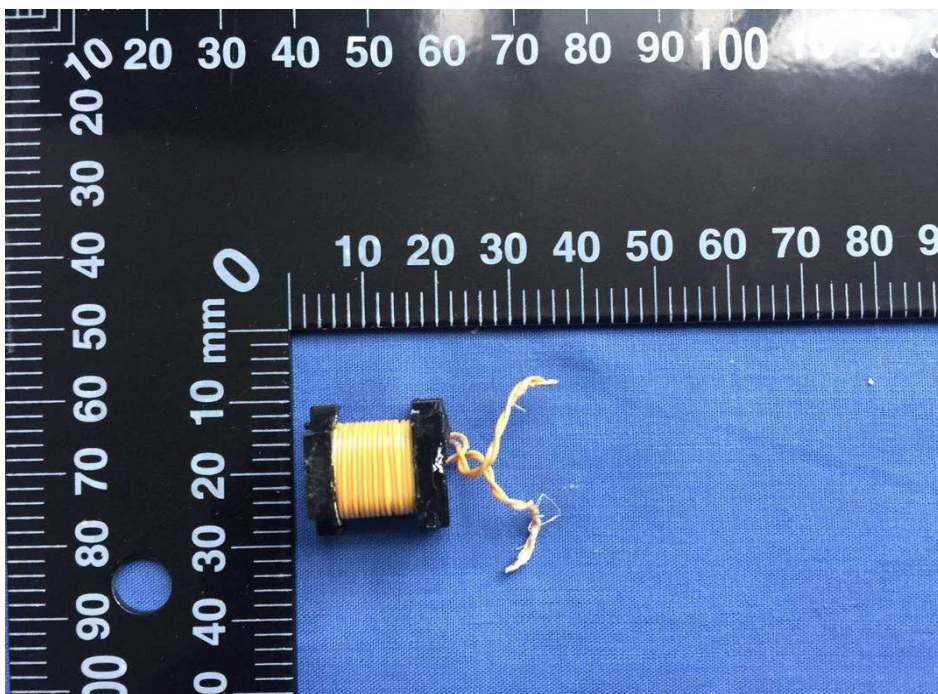


Photo 10: Secondary winding view of mains transformer (TIW)



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Clause	Requirement + Test	Result - Remark	Verdict

Photo 11: Transformer

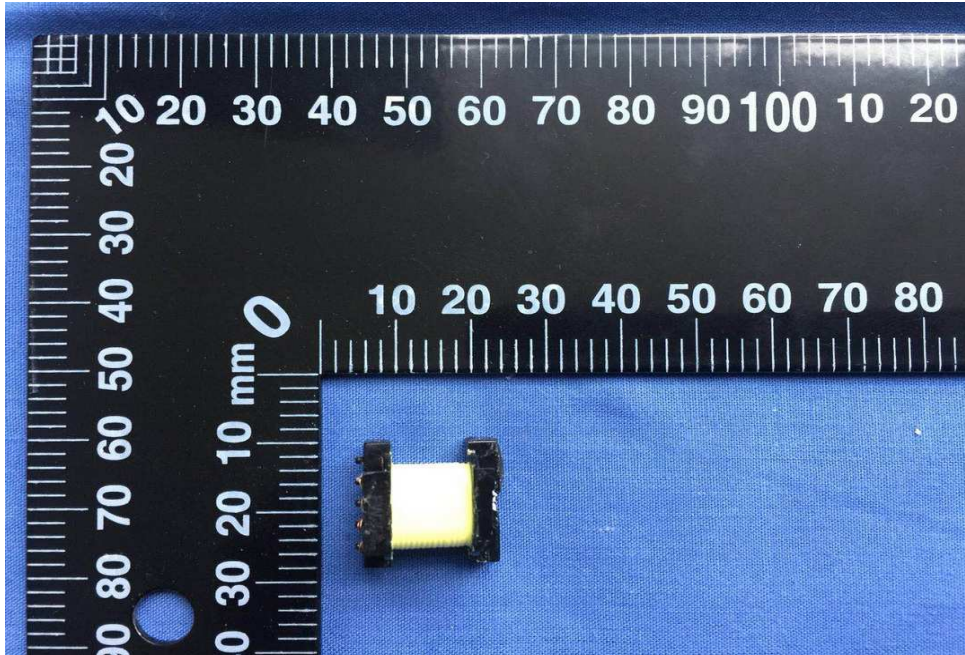
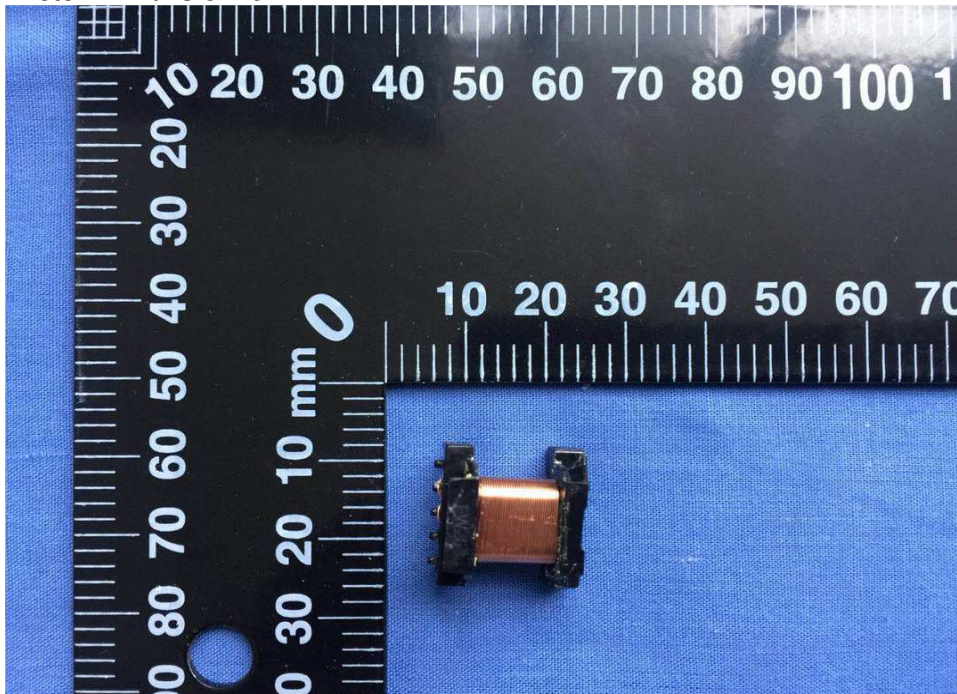


Photo 12: Transformer



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Clause	Requirement + Test	Result - Remark	Verdict

Photo 13: Bobbin view of transformer

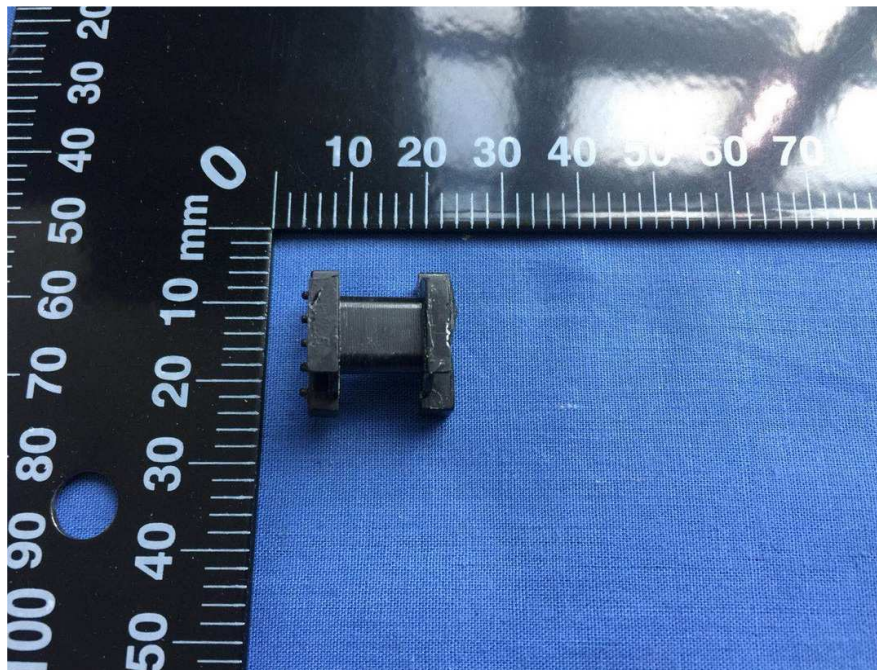


Photo 14: External view of EUT (GTM86100-1005-W2C)



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Photo 15: External view of EUT (GTM86100-1005-W2C)

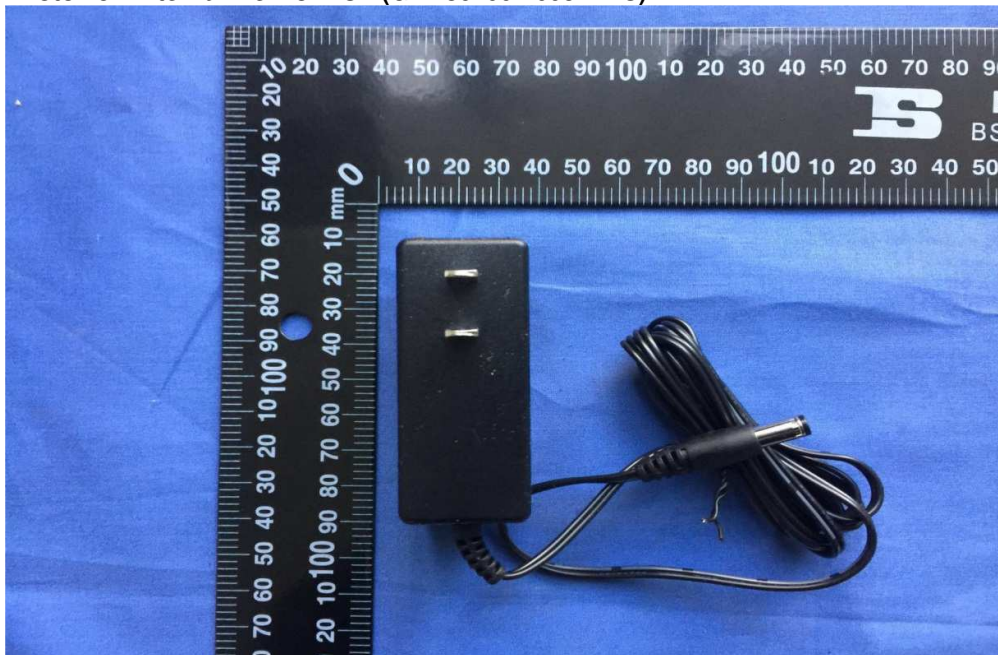


Photo 16: External view of EUT (GTM86100-1005-W2C)



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Clause	Requirement + Test	Result - Remark	Verdict

Photo 17: Internal view of EUT (GTM86100-1005-W2C)

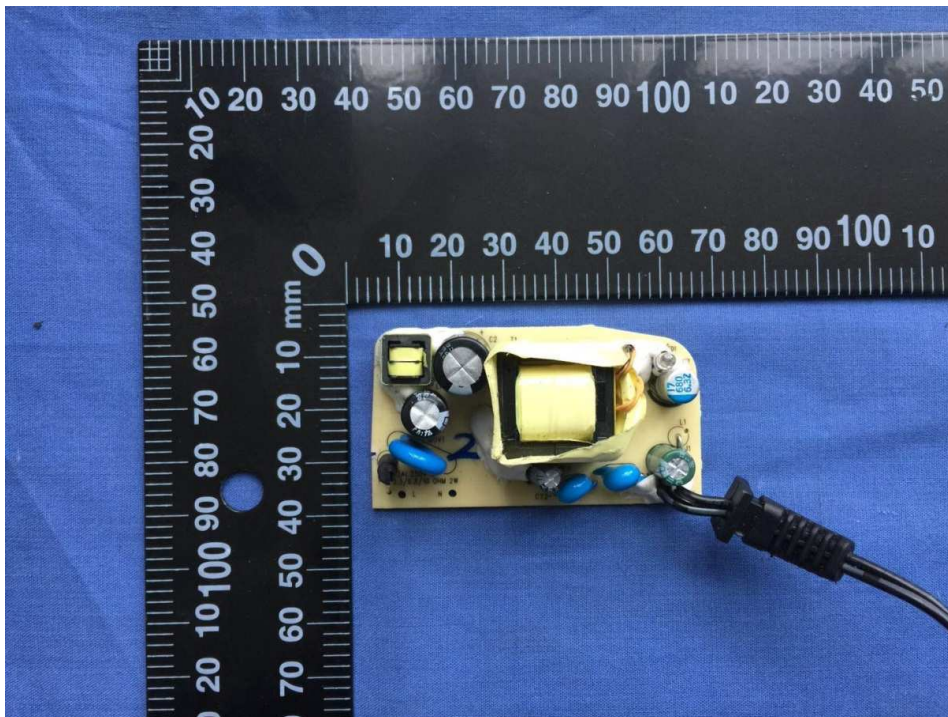
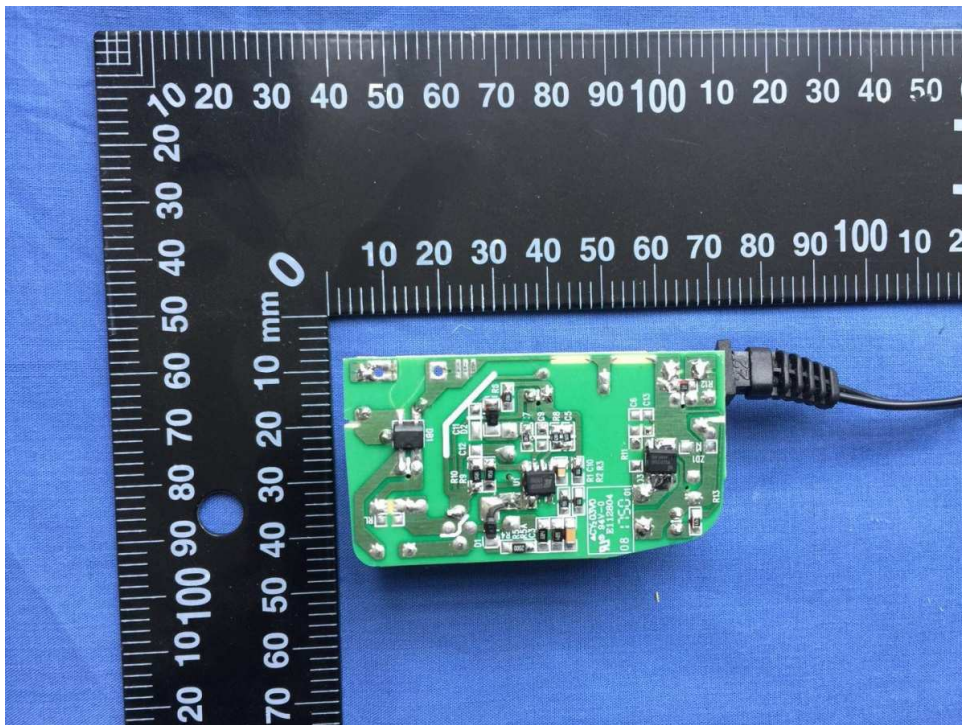


Photo 18: Internal view of EUT (GTM86100-1005-W2C)



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Clause	Requirement + Test	Result - Remark	Verdict

Photo 19: External view of transformer

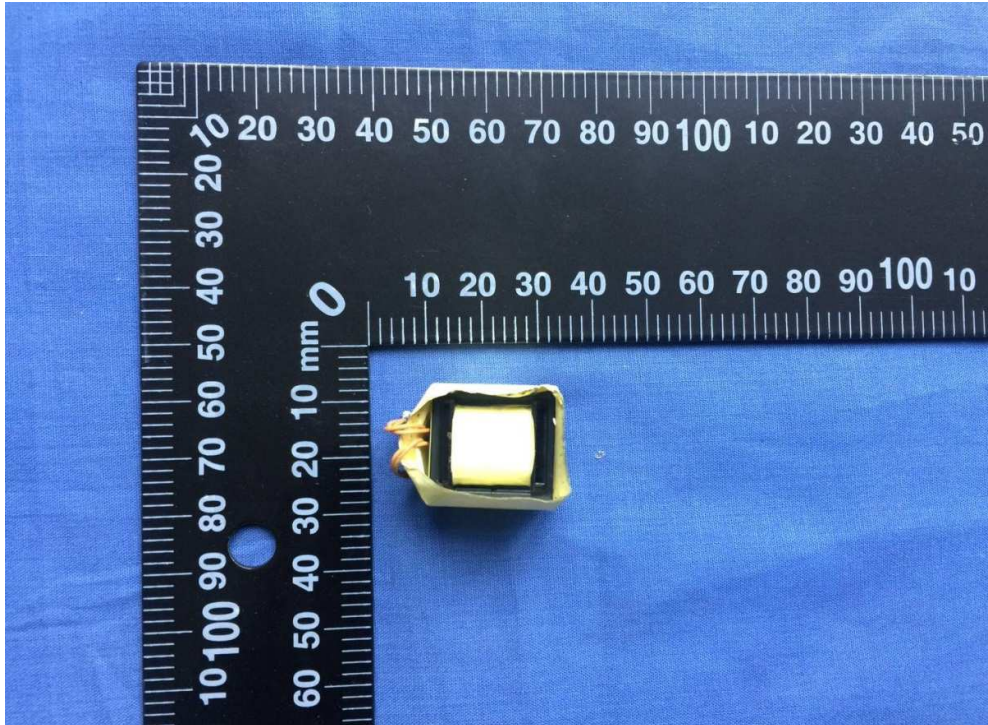
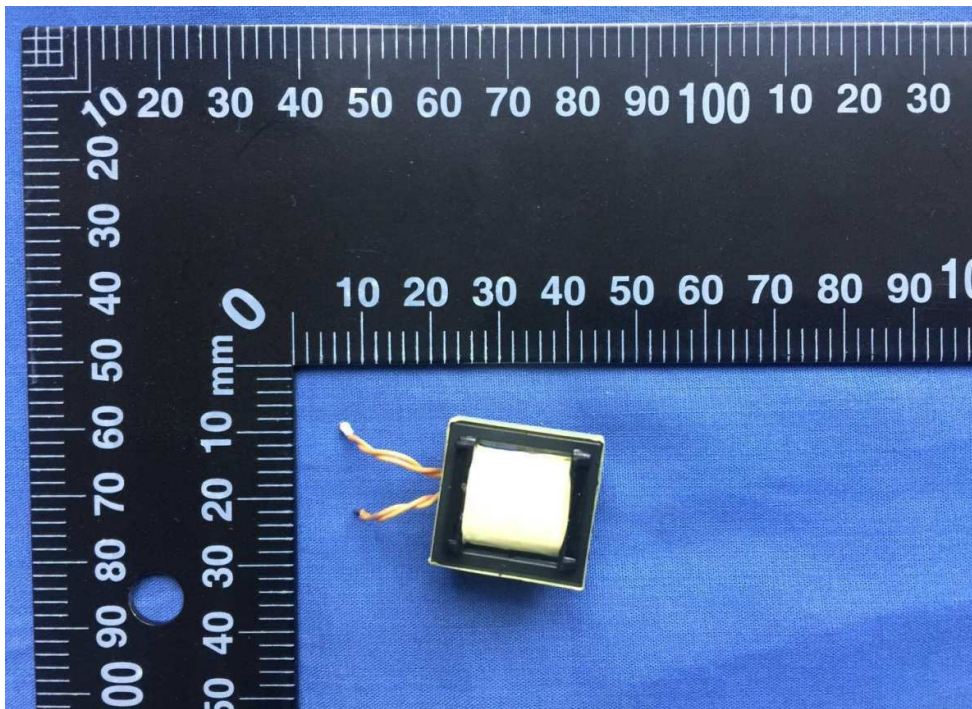


Photo 20: Transformer



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Clause	Requirement + Test	Result - Remark	Verdict

Photo 21: Transformer

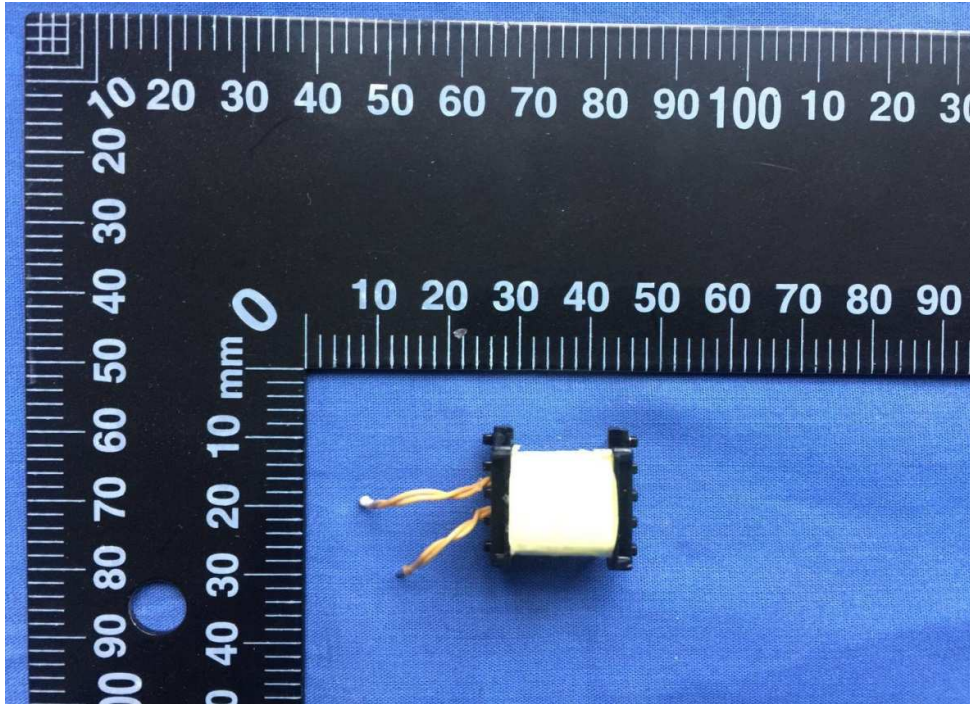
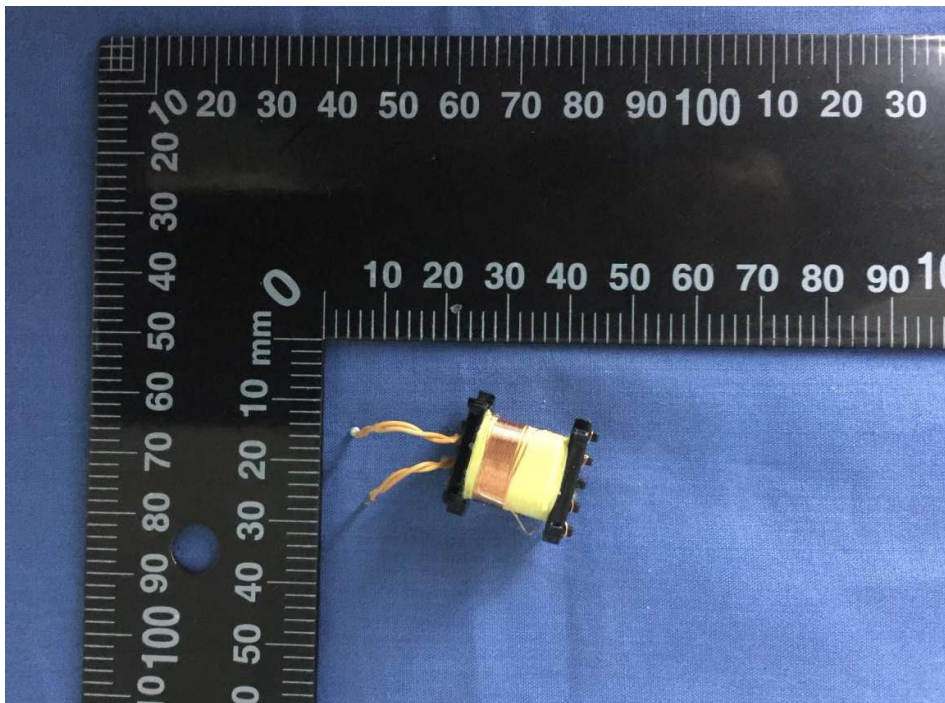


Photo 22: Transformer



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

Photo 23: Secondary winding view of mains transformer (TIW)

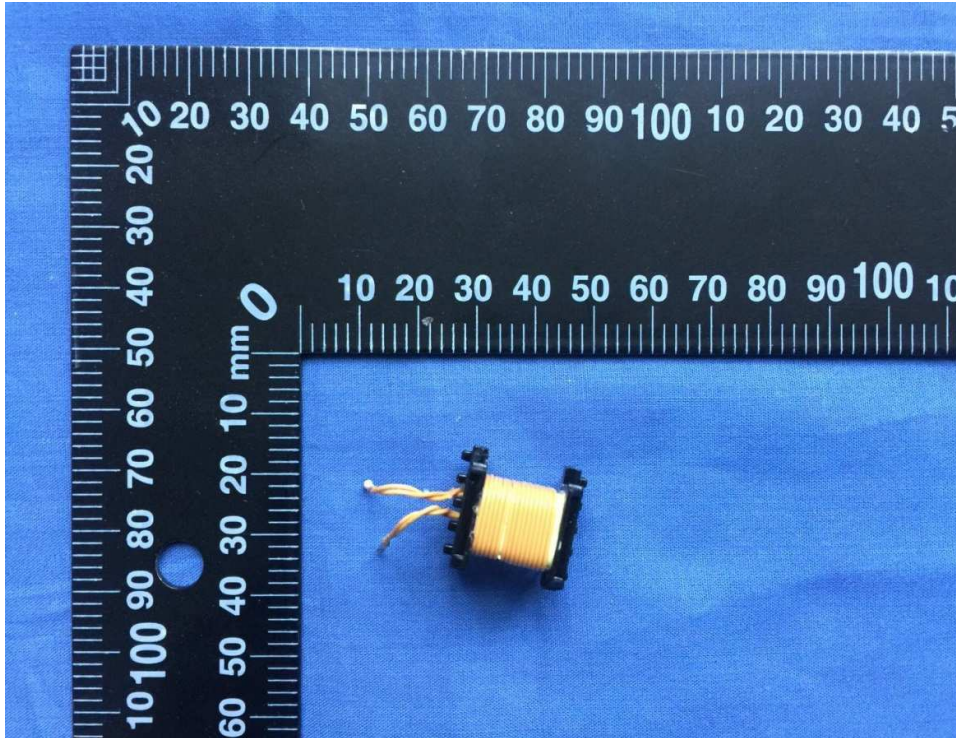
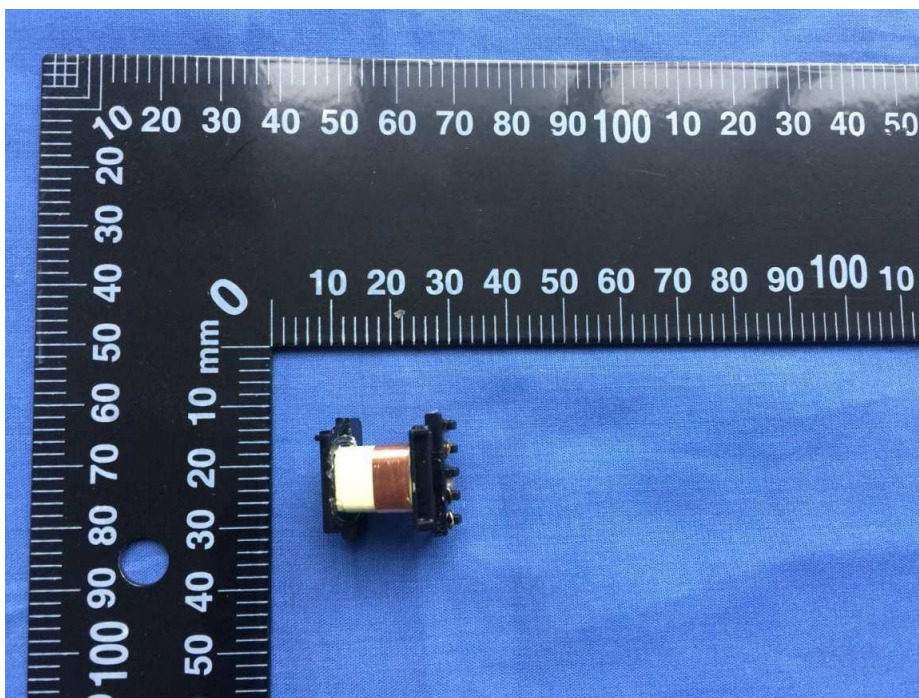


Photo 24: Transformer



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

Photo 25: Primary winding view of mains transformer

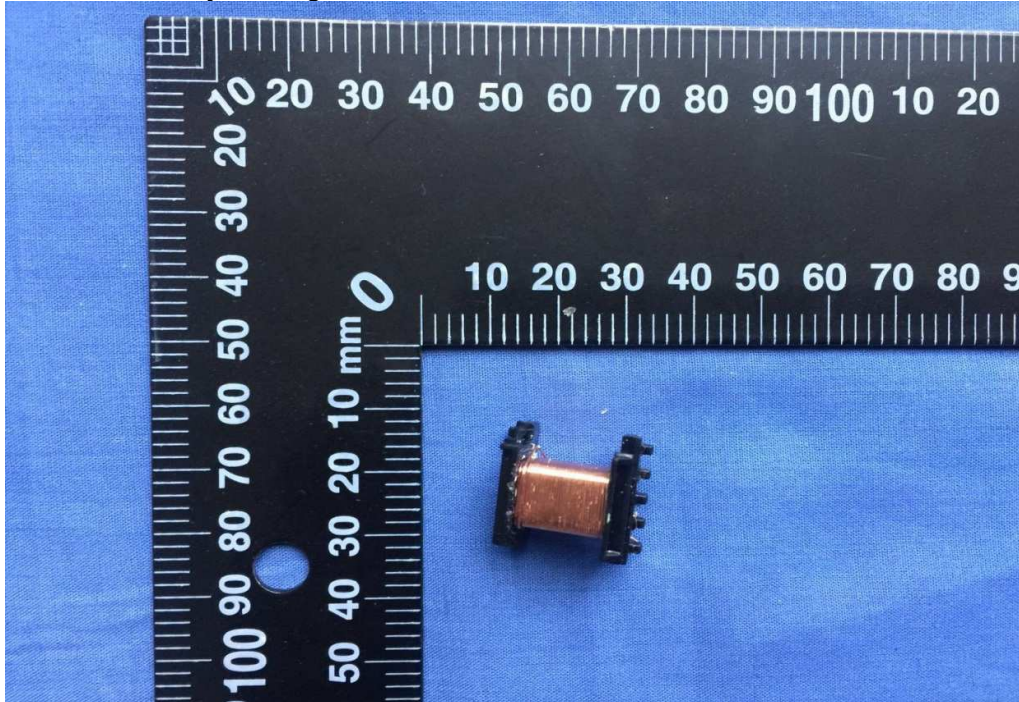
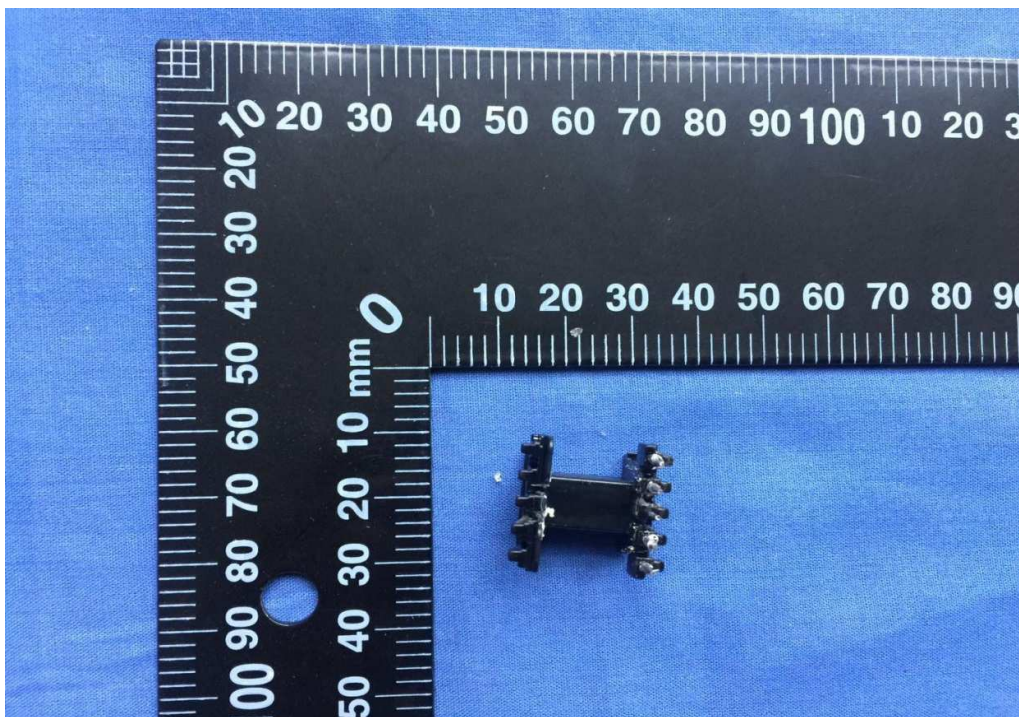


Photo 26: Bobbin view of transformer



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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		P
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	Not fixed & permanently installed ME equipment.	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	No earthing	N/A
	5 mA in NORMAL CONDITION	No earthing	N/A
	10 mA in SINGLE FAULT CONDITION	No earthing	N/A

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8.11	Addition prior to the first paragraph: 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.	N/A
	Installation of connecting cords between EQUIPMENT parts comply with NEC		N/A
	Cable used as external interconnection between units		N/A
	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

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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
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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 <i>Canadian Electrical Code (CEC), Part I, CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32.</i>		P
	NOTE 1A: <i>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.</i>		---
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: <i>When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards.</i>		---
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 <i>Canadian Electrical Code (CEC), Part I</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

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	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 <i>Canadian Electrical Code (CEC), Part I, CSA C22.1:</i>		P
7	ME EQUIPMENT identification, marking and documents		---
7.7.1 to 7.7.5	and shall be in accordance with the <i>Canadian Electrical Code (CEC), Part I, CSA C22.1</i>		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 <i>Canadian Electrical Code (CEC), Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49.....:</i>	No PROTECTIVE EARTH	N/A
8	Protection against electrical HAZARDS from ME EQUIPMENT		---
8.7.3	Allowable values		---
	Allowable values shall be in accordance with the <i>Canadian Electrical Code (CEC), Part I, CSA C22.1.</i>		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

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	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).		---

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Clause	Requirement + Test	Result - Remark	Verdict
	d) Power supply cords shall meet the requirements of the <i>Canadian Electrical Code, Part I</i> , as applicable.....:	No power cord	N/A
	Connecting cords between equipment parts shall meet the requirements of the <i>Canadian Electrical Code, Part I</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 <i>Canadian Electrical Code (CEC), Part I</i> , CSA C22.1.....:		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		---
	bA) 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 <i>Canadian Electrical Code (CEC), Part I</i> , CSA C22.1.....:	No such wiring.	N/A
16	ME SYSTEMS		---

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16.1	General requirements for the ME SYSTEMS		---
	An ME SYSTEM shall provide		---
	- 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

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	National standard reference: SN EN 60601-1:2006		P
	<p>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.</p> <p>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.</p> <p>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).</p>		P
	<p>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:</p> <ul style="list-style-type: none"> - 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 <p>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:</p> <ul style="list-style-type: none"> - 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 <p>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.</p>		N/A

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	KS C IEC 60601-1		—
	LIMITATIONS <Supply voltage rating> National supply voltages are 110,220V and 380V		P
	<Frequency> Only appliances having supply frequency of 60 Hz or a frequency range including 60 Hz are accepted.		P
	<Instruction> Instruction manuals and appliance markings related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC Publication 417. Plugs for connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300) More details are available from KTR on request.	Shall be checked in end product level.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	National standard reference: JIS T0601-1:2012		P
1.1	At the end, add the following: JIS T0601-1:1999 is applicable until 2017.05.31.		—
1.3	In NOTE 3, add the following: In Japan, to check the concerned JIS standard is required.		—
1.4	At the end of NOTE, add the following: In Japan, application of the concerned JIS standard(s) is required.		—
2	<p>Except the part of the first paragraph, Attention and NOTE, replace the existing part listing standards with the following, and apply these properly in the following clauses if any:</p> <p>JIS B7761-3, Hand-transmitted vibration-Part 3: General requirements for measurement and evaluation</p> <p>NOTE: ISO 5349-1, Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration - Part 1: General requirements (IDT)</p> <p>JIS B9707, Safety of machinery-Safety distances to prevent danger zones being reached by the upper limbs</p> <p>NOTE: ISO 13852, Safety of machinery - Safety distances to prevent danger zones being reached by the upper limbs (IDT)</p> <p>JIS B9711, Safety of machinery-Minimum gaps to avoid crushing of parts of the human body</p> <p>NOTE: ISO 13854, Safety of machinery - Minimum gaps to avoid crushing of parts of the human body (IDT)</p> <p>JIS C0445, Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system</p> <p>NOTE: IEC 60445, Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system (IDT)</p> <p>JIS C0447, Man-machine interface (MMI) - Actuating principles</p> <p>NOTE: IEC 60447, Basic and safety principles for man-machine interface, marking and identification</p>		—

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Clause	Requirement + Test	Result - Remark	Verdict
	<p>- Actuating principles (IDT)</p> <p>JIS C0920:2003, Degrees of protection provided by enclosures (IP Code)</p> <p>NOTE: IEC 60529:2001, Degrees of protection provided by enclosures (IP Code) (IDT)</p> <p>JIS C1509-1, Electroacoustics - Sound level meters- Part 1: Specifications</p> <p>NOTE: IEC 61672-1, Electroacoustics - Sound level meters - Part 1: Specifications (IDT)</p> <p>JIS C1509-2, Electroacoustics -Sound level meters - Part 2: Pattern evaluation tests</p> <p>NOTE: IEC 61672-2, Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests (IDT)</p> <p>JIS C2134, Method for the determination of the proof and the comparative tracking indices of solid insulating materials</p> <p>NOTE: IEC 60112, Method for the determination of the proof and the comparative tracking indices of solid insulating materials (IDT)</p> <p>JIS C3301:2000, Rubber insulated flexible cords</p> <p>NOTE: IEC 60245-4:1994, Rubber insulated cables of rated voltages up to and including 450/750 V - Part 4: Cords and flexible cables, Amendment 1:1997 (NEQ)</p> <p>JIS C3306:2000, Polyvinyl chloride insulated flexible cords</p> <p>NOTE: IEC 60227-5:1997, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V - Part 5: Flexible cables (cords) (NEQ)</p> <p>JIS C4003, Electrical insulation-Thermal evaluation and designation</p> <p>NOTE: IEC 60085, Electrical insulation - Thermal evaluation and designation (MOD)</p> <p>JIS C5101-14:2009, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains</p> <p>NOTE: IEC 60384-14:2005, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains (IDT)</p> <p>JIS C6065:2007, Audio, video and similar</p>		

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Clause	Requirement + Test	Result - Remark	Verdict
	<p>electronic apparatus-Safety requirements</p> <p>NOTE: IEC 60065:2001, Audio, video and similar electronic apparatus - Safety requirements (MOD)</p> <p>JIS C6802:2005, Safety of laser products</p> <p>NOTE: IEC 60825-1:1993, Safety of laser products - Part 1: Equipment classification, requirements and user's guide, Amendment 1:1997 and Amendment 2 :2001 (IDT)</p> <p>JIS C6965, Mechanical safety of cathode ray tubes</p> <p>NOTE: IEC 61965, Mechanical safety of cathode ray tubes (IDT)</p> <p>JIS C8282-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements</p> <p>NOTE: IEC 60884-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements (MOD)</p> <p>JIS C8303, Plugs and receptacles for domestic and similar general use</p> <p>NOTE: No corresponding JIS exists. This standard has been listed as normative reference corresponding to IEC60083, Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC, which has been listed in IEC 60601-1:2005. Refer to JIS T1021, too.</p> <p>JIS C60068-2-2:1995, Environmental testing -Part 2-2:Tests -Test B: Dry heat</p> <p>NOTE: IEC 60068-2-2:1974, Environmental testing - Part 2: Tests. Tests B: Dry heat, Amendment 1:1993 and Amendment 2:1994 (IDT)</p> <p>JIS C60079-0, Explosive atmospheres-Part 0: Equipment-General requirements</p> <p>NOTE: IEC 60079-0, Electrical apparatus for explosive gas atmospheres - Part 0: General requirements (IDT)</p> <p>JIS C60079-2, Electrical apparatus for explosive gas atmospheres - Part 2: Pressurized enclosures "p"</p> <p>NOTE: IEC 60079-2, Electrical apparatus for explosive gas atmospheres - Part 2: Pressurized enclosures "p" (IDT)</p> <p>JIS C60079-6, Electrical apparatus for explosive gas atmospheres - Part 6:Oil immersion "o"</p> <p>NOTE: IEC 60079-6, Electrical apparatus for</p>		

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Clause	Requirement + Test	Result - Remark	Verdict
	<p>explosive gas atmospheres - Part 6: Oil-immersion "o" (IDT)</p> <p>JIS C60364-4-41, Low-voltage electrical installations-Part 4-41: Protection for safety - Protection against electric shock</p> <p>NOTE: IEC 60364-4-41, Electrical installations of buildings - Part 4-41: Protection for safety - Protection against electric shock (IDT)</p> <p>JIS C60664-1:2009, Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests</p> <p>NOTE: IEC 60664-1:2007, Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests (IDT)</p> <p>JIS C60695-11-10, Fire hazard testing-Part 11-10: Test flames-50W horizontal and vertical flame test methods</p> <p>NOTE: IEC 60695-11-10, Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods (IDT)</p> <p>JIS T0307, Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied</p> <p>NOTE: ISO 15223, Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied (IDT)</p> <p>JIS T0601-1-3, Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment</p> <p>NOTE: IEC60601-1-3, Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment (IDT)</p> <p>JIS T14971:2003, Medical devices-Application of risk management to medical devices</p> <p>NOTE: ISO 14971:2000, Medical devices - Application of risk management to medical devices (IDT)</p> <p>JIS Z8202 (all parts), Quantities and units</p> <p>NOTE: ISO 31 (all parts), Quantities and units (IDT)</p> <p>JIS Z8203, SI units and recommendations for the use of their multiples and of certain other units</p>		

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Clause	Requirement + Test	Result - Remark	Verdict
	<p>NOTE: ISO 1000, SI units and recommendations for the use of their multiples and of certain other units (IDT)</p> <p>JIS Z8736-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1 : Measurement at discrete points</p> <p>NOTE: ISO 9614-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points (IDT)</p> <p>JIS Z9101:2005, Safety colours and safety signs- Design principles for safety signs in workplaces and public areas</p> <p>NOTE: ISO 3864-1:2002, Graphical symbols - Safety colours and safety signs - Part 1: Design principles for safety signs in workplaces and public areas (IDT)</p> <p>ISO 780, Packaging - Pictorial marking for handling of goods</p> <p>NOTE: The corresponding JIS standard is JIS Z0150 Packaging-Pictorial marking for handling of goods (MOD)</p> <p>ISO 1853, Conducting and dissipative rubbers, vulcanized or thermoplastic—Measurement of resistivity</p> <p>NOTE: The corresponding JIS standard is JIS K6271 Rubber, vulcanized or thermoplastic-Determination of volume and surface resistivity (MOD)</p> <p>ISO 2878, Rubber - Antistatic and conductive products - Determination of electrical resistance</p> <p>ISO 2882, Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits</p> <p>ISO 3746, Acoustics - Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane</p> <p>ISO 7000-DB:2004, Graphical symbols for use on equipment - Index and synopsis</p> <p>ISO 7010:2003, Graphical symbols - Safety colours and safety signs - Safety signs used in workplaces and public areas</p> <p>ISO 10993 (all parts), Biological evaluation of medical devices</p> <p>NOTE: The corresponding JIS standard is JIS</p>		

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Clause	Requirement + Test	Result - Remark	Verdict
	<p>T0993-1 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process (MOD). However, other Parts than Part 1 and Part 7 have still not been published as JIS.</p> <p>ISO 11134, Sterilization of health care products - Requirements for validation and routine control - Industrial moist heat sterilization</p> <p>NOTE: At present, as the corresponding JIS or international standards, the following exist:</p> <p>JIS T0816-1:2010 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices</p> <p>ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (IDT)</p> <p>ISO 11135, Medical devices - Validation and routine control of ethylene oxide sterilization</p> <p>NOTE: At present, as the corresponding JIS or international standards, the following exist:</p> <p>JIS T0801-1:2010 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices</p> <p>ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT)</p> <p>ISO 11137, Sterilization of health care products - Requirements for validation and routine control – Radiation Sterilization</p> <p>NOTE: At present, as the corresponding JIS or international standards, the following exist:</p> <p>JIS T0806-1:2010 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices</p> <p>ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT)</p> <p>ISO 23529, Rubber - General procedures for preparing and conditioning test pieces for physical test methods</p> <p>NOTE: The corresponding JIS standard is JIS</p>		

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Clause	Requirement + Test	Result - Remark	Verdict
	<p>K6250 Rubber-General procedures for preparing and conditioning test pieces for physical test methods (MOD)</p> <p>IEC 60079-5, Explosive gas atmospheres— Part 5: Equipment protection by powder filling “q”</p> <p>IEC/TR 60083, Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC</p> <p>IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries</p> <p>NOTE: The corresponding JIS standard is JIS C8513 Safety of primary lithium batteries (MOD)</p> <p>IEC 60127-1, Miniature fuses - Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links</p> <p>NOTE: The corresponding JIS standard is JIS C6575-1 Miniature fuses-Part 1: Definitions of miniature fuses and general requirements for miniature fuse-links (MOD)</p> <p>IEC 60227-1:1993, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements, Amendment 1:1995 and Amendment 2:1998</p> <p>NOTE: The corresponding JIS standard is JIS C3662-1:2009 Polyvinyl chloride insulated cables of rated voltages up to and including 450/750V - Part 1: General requirements (MOD)</p> <p>IEC 60245-1:2003, Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 1: General requirements</p> <p>NOTE: The corresponding JIS standard is JIS C3663-1:2007 Rubber insulated cables-Rated voltages up to and including 450/750 V-Part 1: General requirements (MOD)</p> <p>IEC 60252-1, AC motor capacitors - Part 1: General - Performance, testing and rating - Safety requirements -Guide for installation and operation</p> <p>IEC 60320-1, Appliance couplers for household and similar general purposes - Part 1: General requirements</p> <p>NOTE: The corresponding JIS standard is JIS C8283-1 Appliance couplers for household and similar general purposes-Part 1: General requirements (MOD)</p> <p>IEC 60335-1:2001, Household and similar electrical appliances - Safety - Part 1: General</p>		

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Clause	Requirement + Test	Result - Remark	Verdict
	<p>requirements</p> <p>NOTE: The corresponding JIS standard is JIS C9335-1:2003 Household and similar electrical appliances - Safety - Part 1 : General requirements (MOD)</p> <p>IEC 60417-DB:2002, Graphical symbols for use on equipment</p> <p>IEC 60601-1-2, Medical electrical equipment - Part 1 - 2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests</p> <p>NOTE: The current "JIS T0601-1-2:2012 Medical electrical equipment - Part 1-2: General requirements for safety - Electromagnetic compatibility - Requirements and tests" corresponds to IEC 60601-1-2:2001 and Amendment 1:2004.</p> <p>IEC 60601-1-6, Medical electrical equipment - Part 1 - 6: General requirements for basic safety and essential performance - Collateral standard: Usability</p> <p>NOTE: As the corresponding international standard, IEC 62336 is applicable.</p> <p>IEC 60601-1-8, Medical electrical equipment - Part 1 - 8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems</p> <p>NOTE: The corresponding JIS standard is now under drafting.</p> <p>IEC 60730-1:1999, Automatic electrical controls for household and similar use - Part 1: General requirements, Amendment 1:2003 and Amendment 2:2007</p> <p>NOTE: The corresponding JIS standard is JIS C9730-1:2010 Automatic electrical controls for household and similar use-Part 1:General requirements (MOD)</p> <p>IEC 60851-3:1996, Winding wires - Test methods - Part 3: Mechanical properties, Amendment 1:1997 and Amendment 2:2003</p> <p>IEC 60851-5:1996, Winding wires - Test methods - Part 5: Electrical properties, Amendment 1:1997 and Amendment 2:2004</p> <p>IEC 60851-6:1996, Winding wires - Test methods -</p>		

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Clause	Requirement + Test	Result - Remark	Verdict
	<p>Part 6: Thermal properties and Amendment 1:1997</p> <p>IEC 60878:2003, Graphical symbols for electrical equipment in medical practice</p> <p>IEC 60884-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements</p> <p>IEC 60950-1:2001, Information technology equipment – Safety - Part 1: General requirements</p> <p>NOTE: The corresponding JIS standard is JIS C 6950-1:2009 Information technology equipment - Safety - Part 1: General requirements (MOD)</p> <p>IEC 61058-1:2000, Switches for appliances - Part 1: General requirements and Amendment 1:2001</p> <p>NOTE: The corresponding JIS standard is JIS C4526-1:2005 Switches for appliances - Part 1: General requirements (MOD)</p> <p>IEC 61558-1:1997, Safety of power transformers, power supply units and similar products - Part 1: General requirements and tests and Amendment 1:1998</p> <p>NOTE: No corresponding JIS exists. However, as the standard corresponding to IEC 61558-1:2005, the following exists:</p> <p>JIS C 61558-1:2008 Safety of power transformers, power supplies, reactors and similar products - Part 1: General requirements and tests (MOD)</p> <p>IEC 61558-2-1, Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications</p> <p>NOTE: The corresponding JIS standard is JIS C61558-2-1 Safety of power transformers, power supplies, reactors and similar products-Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications (MOD)</p>		
3.61	<p>Add NOTE as follows:</p> <p>NOTE In this standard, MECHANICAL HAZARD is understandable suitably by replacing with mechanical HAZARD, mechanical HADARDOUS SITUATION, HARM or unacceptable RISK.</p>		—
3.70	<p>Replace the existing text with:</p> <p>condition in which all means provided for protection against HAZARDOUS SITUATION or</p>		—

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Clause	Requirement + Test	Result - Remark	Verdict
	HAZARDS are intact		
4.2	Replace the existing NOTE 2 with the following: NOTE 2 Conditions or faults that can give rise to HAZARDOUS SITUATIONS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDOUS SITUATIONS are and the tests that need to be done to show that the identified HAZARDOUS SITUATIONS do not arise in the specified circumstances.		—
4.10.1	In the existing text, replace “a separate power supply” with “a separate power supply (e.g., a power supply of other equipment)”.		—
7.3.3	In the third paragraph, replace “could result in a HAZARD” with “could result in a HAZARDOUS SITUATION”.		—
7.4.3	Replace the existing first paragraph with the following: Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to JIS Z8202 (ISO 31 (IDT)) except the base quantities listed in Table 1 may be expressed in the indicated units, which are used in conjunction with the SI units system or as the approved combination. Replace the title of Table 1 with the following: Units which are used in conjunction with the SI units system or as the approved combination		N/A
7.7.4	Under the existing text, add the following: If polyvinyl chloride insulated flexible cord of JIS C3306 or rubber insulated flexible cord of JIS C3301 is used, the conductor may be coloured "white".		N/A
7.7.5	Under the existing text, add the following: If polyvinyl chloride insulated flexible cord of JIS C3306 or rubber insulated flexible cord of JIS C3301 is used, conductors may be of the colour specified in the said standards.		N/A
7.9.3.2	In the fourth dash, replace “the nature of the HAZARD” with “the HAZARDOUS SITUATION”.		—
8.4.2	For Item c), at the end of the paragraph of “For such parts, the voltage to earth or --,” replace “at a potential up to 2 V” with “at a potential of 2 V or more”. For Item c), replace the existing NOTE with NOTE 1, and add the following new NOTE 2: NOTE 2 – The corresponding international		—

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Clause	Requirement + Test	Result - Remark	Verdict
	standard specifies as “not exceed 20 J at a potential up to 2 V”. However, 1.2.8.9 of IEC 60950-1, which was quoted by the said international standard, specifies as “2 V or more”. Therefore, this JIS standard was harmonized to IEC 60950-1.		
8.8.2	For a), add the following NOTE: NOTE – Generally, “distance through insulation” means the thickness of insulation. However, for example, if a transformer installed into a metal case is insulated by filler, the thickness is always not uniformly. Therefore, such expression was used.		P
8.8.3	Between the third dash and the paragraph of “Initially, not more than --”, add the following new paragraph. During the above-mentioned tests, the state of the power switch shall be kept with closed circuit.		P
8.9.1.2	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.3	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.4	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.5	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.6	At the end of the title of this sub-clause, add “(Apply to MOOP and MOPP)”.		—
8.9.1.7	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.8	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.9	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.10	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.11	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.12	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.13	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.14	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—

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Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.2	<p>Add the following between the first paragraph and the second paragraph: And, rubber insulated flexible cords of JIS C3301, polyvinyl chloride insulated flexible cords of JIS C3306 or cords of which the robustness is equal to or more than those are usable. Add the following between the second paragraph and the last paragraph: And, in the case of cords of JIS C3306, shall not use;</p> <ul style="list-style-type: none"> - for polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 60 °C, and; - for grade heat-resistant polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 75 °C. 		N/A
9.2.2.2	<p>In the bottom column of Table 20, replace the existing text with the following: ^a The values in this table are taken from JIS B9711 (ISO 13854 (IDT)).</p>		—
9.2.2.4.4	In the second dash, replace “no HAZARD or damage shall result” with “any HAZARDOUS SITUATION or unacceptable RISK shall result”.		—
9.2.4	In e), replace “no HAZARD or damage shall result” with “no HAZARDOUS SITUATION or unacceptable RISK shall result”.		—
9.4.4	In the first paragraph of a), replace “and no HAZARDS can develop” with “and no HAZARDOUS SITUATION can develop”.		—
9.7.5	In the last paragraph, delete “unmarked”.		—
9.8.4.1	Replace the existing NOTE with the following: NOTE The upper carriage of the human body test mass apparatus is formed of wood or a similar material. The bottom portion is foam. The resiliency or spring factor of the foam (ILD or IFD ratings) has not been specified. The foam is cylindrical, rather than spherical.		N/A
10.1.1	In the paragraph, replace “0,5 mR/h” with “0,5 mR/h \approx 5 μ Gy/h”; and in NOTE 2, “0,1 mR/h” with “0,5 mR/h \approx 1 μ Gy/h”.		N/A
11.1.1	To the existing text of a in the Table 22, add the following: (For example, the maximum temperature limit of a transformer with three insulating materials of Class A, Class B and Class E shall be 105 °C of Class A of the lowest limit.)		P
13.2.7	In the title of this sub-clause, replace “in a		—

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Clause	Requirement + Test	Result - Remark	Verdict
	HAZARD" with "in a HAZARDOUS SITUATION".		
13.2.10	In Table 26, replace the existing NOTE with the following: NOTE The temperature limits in this table were derived from Table B.1 of IEC 60950-1:2001 (in the corresponding international standard, IEC 61010-1:2001 [22]).		—
15.4.2.1	In c), replace "could constitute a HAZARD" with "could constitute a HAZARDOUS SITUATION".		—
15.4.3.4	In the first paragraph, replace "could become a HAZARD" with "could become a HAZARDOUS SITUATION".		—
16.1	Replace the last two paragraphs with the following: Otherwise, non-medical equipment shall be those which are in compliance with relevant JIS standards or the Technical Requirements of the Electrical Appliance and Material Safety Act or which ensure safety equivalent to the said standards/technical requirements. Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM. For the measures for ensuring safety, e.g., the case combined with a separating transformer with DOUBLE INSULATION or REINFORCED INSULATION, equipment only with BASIC INSULATION may be used. Compliance is checked by inspection of appropriate documents or certificates.		N/A
16.6.4.1	In NOTE, replace "no possibility of any HAZARD" with "no possibility of any HAZARDOUS SITUATION".		—
Annex D	In Table D.2, replace the sign of No. 10, which is shown as "IEC 60878 Safety 01 b", with the sign of "ISO 7010-M002 b". In the bottom column of Table D.2, replace the existing a and b with the following: a The description of this commonly used safety sign appeared in Annex B of ISO 3864:1984. b In accordance with the corrigendum of IEC 60601-1, Replaced "IEC 60878 Safety 01 " with "ISO 7010-M002		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
Annex I	<p>In 1.1.3, replace the first dash with the following:</p> <p>- PATIENTS should only be connected to APPLIED PARTS of ME EQUIPMENT complying with this standard. Other equipment should comply with relevant IEC or ISO standards or comply with relevant JIS safety standards or the Technical Requirements of the Electrical Appliance and Material Safety Act, or ensure safety equivalent to the said standards/technical requirements.</p> <p>Replace the existing NOTE 2 with the following:</p> <p>NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601 (all parts) or JIS T0601 (all parts).</p> <p>Replace the existing NOTE 3 with the following:</p> <p>NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards. Include non-medical equipment in compliance with relevant JIS safety standards or the Technical Requirements of the Electrical Appliance and Material Safety Act, or non-medical equipment ensuring safety equivalent to the said standards/technical requirements.</p>		N/A
Annex L	In the text of c), replace "IEC 60884-1" with "IEC 60884-1 or JIS C8282-1".		—
Bibliography	<p>Add the following at the end:</p> <p>[55] JIS T1021, "Hospital grade" outlet-sockets and plugs</p> <p>[56] JIS Q13485, Medical devices - Quality management systems - Requirements for regulatory purposes</p>		—

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Clause	Requirement + Test	Result - Remark	Verdict

Appendix: Equipment combined with two-pole plug (Class II)

Supplementary tests on plug portion according to EN 50075:1990

	First testing set: Sample No. 1, 2 and 3	
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5	RATING	
	2,5 A AC 250 V	Input: 100-240V~, 50-60Hz, 0.3A; Output: 5-5.2VDC, Max.2A Max 10W (end product)
		N/A

6	MARKING (It should be checked with end product in main test report)	
6.1/2	Rated current:	N/A
	Rated voltage:	N/A
	Nature of supply:	N/A
	Name of manufacturer or responsible vendor	N/A
	Type reference	N/A
6.3	Symbol for Class II construction not allowed	N/A
6.4	Marking durable	N/A
	Easily legible	N/A
	Test: 15 s water and 15 s petroleum spirit	N/A

7	DIMENSIONS	
	Compliance with Standard Sheet 1	P
	Gauges of figures 1 and 2	P

8	PROTECTION AGAINST ELECTRIC SHOCK	
8.1	Test finger of fig. 3	P
	Ambient temperature	35°C
	Force: 75 N	P
8.2	Gauge of fig. 4	P
	Ambient temperature: 35 ± 2 °C	P
8.3	External parts of insulating material	P
9	CONSTRUCTION	
9.1	Non-rewirable plug	P

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Clause	Requirement + Test	Result - Remark	Verdict
9.2	Switches, fuses and lampholders not incorporated	No such components	P
9.3	Pins of plug solid		P
9.4	Pins of plug locked against rotation		P
9.5	Effective permanent connections:		
	- soldered, welded, crimped	riveted	P
	- screwed and snap-on connections not used		P
	- pre soldered flexible conductor for crimping not permitted		P
9.6	Gripping operation:		
	- length ≥ 55 mm		N/A
	- ball test	Test with end appliance	P
10	RESISTANCE TO HUMIDITY		
	No damage after 48 h		P
11	INSULATION RESISTANCE AND ELECTRIC STRENGTH		
11.1	Resistance ≥ 5 M Ω (500 V, 1 min)	199M Ω (only for plug portion)	P
11.2	Electric strength test (2000 V, 1 min): no flashover or breakdown		P
12	FLEXIBLE CORDS AND THEIR CONNECTION		
12.1	Cords in compliance with HD 21.5 or HD 22.4		N/A
13	MECHANICAL STRENGTH		
13.1	Compression test (150 N, 5 min)		P
13.2	Tumbling barrel test: number of falls.....:	It will be checked with end product in main test report	N/A
	Torque test on pins (0,4 Nm, 1 min)	It would be checked again after tumbling barrel test	P
13.3	Abrasion test (20.000 movements): no damage		P
14	RESISTANCE TO HEAT AND TO AGEING		
14.1.1	Heating test (100 °C, 1 h): no damage	performed on the delivered samples	P
14.1.2	Pressure test (80°C, 20 N, 1 h): no damage	performed on the delivered samples	P

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Clause	Requirement + Test	Result - Remark	Verdict

15	CURRENT-CARRYING PARTS AND CONNECTIONS		
15.1	Connections withstand the mechanical stresses occurring in normal use		P
15.2	Contact pressure		P
15.3	Material of current-carrying parts	> 58% (in copper)	P

16	CREEPAGE DISTANCES, CLEARANCES AND DISTANCES THROUGH INSULATION		
	Creepage distances and clearances between live parts ≥ 3 mm	>4,0 mm (by gauge)	P
	Creepage distances and clearances between live parts and accessible external surfaces ≥ 3 mm	>4,0 mm (by gauge)	P
	Distance through insulation $\geq 1,5$ mm	Non mould-on	N/A

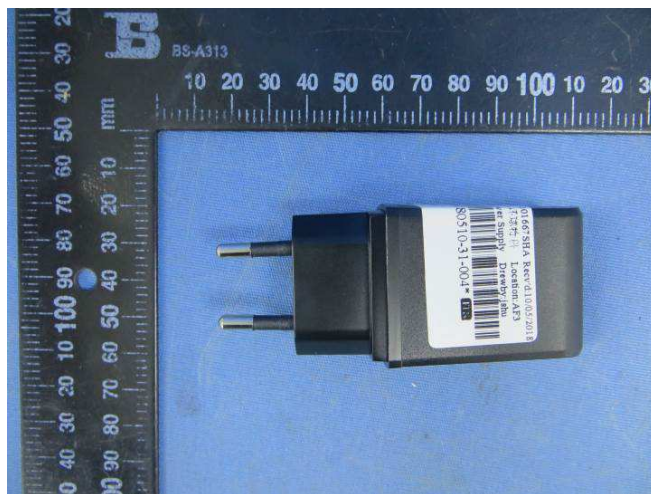
17	RESISTANCE OF INSULATING MATERIAL TO ABNORMAL HEAT AND TO FIRE		
	Glow-wire test (750 °C): no visible flame, no sustained glowing or flames and glowing extinguish within 30 s after removal of glow-wire	no visible flame(plug holder)	P
	Glow-wire test (650 °C): no visible flame, no sustained glowing or flames and glowing extinguish within 30 s after removal of glow-wire	no visible flame(enclosure, performed on the delivered samples)	P

	Second testing set: Sample No. 4, 5 and 6		
--	--	--	--

12.2	Moulded-on plugs		
	Pull test (100 times, 50 N, 1 s)		N/A
	Torque test (1 min):		
	cross-sectional area $\leq 0,5$ mm ² , 0,1 Nm: displacement ≤ 2 mm; no break in electrical connections		N/A
	cross-sectional area $\geq 0,75$ mm ² , 0,15 Nm: displacement ≤ 2 mm; no break in electrical connections		N/A
13.4	Mechanical strength		
	Pull test with steel plate on pin (40 N, 70 °C, 1 min): displacement of pin ≤ 1 mm	Max. 0,4mm	P

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Clause	Requirement + Test	Result - Remark	Verdict
14	Resistance to heat and to ageing		
14.2	Heating test (70 °C, 168 h): no damage, no cracks visible	performed on the delivered samples	P
	Pressure test (5 N): no traces	performed on the delivered samples	P
Third testing set: Sample No. 7, 8 and 9			
12.3	Flexible cords and their connection		
	Flexing test (10.000 flexings, 2,5 A, AC 250 V) - 10 N (cross-sectional area $\leq 0,75 \text{ mm}^2$) - 20 N (cross-sectional area $> 0,75 \text{ mm}^2$) no damage		N/A
	Voltage drop $\leq 10 \text{ mV}$ test current: - 1 A with H03 VH-Y - 2,5 A with other cords		N/A

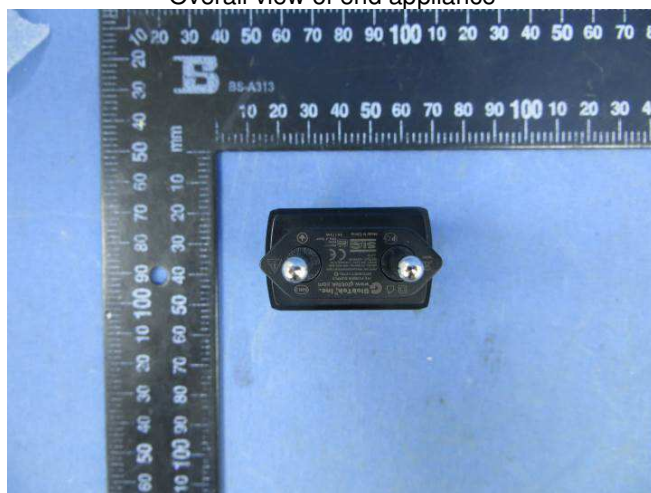
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Clause	Requirement + Test	Result - Remark	Verdict



Overall view of end appliance



Overall view of end appliance



Front view of end appliance

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Clause	Requirement + Test	Result - Remark	Verdict



Rear view of end appliance



Plug portion



Riveting connection for plug portion

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Clause	Requirement + Test	Result - Remark	Verdict

Appendix: Equipment's combined with Australian plug.

The Australian plug was tested according to Annex J of AS/NZS 3112:2011+A1:2012+A2:2013+A3:2016:

AS/NZS 3112:2011+A1:2012+A2:2013+A3:2016

CLAUSE	TITLE/DESCRIPTION	RESULT
SECTION 1	SCOPE AND GENERAL	NOTED
SECTION 2	PLUGS	COMPLIED
2.1	TERMINALS AND INTERNAL CONNECTIONS	COMPLIED
2.1.1	MATERIALS	COMPLIED
2.1.2	CONSTRUCTION OF TERMINALS -riveting terminations	NOT APPLICABLE
2.2	PLUG PINS	COMPLIED
2.2.1	MATERIAL FOR PINS: - Copper alloy containing at least 58% copper for parts made from cold rolled sheet	COMPLIED
2.2.2	ASSEMBLY OF PINS - Assembled in factory and non-rewirable	COMPLIED
2.2.3	FORM OF PIN	COMPLIED
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.	COMPLIED
2.3	INSULATING MATERIALS	COMPLIED
2.3.1	GENERAL	COMPLIED
2.3.2	PLUG BODY - Consisting of PPE+PS which has properties not inferior to those specified in AS 3121 for insulating mouldings having a temperature class of 80°C -Test was performed on the delivered samples	COMPLIED
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	NOT APPLICABLE
2.4	NON-REWIREABLE PLUGS - The conductors are attached to the plug pins by riveting, but without flexible cord in ITE power supply portion.	COMPLIED

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Clause	Requirement + Test	Result - Remark	Verdict

AS/NZS 3112:2011+A1:2012+A2:2013+A3:2016

CLAUSE	TITLE/DESCRIPTION	RESULT
2.5	MEANS OF ENTRY AND CORD ANCHORAGE FOR FLEXIBLE CORD - No such device	NOT APPLICABLE
2.6	RADIO INTERFERENCE SUPPRESSION DEVICES - No such device	NOT APPLICABLE
2.7	FINGER-GRIP	COMPLIED
2.8	RATINGS AND DIMENSIONS OF LOW VOLTAGE PLUGS - Comply with Figure 2.1 (c), rated 10A 250V~. Refer to annex 1 - Distance between live pin and edge of plug moulding more than 9 mm	COMPLIED
2.9	INTERNAL CONNECTIONS	COMPLIED
2.10	ARRANGEMENT OF EARTHING CONNECTIONS - Earth pin complies with Figure 2.1 (c)	COMPLIED
2.11	FUSES - no fuse incorporated	NOT APPLICABLE
2.12	MARKING	COMPLIED
2.12.1	REQUIRED MARKING (It should be checked with end appliance in main test report) - Trademark: - Rated current: - Rated voltage: - Type number:	NOT APPLICABLE
2.12.2	LOCATION OF MARKING - All markings are located on the external body	NOT APPLICABLE
2.12.3	ADDITIONAL REQUIREMENTS FOR REWIREABLE PLUGS - non-rewirable	NOT APPLICABLE
2.12.4	EARTHING CONNECTIONS - non-rewirable	NOT APPLICABLE
2.12.5	LIVE CONNECTIONS - non-rewirable	NOT APPLICABLE
2.12.6	CONFIGURATION OF PLUGS - Figure 2.1 (c), the pin configuration is earth, neutral and active in a clockwise direction.	COMPLIED
2.13	TESTS ON PLUGS	COMPLIED
2.13.1	GENERAL	COMPLIED
2.13.2	INSULATION RESISTANCE TEST - refer to annex 2	COMPLIED

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Clause	Requirement + Test	Result - Remark	Verdict

AS/NZS 3112:2011+A1:2012+A2:2013+A3:2016

CLAUSE	TITLE/DESCRIPTION	RESULT
2.13.3	HIGH VOLTAGE TEST - refer to annex 2	COMPLIED
2.13.4	FLEXIBLE CORD ANCHORAGE TEST – non-rewirable, refer to cl.2.13.12	NOT APPLICABLE
2.13.5	TEST OF EXTERNAL NUT OR CLAMPING RING - no such part	NOT APPLICABLE
2.13.6	ATTACHMENT OF COVERS - no removable covers	NOT APPLICABLE
2.13.7	TUMBLING BARREL TEST - Tumbling barrel test was tested together with end appliance ITE power supply, refer to annex 3 (test according to APPENDIX J).	COMPLIED
2.13.7.2	PIN BENDING TEST - refer to annex 4	COMPLIED
2.13.8	TEMPERATURE RISE TEST – it should be checked with end appliance	NOT APPLICABLE
2.13.9	SECUREMENT OF PLUG	COMPLIED
2.13.9.1	MOVEMENT OF PINS -refer to annex 6	COMPLIED
2.13.9.2	FIXING OF PINS - refer to annex 7	COMPLIED
2.13.10	DETERMINATION OF IP RATING	NOT APPLICABLE
2.13.11	DETERMINATION OF IGNITABILITY AND COMBUSTION PROPAGATION - refer to annex 8	COMPLIED
2.13.12	ADDITIONAL TESTS ON NON-REWIREABLE PLUG AND FLEXIBLE CORD	NOT APPLICABLE
2.13.12.1	GENERAL	NOT APPLICABLE
2.13.12.2	ATTACHMENT OF FLEXIBLE CORD	NOT APPLICABLE
2.13.12.3	ATTACHMENT OF INSULATED CORES	NOT APPLICABLE
2.13.12.4	ATTACHMENT OF SHEATHING (sheathed cords)	NOT APPLICABLE
2.13.12.5	ATTACHMENT OF INSULATION (unsheathed cords)	NOT APPLICABLE
2.13.12.6	ATTACHMENT OF CONDUCTORS	NOT APPLICABLE
2.13.13	ADDITIONAL TESTS ON THE INSULATION MATERIAL OF INSULATED PIN PLUGS - refer to annex 9-13	COMPLIED
SECTION 3	SOCKET-OUTLETS	NOT APPLICABLE

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Clause	Requirement + Test	Result - Remark	Verdict

APPENDIX J EQUIPMENT WITH INTEGRAL PINS FOR INSERTION INTO SOCKET-OUTLETS			
Clause	TITLE/DESCRIPTION	RESULT	Verdict
J1	Scope		-
J2	Requirements for the plug portion		-
J2.1	Definition		-
J2.1.1	Plug portion That portion of equipment with integral pins shown in Figure 2.1, including the plug pins, terminals of the plug pins and external dimensions of the 'maximum projection'.	See annex	P
J2.2	Requirements		-
J2.2.1	General The following provisions apply to the dimensional and constructional requirements of the plug portion of equipment with integral pins. It is not intended that this Appendix apply to equipment with integral pins which are covered by particular product standards however, where such devices have plug portions, these standards may refer to this Appendix, to supplement the requirements contained in those particular product standards.		-
J2.2.2	Plug pins of plug portions The requirements of Clause 2.2 are applicable for plug pins.	See annex	P
J2.2.3	Ratings and dimensions for low voltage plug portions The requirements of Clauses 2.8.1 and 2.8.4 are applicable for ratings and dimensions.	See annex	P
J2.2.4	Internal connections for plug portions The requirements of Clause 2.9 are applicable for internal connections unless requirements are contained in the relevant product standard.		P
J2.2.5	Arrangement of earthing connections for plug portions The requirements of Clause 2.10 are applicable for the arrangement of earthing connections.	Without earthing connection	N/A
J2.2.6	Configuration of plug portions The requirements of Clause 2.12.6 are applicable to the configuration of the plug portion.		P
J2.2.7	Tests		-
J2.2.7.1	General Plug portions of equipment with integral pins shall be subjected to the following tests and unless stated otherwise, shall comply with the requirements specified in Section 2 for each test. The number of test samples shall be in accordance with Table 2.2.	See annex	P
J2.2.7.2	High voltage test The requirements of Clause 2.13.3 are applicable unless requirements are contained in the relevant product standard.	See annex	P
J2.2.7.3	Mechanical strength of pin tests		P

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Clause	Requirement + Test	Result - Remark	Verdict

APPENDIX J EQUIPMENT WITH INTEGRAL PINS FOR INSERTION INTO SOCKET-OUTLETS			
Clause	TITLE/DESCRIPTION	RESULT	Verdict
J2.2.7.3.1	<p>Tumbling barrel test</p> <p>The tumbling barrel test is applied to determine the mechanical strength of the plug pins. Three samples which have not been subjected to any previous test are tested to the requirements of Clause 2.13.7 however, the test is modified for plug portions of equipment with integral pins as follows:</p> <p>A sample of equipment with integral pins is dropped—</p> <p>(a) 500 times if the mass of the specimen does not exceed 250 g. The pins being straightened after 100 drops and at the completion of the test to pass through the appropriate gauge of Figure A1, B1 or F1; and</p> <p>(b) 250 times if the mass of the specimen exceeds 250 g. The pins being straightened after 25 drops and at the completion of the test to pass through the appropriate gauge of Figure A1, B1 or F1.</p> <p>Following each test the samples shall comply with item (e).</p>	See annex Max. 44g(end appliance); Item (a) is applicable	P
J2.2.7.3.2	Pin bending test	See annex	P
J2.2.7.4	<p>Temperature rise test</p> <p>The relevant requirements of Clause 2.13.8 are applicable for the temperature rise test, except that the test current shall be that specified in the relevant product Standard. The temperature rise of the pins shall not exceed 45 K irrespective of the temperature rise of parts specified in end product standards.</p>	It should be checked with end appliance in main test report	N/A
J2.2.7.5	<p>Securement of pins of the plug portion</p> <p>The requirements of Clause 2.13.9 are applicable for the securement of pins.</p>	See annex	P
J2.2.7.6	<p>Tests on the insulation material of insulated pin plug portions</p> <p>The requirements of Clause 2.13.13 are applicable for insulating material of insulated plug pins.</p>	See annex	P
J2.2.7.7	Equipment with integral pins intended to be supported by the contacts of a socket-outlet Equipment with integral pins intended to be supported by the contacts of socket-outlets shall not impose undue strain on those socket-outlets.	<0,25 Nm	P
J2.3	Detachable plug portions		N/A
	Where a plug portion is detachable, compliance shall be established by assessment with the plug portion fully assembled with the equipment.	Non-rewirable	N/A
	Access to live parts shall be assessed for incorrect assembly of the plug portion.		N/A
	It shall not be possible to assemble the plug portion to the equipment resulting in a dangerous situation allowing access to live parts.		N/A
	The plug portion shall not expose live parts prior to assembly.		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

Annex A: Additional requirement of AS/NZS 3100:2009+A1:2010+A2:2012+A3:2014+A4:2015

AS/NZS 3100			
Cl.	Requirement – Test	Result - Remark	Verdict
3	DESIGN AND CONSTRUCTION		P
3.1	General		P
	All equipment shall comply with the provisions of this Standard in respect of selection of materials, design, and construction, and with the tests specified herein.		P
	The selection of materials and the construction of all equipment shall be such that no person will be exposed to risk of injury or electric shock.		P
	There will be no unwarrantable risk of fire either-		P
	(a) through the functioning of the equipment under conditions required by its use at rated loading; or		P
	(b) through the mechanical or electrical failure of any material or of the equipment itself or of any part thereof.		P
3.2	Equipment to be suitable for conditions of use		N/A
	All equipment shall be such that will enable it to be installed in accordance with the National Wiring Rules and will provide protection against mechanical and electrical failure.	Non-rewirable, assembled in factory.	N/A
	Non-hygroscopic insulating materials shall be used where required in individual Standards.		N/A
	Hygroscopic materials may be used for insulation, provided that the materials are suitably treated if liable to exposure to dampness.		N/A
3.3	Selection of materials and parts		P
	Any material or part used in, or in the construction of, any equipment shall comply with any specific requirements set out in respect thereto in this Standard or in an individual Approval and test specification dealing with such materials or parts.		P
	The use of a particular kind of material or part, a material or part of another kind may be used instead, provided that its use		N/A
	- will not introduce any risk of electric shock or fire;		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	- will not render the equipment less resistant to mechanical or electrical failure than would the use of a material or part of the kind prescribed.		N/A
3.4	Selection of components		P
	Any component part that is used in or in the construction of any equipment and which is depended upon for safety shall comply with the appropriate requirements of any relevant individual Approval and test specification.		P
3.5	Workmanship		P
	All fabrication and construction shall be carried out in a thoroughly workmanlike fashion complying with the appropriate requirements of this Standard and the generally accepted principles of sound and safe practice.		P
3.6	Fuses		N/A
3.6.1	Accessibility and shrouding		N/A
	This Clause shall not apply to internal fuses not intended to be replaced other than by appropriate servicing personnel.		N/A
	For all other fuses:		—
	(a) Fuse exposed to view or location clearly indicated by suitable visible marking or by instructional literature.		N/A
	(b) Fuse shall be in an accessible position.		N/A
	(c) Fuse shall be arranged so as to prevent inadvertent contact with:		—
	(i) any part of a fuse that in a compartment accessible for normal routine cleaning; or		N/A
	(ii) live parts, when covers are removed to gain access to any fuse		N/A
	(d) Fuse-links, fuse-contacts and fixed contacts shall be so shielded as to protect against accidental contact with live metal while the fuse-carrier is being inserted or withdrawn.		N/A
3.6.2	Mounting		N/A
	A semi-enclosed fuse that is marked 'R' shall be mounted that no earthed metal is introduced in, or adjacent to, the fusing chamber.		N/A
3.7	Identification of wiring		N/A
	For equipment other than that having a Type Z attachment insulated or covered conductors used as earthing conductors shall be coloured:		—
	(a) green; or		N/A
	(b) green and yellow in the proportions specified in AS/NZS 3191.		N/A
	The colour green in combination with colours covers not less than 30% of the surface of the conductor in any 15 mm length.		N/A
	The single colour green shall not be used to identify any live conductor except:		—

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Clause	Requirement + Test	Result - Remark	Verdict
	(i) where the conductor forms portion of the complex wiring of equipment; or		N/A
	(ii) where it is specified by an individual Approval and test specification.		N/A
3.8	Regulating devices and switches		N/A
3.8.1	Fixing and mounting		N/A
	All regulating devices and switches shall be securely fixed in position.		N/A
	Rotary regulating devices and rotary switches shall be so fixed or located that they cannot turn bodily during operation.		N/A
	No regulating device or switch shall be mounted or marked as to incorrectly indicate the intended contact position.		N/A
3.8.2	Visual indications of positions		N/A
	The different positions of regulating devices and switches may be indicated by visual means.		N/A
	Figures used: the 'off' position shall be indicated by '0' or 'OFF' and the position of any energized state shall be indicated by a higher figure. The figure '0' shall not be used for other indication.		N/A
	Any marking shall be visible when the device or switch is in the corresponding position.		N/A
3.8.3	Voltage and current limitation		N/A
	No regulating device or switch shall operates at voltage exceeding 15% in excess of the rated voltage.		N/A
3.8.4	Switches for transportable machinery		N/A
	Transportable machinery, with moving parts that may cause injury, shall be fitted with a switch that operates in all live conductors and isolates the entire equipment from the supply.		N/A
3.8.5	Switches		N/A
	Any switch shall be a Category 1, 2 or 3 switch comply with AS/NZS 61058 series, in accordance with the conditions occurring in the equipment.		N/A
	A Category 1 switch shall comply with AS/NZS 3133 and its 'off' position shall be marked in accordance with Clause 3.8.2 herein.		N/A
	A Category 2 switch shall comply with AS/NZS 3133 and its 'off' position need not be marked.		N/A
	A Category 3 switch shall satisfy Clauses 13.1(j), 13.3 and 13.4 of AS/NZS 3133 and its 'off' position need not be marked.		N/A
	Where Category 1 and 2 switches control circuits containing motors, they shall be subjected to a further 50 operations with rotors locked and the rate of operation shall be in accordance with Clause 13.3 of AS/NZS 3133.		N/A
	A Category 1 switch shall be used when:		—
	(a) the equipment is intended for connection to the supply by a plug and flexible cord;		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	(b) it is not usual or possible to guard live parts completely against personal contact, because of the intended use and accepted practice with any particular equipment; and		N/A
	(c) the equipment is usually left connected to the outlet socket indefinitely and has no means to indicate whether it is energized or not.		N/A
	For accessories, any single pole switch shall be in the active conductor.		N/A
3.8.6	Electronic regulating devices and switches		N/A
	Electronic thermostats and switches without a mechanical switch in the main circuit may not provide a reliable off-state. Therefore the circuit on the load side shall be considered to be live.		N/A
3.9	Socket-outlets		N/A
	Socket-outlets shall not be permitted in equipment intended for connection by flexible cord except in the following circumstances:		—
	(a) Specifically accepted by an approvals authority where there is little likelihood of cascading equipment resulting in circuit overloading and extension of fault conditions.		N/A
	(b) Permitted by an individual Approval and test specification or by National Wiring Rules.		N/A
	(c) The equipment is basically providing a switching or control function.		N/A
3.10	Equipment intended to be supported by contacts of socket-outlets		N/A
	Equipment having integral pins for insertion into socket outlets shall comply with Appendix J of AS/NZS 3112.		N/A
3.11	Static charge in equipment		N/A
	Attention is drawn to the hazard of shocks caused by the build-up of electrostatic charge in equipment such as hand-held tools. AS/NZS 1020 gives guidance on the control of undesirable static electricity.		N/A
3.12	Control methods		N/A
	For equipment suitable for connection to the supply mains, asymmetrical control of the input current is prohibited in normal use.		N/A
	half-wave rectification directly on the supply mains may be used:		—
	-the controlled active input power does not exceed 100 W; or		N/A
	-the controlled equipment is class II, portable equipment is only operated for short periods of time and the rated power does not exceed 1200W.		N/A
3.13	Stability		N/A
	Freestanding equipment intended to be used on a surface shall have adequate stability and shall be tested in accordance with Clause 8.14.		N/A
3.14	Equipment connected to supply by a plug		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	No risk of electric shock from charged capacitors having a rated capacitance exceeding 0,1 μ F, when the pins of the plug are touched.		N/A
	The voltage shall not exceed 34 V.	Measured:	N/A
3.15	Capacitors		N/A
	Capacitors shall comply with IEC 60384-14;		N/A
	If have to be tested, in accordance with Annex G.		N/A
3.16	Metal Oxide Varistors incorporated in accessories		N/A
	This clause applies to Metal Oxide Varistors ("MOVs") connected to live parts incorporated in accessories.		N/A
	(a) MOVs shall comply with IEC 61051-2.		N/A
	(b) MOVs shall have a maximum continuous voltage rating of:		—
	– at least 1.25 times the rated voltage of the accessory or		N/A
	– at least 1.25 times the upper voltage of the rated voltage range.		N/A
	(c) The body of any MOV shall have a flammability category of V-0 or better according to AS/NZS 60695.11.10.		N/A
	(d) Accessories shall be protected against sudden failure of MOVs. Protection shall be provided by:		—
	– a 10 A maximum rated fuse of adequate breaking capacity, or equivalent, connected in series with the MOV; or		N/A
	– another protective device, provided that the combination complies with a limited shortcircuit test, with the MOV shorted out. The accessory shall be tested in accordance with 9.3.1 of IEC 60127-1:2006, Method A, for breaking capacity of 1500 A. The test result shall be assessed against the criteria of clause 8.15.10.		N/A
	(e) Accessories shall be protected against gradual failure of MOVs. Compliance is checked by the test of clause 8.15.9.		N/A
	Accessories that comply with clauses G10.2 and G10.3 of IEC 62368-1 are deemed to comply with this clause.		N/A
4	PROTECTION AGAINST MECHANICAL AND ELECTRICAL FAILURE		P
4.1	Prevention of short-circuit and arcing		P
4.1.1	General		P
	All terminals, contacts and other live parts shall be so arranged that short-circuit or destructive arcing cannot take place, and that no part other than an easily replaceable contact can be appreciably damaged by an arc or overheating arising from the normal operation.		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Holes for fixing screws shall be so placed that no short-circuit or arcing can occur when the screws are in position.		P
4.1.2	Segregation of internal wiring		N/A
	Where extra-low voltage and low voltage equipment wiring is within the one enclosure and the extra-low voltage wiring or parts connected thereto are accessible to the standard test finger, either of the following requirements or a combination thereof, shall apply:		—
	(a) The extra-low voltage wiring and associated connections shall be effectively separated from low voltage wiring by means of rigidly fixed screens or barriers or by other effective means.		N/A
	(b) The extra-low voltage wiring and exposed parts shall be insulated for the highest voltage and so arranged or fixed that bare extra-low voltage parts cannot come into contact with uninsulated low voltage parts or vice versa.		N/A
	Parts of one voltage system provided with basic insulation shall not come into contact with live parts of other systems.		N/A
	The requirements of Clauses 5.1, 5.2 and 5.3 shall not be applicable to extra-low voltage wiring complying with the requirements of this Clause.		N/A
	Separate external equipment at extra-low voltage, separation from low voltage wiring as in Item (a).		N/A
4.1.3	Creepage distances and clearances for appliances		N/A
	Creepage distances and clearances shall be not less than the values in shown in Table 4.1.		N/A
4.1.4	Additional requirements for appliances		N/A
4.1.4.1	General		N/A
	The requirements in Clauses 4.1.4.2 to 4.1.4.5 are applicable only to appliances.		N/A
4.1.4.2	Printed circuit boards		N/A
	Conductive patterns of printed circuit boards; permitted reduction in distance between live parts of opposite polarity.		N/A
	Further reduction permitted where appliance complies with requirements of clause 8.15 with the distances short-circuited.		N/A
4.1.4.3	Distances through insulation		N/A
	The distance through insulation shall be not less than 1.0 mm for supplementary insulation and 2.0 mm for reinforced insulation.		N/A
4.1.4.4	Insulation in sheet form		N/A
	The requirement in Clause 4.1.4.3 does not apply if the insulation is applied in thin sheet form, other than mica or similar scaly material, and:		—
	(a) for supplementary insulation, consists of at least two layers and each of the layers withstands the electric strength test of Clause 8.4 for supplementary insulation; or	Number of layers:	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	(b) for reinforced insulation, consists of at least three layers and any two layers together withstand the electric strength test of Clause 8.4 for reinforced insulation.	Number of layers:	N/A
4.1.4.5	Supplementary insulation and reinforced insulation		N/A
	The requirement in Clause 4.1.4.3 does not apply if the supplementary or reinforced insulation is inaccessible and meets one of the following conditions:		—
	(a) The maximum temperature rise determined during the tests of Clause 8.15 does not exceed the value specified in Table 5.7.		N/A
	(b) The insulation, after having been conditioned as specified, withstands the electric strength test of Clause 8.4 both at the temperature occurring in the oven and room temperature.		N/A
4.2	Mechanical protection of conductors and cables		P
4.2.1	General		P
	All conductors and cables shall be of such a type or be so located or protected that mechanical or electrical failure is not likely to occur.		P
4.2.2	Adjacent material		P
	Material adjacent to or in contact with conductors shall be so shaped that it will not cause abrasion of conductors or its insulation, braiding or sheathing.		P
4.2.3	Passage for conductors		N/A
	Where conductors and cables are threaded through tubes or channels or passed through openings in metal work:		—
	The tubes, channels or openings of ample size		N/A
	If not bushed, no sharp angles or projecting edges.		N/A
	Conduit ends and other open ends shall be bushed or shaped so as to guard against abrasion.		N/A
	Bushes shall be fixed securely in position.		N/A
4.2.4	Protection near moving parts		N/A
	Equipment wiring near moving parts shall be so located or arranged as to guard against abrasion.		N/A
4.2.5	Unprotected conductors with fibrous insulation		N/A
	Fibrous insulated cables shall be used only where they can be installed without damage, not subjected to undue bending and abrasion, and are protected from mechanical damage.		N/A
4.3	Terminals and connecting facilities for supply conductors		P
4.3.1	Connecting facilities required		P
	All equipment shall be provided with facilities for the connection of supply conductors in one of the following forms:		—
	(a) Terminals.		N/A

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	(b) Contact pins or spring contacts intended to engage with the corresponding contacts of a connector, socket-outlet or cord extension socket.		N/A
	(c) Connection of the conductors, flexible cord or cable to internal leads, terminals, lugs or the like, by crimping or other similar suitable devices.	Riveting	P
	Twist-on connectors with suitable metal inserts may be used for live conductors but not for earthing connections.		N/A
	(d) Soldering may be used for Type X attachments having a rated input not exceeding 250 W and for Type Y and Type Z attachments and shall comply with Clause 4.3.5.		N/A
	No portable equipment shall be provided with facilities for more than one supply flexible cord.		N/A
	Equipment intended for permanent connection to fixed wiring shall be provided with terminals as specified in Item (a).		N/A
4.3.2	Design and construction of terminals		P
	Terminals shall be corrosion-resistant or suitably protected against corrosion.		P
	Terminals designed and proportioned that connections will not loosen or overheat.		P
	Terminals shall be so designed that conductors can be rigidly and effectively clamped between metal surfaces and comply with Clause 4.6.1.		N/A
	Connecting plates shall be in effective electrical contact with the associated terminal in accordance with Clause 4.6.1.		N/A
	Terminals shall be either securely fixed in position within a terminal box or enclosure, or		N/A
	Movement of the connections limited by location in a suitable enclosure, recess, housing or the like.		P
	Screws of tunnel-type terminals shaped and finished so that strands of the conductor are not likely to be severed when the screw is tightened.		N/A
	The clamped surfaces shall have no sharp angles or projecting edges likely to damage conductor		N/A
	For tunnel-type terminals, the hole for pinching screw shall not extend through the conductor-way beneath the clamped conductor.		N/A
	Aluminium conductors shall not be clamped directly by screws in tunnel-type terminals other than special types designed to evenly distribute stress and break the oxide film.		N/A
	Indirect clamping shall be acceptable provided that the clamping means breaks the oxide film.		N/A
	Self-tapping screws shall not be used as a terminal screw for conductors.		N/A
	Die-cast terminal blocks made from zinc-base alloy shall not be used.		N/A
	Terminals for direct connection to fixed wiring permit the supply cables to be connected in accordance with one of the following methods:		—
	(a) Soldered into a cable-socket of appropriate size.		N/A

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	(b) Clamped in a terminal or binding post.		N/A
	(c) Terminated in an approved solderless tag or terminating device.		N/A
4.3.3	Location of terminals		N/A
	The live terminals shall be within a terminal box or an enclosure, and shall be grouped together.		N/A
	Earthing terminal within the terminal box or enclosure or on external surface of equipment adjacent to the terminal box or enclosure.		N/A
	Earthing terminal on the external: provision shall be made for the earthing conductor to pass through an opening to the earthing terminal.		N/A
	Earthing terminal of the quick-connect type shall not be acceptable on the external surface.		N/A
	Equipment except for Type Y or Type Z, the terminal box or enclosure shall allow access to the terminals and replacement of the flexible cord without dismantling the equipment that will disturb the assembly of internal wiring and live parts.		N/A
4.3.4	Terminal arrangements		N/A
	Except for equipment provided with a Type Y or Type Z attachment, the following provisions shall apply:		—
	(a) Supply flexible cord or cable can be disconnected and replaced without removing any internal wiring or connections from the terminals.		N/A
	(b) Clamping of the supply conductor at a terminal shall be independent of the clamping of any internal lead at that terminal, unless		N/A
	Internal lead is anchored to the terminal by means other than the terminal screw.		N/A
	(c) Screwless terminals that require special preparation of conductors shall not be used.		N/A
4.3.5	Soldered connections		N/A
	Facilities for soldered connections shall comply with the following requirements:		—
	(a) Conductors are held in position independently of the soldering.		N/A
	(b) Insulation isn't bridged by excess solder.		N/A
4.3.6	Prevention of slipping or spreading of conductors		P
	Terminals prevent slipping or spreading of conductors or conductor strands.		P
	Except for Type Y or Z attachments, unless it can be readily re-used when connection of the supply flexible cord is renewed.		N/A
4.3.7	Earthing conductors		N/A
	Provision shall be made to ensure that the connection is made without the earthing conductor of the flexible cord being held or pressed against live terminals or other live parts.		N/A
	Provision shall be made for adequate basic insulation of supplementary earthing conductor.		N/A

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4.3.8	Conductors and terminals not to be stressed		N/A
	Conductors shall be so supported and connected to prevent mechanical stress on either the conductors or the terminals to which they are connected.		N/A
4.3.9	Temperature at terminals		N/A
	Conductors or cables connected thereto will not be exposed to temperatures in excess of those permissible where such insulation is relied upon.		N/A
	Connecting cables of heat-resisting type, prominent marking shall be provided adjacent to the terminals.		N/A
4.3.10	Access to terminal devices		N/A
	Terminal devices shall not be accessible without the aid of a tool.		N/A
4.4	Flexible cord and connecting plug		N/A
4.4.1	When required		N/A
	Portable equipment having a rating not exceeding 20A shall be provided with a supply flexible cord, except for:		N/A
	equipment intended for direct insertion into a socket-outlet;		N/A
	or incorporating a Group 3 appliance inlet, or a Group 2 appliance inlet.		N/A
	The flexible cord shall:		—
	(a) comply with AS/NZS 3191;		N/A
	(b) unless varied in the individual test specification, have a length of not less than:		—
	(i) 0.9 m for table top or bench mounted equipment; or		N/A
	(ii) 1.8 m for other equipment.		N/A
	(c) unless varied in the individual Approval and test specification, be not less than:		—
	(i) if elastomer insulated, ordinary duty sheathed flexible cord; or		N/A
	(ii) if polyvinyl chloride insulated, light duty sheathed flexible cord for equipment having a mass not exceeding 3 kg; or		N/A
	ordinary duty sheathed flexible cord for equipment having a mass exceeding 3 kg.		N/A
	(d) be of the appropriate current rating;		N/A
	(e) be correctly wired to a plug of appropriate type complying with AS/NZS 3112; or		N/A
	for equipment with a rating not exceeding 600 W, with a plug socket adaptor complying with AS/NZS 3122;		N/A
	(f) correctly connected to a connector of appropriate type if the equipment incorporates an appliance inlet; or		N/A
	correctly connected to terminals of equipment;		N/A

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	(g) incorporate an earthing conductor where the equipment has earthing facilities; and		N/A
	(h) not incorporate an earthing conductor where the equipment is of the double-insulated type.		N/A
	Polyvinyl chloride insulated flexible cords shall not be used where temperature rise of external metal exceeds 75K during normal use; unless		N/A
	The power supply cord is not likely to touch such metal parts.		N/A
	Tinsel flexible cords and flexible cords with conductors having a nominal cross-sectional area of 0.5 mm ² shall not be used for earthing purposes.		N/A
	Power supply cords shall have a nominal cross-sectional area not less than Table 4.4.		N/A
	Rated current of equipment.....:		N/A
	Nominal cross-sectional area.....:		N/A
4.4.2	Warning notice		N/A
	Equipment with a current rating above 10 A but not exceeding 20 A and provided with flexible cord and plug to a socket-outlet, notice affixed regarding use of socket-outlet with appropriate current rating.		N/A
4.5	Supply connection and external flexible cables and cords		N/A
4.5.1	General		N/A
	Power supply cords shall be assembled by one of the following methods:		—
	(a) Type X attachment.		N/A
	(b) Type Y attachment.		N/A
	(c) Type Z attachment.		N/A
	Type Y or Type Z attachments may be provided in the following circumstances:		—
	(i) Where sealing or encapsulation provides an essential safety feature.		N/A
	(ii) Where the replacement of the flexible cord or flexible cable by the user of the equipment is not intended or is unlikely		N/A
4.5.2	Provision for entry of flexible cord		N/A
	The equipment shall include provision for entry of the flexible cord or cable within its protective covering or sheath.		N/A
	The opening bushed or shaped to minimize abrasion of the protective covering and insulation.		N/A
	A sleeve, guard or other device prevent bending of the supply flexible cord not integral with cord for Type X attachment, unless part of a specially prepared cord available.		N/A
	It shall be fixed in a reliable manner and not incorporated in the cord anchorage device, unless the anchorage device effectively clamp the cord with the sleeve removed.		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
4.5.3	Cord anchorage		N/A
	A suitable means so that the stress on the connecting terminals shall be reduced.		N/A
	Cord anchorage means.....:		N/A
	Tortuous path in equipment with type X attachment shall be clear indicated how cord is fitted.		N/A
	Cord anchorage is obtained by screw bearing on the sheathing of a flexible cord, the assembly shall be no way to damage the flexible cord, the screw shall:		—
	(a) be made of suitable insulating material;		N/A
	(b) have a nominal diameter not less than that of the aperture for the flexible cord; and		N/A
	(c) be so shaped as not to damage the flexible cord.		N/A
	The method shall ensure that necessary insulation will not be damaged.		N/A
	The knotting of a flexible cord shall not be used.		N/A
	Floating-type cord anchorage shall not be used unless it is located in position within terminal compartment, independent of flexible cord.		N/A
	The cord anchorage shall be capable of accommodating a flexible cord of size and type appropriate to the equipment.		N/A
	Cord anchorage capable of accommodating flexible cord that includes an earthing conductor.		N/A
	If the cord anchorage dependent on the relative location of component parts, the arrangement shall prevent inadvertent assembly.		N/A
4.5.4	Protection of supply flexible cord		N/A
	Porcelain beads, heat-resistant sleeving, tubing, taping do not provide insulation or protection on flexible cord with Type X attachment.		N/A
	Beads and similar ceramic insulators on live wires cannot change position or rest on sharp edges.		N/A
	The supply flexible cord against damage from internal moving parts,		N/A
	and internal surfaces having normal excessive operating temperatures.		N/A
4.5.5	Interconnection cables and cords		N/A
	Facilities for the connection of interconnection flexible cables or cords shall comply with the requirements for the supply cable or cord, except that:		—
	(a) connectors and appliance inlets used for the interconnection flexible cable or cord shall not be interchangeable with the connectors and appliance inlets used for the power supply cord, if this might impair compliance; and		N/A
	(b) the cross-sectional area of the conductors of the interconnection flexible cable or cord is determined on the basis of the maximum current during the normal operation tests.		N/A
4.6	Joints and connections		P

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Clause	Requirement + Test	Result - Remark	Verdict
4.6.1	Joints and insulation		P
	Insulation is required on joints or connections, the thickness equivalent to required by Clause 5.2.3.		P
	Joints and connections shall utilize materials and forms of construction that will avoid deterioration or loss of contact pressure in service.		P
	Insulating materials which may shrink or deform in service such as to cause loss of contact pressure not be used; unless		N/A
	- suitably treated or proofed to prevent such shrinkage or deformation; or		N/A
	- metallic parts have sufficient resiliency to compensate for such shrinkage or deformation and to retain adequate contact pressure		P
	Stranded conductors shall not be consolidated by lead-tin soldering where they are subject to contact pressure, unless		N/A
	clamping means is so designed that there is no risk of bad contact due to cold flow of the solder.		N/A
4.6.2	Soldered joints		N/A
	Soldered joints shall be made without the use of fluxes containing corrosive substances.		N/A
4.6.3	Limitations of soldered joints		N/A
	Soft-soldered joints and soft soldering shall not be used for the connection of conductors where the temperature of the joint is likely to exceed 120 °C in normal operation.		N/A
4.6.4	Joints and connections in lighting fittings		N/A
	No joint or connection shall be made within a lighting fitting except in a space incorporated for the purpose.		N/A
4.6.5	Solderless joints		N/A
	Attachment of conductors by crimped or similar solderless pressure joints shall be made only with the use of the appropriate tools.		N/A
4.6.6	Cascading of adaptors		N/A
	Two-way quick-connect tab and receptacle adaptors and the like shall not be cascaded.		N/A
4.7	Strength of screw threads and fixings		N/A
	Components with screw threads and which will be removed or loosened with the aid of a tool for the purpose of connecting supply conductors shall be capable of withstanding the test in Clause 8.7.		N/A
	Single failure permitted if omission of failed component does not impair compliance.		N/A
	Where the screwed component or its fixing is of thermoplastic material, the length of engagement not less than the nominal screw diameter.		N/A
	This Clause shall not be required for equipment with Type Y or Type Z attachments.		N/A
4.8	Space-threaded and thread-cutting screws		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Space-threaded (sheet metal) screws not used for connection of current-carrying parts; unless		N/A
	they clamp directly in contact with each other and provided with suitable means of locking.		N/A
	Thread-cutting (self-tapping) screws not used for the electrical connection of current-carrying parts; unless		N/A
	full-form standard machine screw thread.		N/A
	such screws are likely to be removed or replaced during installation or servicing; unless thread is formed by a swaging action.		N/A
	Thread-cutting and space-threaded screws used to provide earthing continuity:		—
	not necessary to disturb the connection in normal use and at least two screws are used for each connection.		N/A
4.9	Direct connection to fixed wiring		N/A
	Equipment for direct connection to the supply circuit wiring shall comply with the following:		—
	(a) Provision shall be made for the entry of insulated conductors within their conduit, sheathing or other protective covering.		N/A
	(b) Terminals provided for conductor connection		N/A
	shall be fixed in position		N/A
	and shall be grouped together, except that the earthing terminal may be located adjacent.		N/A
	(c) live terminals shall be marked in accordance with Clause 7.6.		N/A
	(d) Terminals of a heating element or thermostat shall not be used as a means for the connection of supply conductors.		N/A
4.10	Mechanical strength		P
	Equipment shall have adequate mechanical strength and be so constructed as to withstand rough handling in normal use.	Performed on the delivered samples only, it will be checked with end appliance with various materials in main test report	P
	The equipment shall withstand the tests of Clause 8.8.		P
4.11	Degree of protection (IP classification)		N/A
	Equipment marked with IP rating shall comply with the appropriate requirements of AS 60529.	IP20	N/A
	For equipment assigned with a second characteristic numeral greater than 0, the equipment shall withstand the tests of Clause 8.4.		N/A
5	PROTECTION AGAINST RISK OF ELECTRIC SHOCK		P
5.1	Guarding of live parts		P
	No contact with live parts using test finger of fig.8.10.		P

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Clause	Requirement + Test	Result - Remark	Verdict
	No contact with live parts using test pin with force of 10N through openings in enclosures giving access to preset control.		N/A
	Covers relied upon to prevent inadvertent personal contact with live parts shall be fixed that a tool is necessary to remove them.		N/A
	A slot that will accept a coin is regarded as intended to accommodate a tool for the purpose of this Clause.		N/A
	The opening or removal of cover or component shall not expose live parts to inadvertent personal contact.		N/A
	If manufacturers instruct user to remove covers or components for maintenance, this shall not expose live parts to inadvertent personal contact.		N/A
	Metal cover or casing enclosing live parts shall be of a strength sufficient to ensure that it cannot be deformed readily to contact with live parts.		N/A
	Edison-type screw lampholders shall be provided with adequate shielding facilities appropriate to the type of lamp used.		N/A
5.1.1	Class II construction		P
	Class II equipment and class II constructions adequately protection against accidental contact with basic insulation and metal parts separated from live parts by basic insulation only.		P
	Only possible to touch parts separated from live parts by double insulation or reinforced insulation.		P
5.2	Insulation of live parts		P
5.2.1	General		P
	Live parts of electrical equipment shall be adequately insulated and supported and shall comply with the following:		—
	(a) Clauses 8.3 and 8.4 of this Standard.		P
	(b) Specified requirement for insulation thickness.		P
5.2.2	Separation of live parts from non-current-carrying conductive parts		P
	No live part can make contact with any non-current-carrying conductive part exposed to personal contact.		P
	Adequate clearances provided from terminals of components and connected conductors.		P
5.2.3	Equipment wiring		N/A
5.2.3.1	General requirements		N/A
	Where equipment wiring is insulated to comply with Clauses 5.1, 5.2.1 and 5.2.2, such insulation shall be of a grade appropriate to the voltage.		N/A
	Insulants covered by this Standard shall comply with:		—
	(a) the thickness requirements of Clauses 5.2.3.2 or 5.2.3.3; or		N/A
	(b) the thickness requirements of AS/NZS 3191.		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	For other insulation, the suitability verified by electric strength test of 2000 V for 15 min.		N/A
5.2.3.2	Specific requirements – PVC insulation		N/A
	Specific requirements for wiring with PVC insulation are as follows:		—
	(a) For internal equipment wiring and accessible equipment wiring not subject to flexing or damage:		—
	(i) Average aggregate thickness between any two live conductors and between any live conductor and exposed metal shall be no less than 0.5 mm.	Measured:	N/A
	The minimum aggregate thickness shall be no less than 0.35 mm.	Measured:	N/A
	Insulating sleeving shall be a close fit or shall be securely fixed in position.		N/A
	(ii) Flexible cords with V70, V75 and V90 insulants may have a maximum operating temperature of 80 °C, 95 °C and 100 °C, when used as internal wiring not subjected to flexing.		N/A
	(b) For accessible equipment wiring subject to flexing or damage, or external equipment wiring of 250 V grade:		—
	Average aggregate thickness shall be no less than 0.8 mm.		N/A
	Minimum thickness shall be not less than 0.6 mm.		N/A
5.2.3.3	Specific requirements – fibrous insulation		N/A
	The thickness of 250 V grade fibrous insulation shall comply with AS 3158 or AS/NZS 3191.		N/A
5.2.4	Arrangement of equipment wiring		N/A
	Support and fixing of equipment wiring shall ensure that live parts cannot become exposed to personal contact by protruding through an opening without contacting with exposed metal.		N/A
5.3	Earthing facilities		P
5.3.1	Exposed metal parts to have means of earthing		N/A
	Exposed metal parts shall be in good electrical contact with a common earthing facility.		N/A
	For combination gas-electric equipment, main metallic gas pipe bonded to the earthing terminal.		N/A
	Metal parts coated with porcelain enamel, paint or similar not earthed by contact with coated surface.		N/A
	The coating of metal parts with porcelain enamel is not acceptable alone as justification of absence of earthing of such parts.		N/A
	Flexible metallic conduit or tubing enclosing the conductors between movable component parts shall not be relied upon for earthing purposes.		N/A
5.3.2	Method of making the earth connection		N/A
	Facilities for earthing shall take one of the following forms:		—
	(a) A terminal suitable for the attachment of an earthing conductor.		N/A
	(b) The earthing contact of an appliance inlet.		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	(c) Other approved means(specify).		N/A
	Constructional bolt, stud, or screw may be used as the earthing terminal only if all the following conditions are observed:		—
	(i) Earthing conductor can be removed from the terminal without reducing the effectiveness of the bolt, stud or screw as a constructional medium.		N/A
	(ii) Removal of any covers, or parts to access terminals, shall not disturb or reduce the effectiveness of the earthing connection.		N/A
	(iii) Bolt, stud or screw is not used for fixing the equipment in position or for adjusting the position.		N/A
5.3.3	Design and construction of earthing terminal		N/A
	Earthing terminal shall be capable of accommodating appropriate internal earthing conductor and supply earthing conductor.		N/A
	Current-carrying capacity of earthing terminal not less than that of connected earthing conductors.		N/A
5.3.4	Resistance of earthing connection		N/A
	Resistance shall not exceed 1Ω for readily accessible parts that rotate, reciprocate or oscillate; and		N/A
	Not exceed 0.1Ω in all other cases.		N/A
	Measured resistance.....: Measured:		N/A
5.3.5	Printed conductors		N/A
	Printed conductors of printed circuit boards shall not be used to provide earthing continuity in hand-held equipment.		N/A
	Printed conductors used to provide earthing continuity in other equipment if:		—
	at least two tracks are used with independent soldering points; and		N/A
	compliance with Clause 8.4 for each circuit.		N/A
5.4	Equipment with double insulation		P
5.4.1	General		N/A
	(a) Equipment having metal parts that can be touched and separated from live parts by insulation is considered to be double insulation.		N/A
	(b) Equipment having metal parts that can be touched and intentionally connected to live parts through a protective impedance shall be separated by double insulation or reinforced insulation.		N/A
5.4.2	Supplementary insulation		N/A
	Supplementary insulation shall consist of suitable non-hygroscopic insulating materials possessing adequate mechanical strength and shall comply with the test requirements in Clause 8.4.3.		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Supplementary insulation in the form of coverings, linings and the like securely fixed in position and maintain its position and insulating properties under any conditions in service.		N/A
	Effectiveness of supplementary insulation not impaired in the event of failure of the basic insulation due to a fault condition.		N/A
5.4.3	Basic insulation		P
	Basic insulation shall consist of suitable material possessing adequate mechanical strength and shall comply with the test requirements specified in Clause 8.4.3.		P
5.4.4	Reinforced insulation		P
	Single layer of insulation may be accepted as affording equivalent protection under the following conditions:		—
	(a) Single layer of reinforced insulation shall be of non-hygroscopic insulating material possessing adequate mechanical strength.		P
	(b) Insulation suitable for application		P
	(c) Precautions taken to guard against accidental bridging of the insulation.		P
	(d) Insulation comply with Clause 8.4.3.		P
5.4.5	External metal parts		N/A
	No external metal other than the parts listed in Items (b) to (d) of Clause 2.1.23.		N/A
5.4.6	Detachable covers		N/A
	The removal of any covers that are detachable without the use of tools shall not expose to personal contact:		—
	(a) live parts;		N/A
	(b) metal parts separated from live parts by basic insulation; or		N/A
	(c) the surface of basic insulation.		N/A
5.4.7	Arrangement of equipment wiring		N/A
	Precautions shall be taken in the support and fixing of equipment wiring to ensure:		—
	(a) Live parts cannot come into contact with supplementary insulation or external metal parts or become exposed.		N/A
	(b) Basic insulation cannot come into contact with external metal parts.		N/A
	(c) Basic insulation cannot become exposed to personal contact by protruding through an opening.		N/A
5.4.8	Insulation of internal wiring		N/A
	Average aggregate thickness of basic insulation between any two live conductors not less than 0.5 mm.	Measured:	N/A
	Average aggregate thickness of supplementary insulation not less than 0.6 mm.	Measured:	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Aggregate thickness of insulation shall be not less than 0.35 mm; and	Measured:	N/A
	Not less than 0.44 mm for basic and supplementary insulation respectively.	Measured:	N/A
	Insulating sleeving securely fixed in position.		N/A
	Insulation thickness complying with AS/NZS 3191 is deemed to be satisfactory.		N/A
5.4.9	Openings in external metal walls		N/A
	Insulating bush shall be securely fixed in the opening and shall comply with Clause 8.4.3 for supplementary insulation.		N/A
5.4.10	Radio interference suppression devices		N/A
	No radio interference suppression device shall be connected between live parts and external metal parts of double-insulated equipment.		N/A
	Radio interference capacitor connected between live parts and internal metal parts shall have a capacitance not exceeding 0.05 μ F.		N/A
5.5	Extra-low voltage equipment		N/A
	Clauses 5.1, 5.2 and 5.3 shall not apply to equipment rated at extra-low voltage, except that d.c. equipment rated above 50 V shall be capable of withstanding high voltage test in Clause 8.4.		N/A
	If extra-low voltage wiring or parts connected are accessible to the standard test finger without the use of tools, they shall be connected to a safety extra-low voltage supply.		N/A
5.6	Switches in portable heating appliances		N/A
	Switch controlling an element that is accessible to personal contact shall open all live conductors connected to the element; or		N/A
	A single-pole switch may be used under the following conditions:		—
	(a) If it controls only a portion of the element, the remaining portion of which is not controlled and is open to view and is luminous when energized.		N/A
	(b) If it controls only a portion of the element, the whole of which is controlled by a switch opening all live conductors and if the portion not controlled is open to view and is luminous when energized.		N/A
5.7	Temperature rises for components and insulating material		N/A
	The temperature rises shall not exceed the values specified in Table 5.7	See summary of testing on page 2	N/A
5.8	Fault-indicating devices		N/A
	Fault indicating device, other than a circuit-interrupting device, constructed that a defect shall not give rise to a false indication.		N/A
	Device indicate dangerous potential shall indicate when potential difference reaches predetermined voltage which shall not exceed 32 V r.m.s.	Measured:	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	External metal parts of such devices not reaching potential exceeding 32 V r.m.s, or that a leakage current cannot in excess of 2 mA.	Measured:	N/A
5.9	Fixing of handles, knobs, or the like		N/A
	Handles, knobs, grips, levers, or the like, shall be fixed so they will not work loose.		N/A
	Handles, knobs, or the like, used to indicate the position of switches or similar components, shall not be possible to be fixed in a wrong position.		N/A
	Compliance is checked by inspection and manual test:		—
	(a) If the shape is such that an axial pull is unlikely to be applied, the force is		—
	(i) 15 N for actuating members of electrical components; and		N/A
	(ii) 20 N in other cases.		N/A
	(b) If the shape is such that an axial pull is likely to be applied, the force is		—
	(i) 30 N for actuating members of electrical components; and		N/A
	(ii) 50 N in other cases.		N/A
7	MARKING (It should be checked with end product in main test report)		N/A
7.1	All equipment shall be marked:		N/A
	(a) Trade name or mark of manufacturer or of the responsible vender.....:		N/A
	(b) Rating (A / V / or W).....:		N/A
	(c) Symbol for nature of supply.....:		N/A
	(d) Type reference or a catalogue number.....:		N/A
	(e) Degree of protection.....:		N/A
7.2	Method of marking		N/A
	Marking required under Items (a), (b), (c), (d), (e) and (f) of Clause 7.1 shall be legible.		N/A
	Indications for switches, thermostats, thermal cut-outs and other control devices shall be placed in the vicinity of these components, not be placed on removable parts.		N/A
7.3	Double marking		N/A
	If any equipment is to be marked with its load in watts and is marked with more than one voltage but only one wattage:		—
	The marked wattage shall correspond to the wattage measured at the highest marked voltage.		N/A
7.4	Marking of earth connections		N/A
	The provisions of this Clause shall apply to all equipment except that which has a Type Z attachment:		—
	The earthing terminal shall be identified		N/A
	This marking may be supplemented by other identifying features.....:		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	The marking shall not be used to identify anything other than an earthing terminal or facility.		N/A
7.5	Marking of class II equipment		N/A
	For all class II equipment, other than accessories, shall be identified by.....: Accessories		N/A
7.6	Marking of live supply connections		N/A
	Where it is necessary to mark and identify live supply connections:		—
	(a) For active connections.....:		N/A
	(b) For neutral connections.....:		N/A
	Marking as above shall not be used other than to indicate live connection.		N/A
7.7	Additional marking of multi-rated equipment		N/A
	The equipment shall be marked with the following information:		—
	(a) Instructions which clearly indicate how the equipment is to be converted to any higher rating.		N/A
	(b) Details for fitting the correct type of supply flexible cord and plug and the appropriate socket-outlet to be used for each rating exceeds 10A.		N/A
7.8	Equipment with type X, type Y and type Z attachments		N/A
	The instructions shall contain the substance of the following:		—
	(a) Type X attachment, if the supply cord is damaged, it shall be replaced by a special cord or assembly available from the manufacturer or its service agent.		N/A
	(b) Type Y attachment, if the supply cord is damaged, it shall be replaced by the manufacturer or its service agent.		N/A
	(c) Type Z attachment, the supply cord cannot be replaced.		N/A
7.9	Legibility of marking		N/A
	Test of marking shall be performed according to Clause 8.13.		N/A
7.10	Instructions for installation and use		N/A
	Special precautions when installing or using equipment, details shall be given in an instruction sheet and accompany the equipment.		N/A
8.15.8	Equipment incorporating electronic components		N/A
	Equipment operated at rated input with simulated component faults		N/A
8.15.9	Equipment incorporating MOVs		N/A
	This test is applied if required by clause 3.16(e).		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	If the voltage rating of a MOV connected to live parts is such that it will conduct at twice the maximum rated voltage of the accessory, ($2 V_r$) or lower, the accessory and a test resistor R_x connected in series with the mains supply to the accessory is energized from an a.c. source of $2 V_r$.		N/A
	Components in parallel with the MOV that may be affected by this test shall be disconnected. The test shall be performed with $R_{X(1)} = 2 V_r / 0.125$.		N/A
	If the circuit does not open, the test shall be continued for 4 h, then repeated with lower values of R_x in turn, until the circuit opens: $R_{X(2)} = 2 V_r / 0.5$, $R_{X(3)} = 2 V_r / 2.5$, $R_{X(n)} = R_{X(n-1)} / 2$, half the previous value, etc.		N/A
8.15.10	Test results		N/A
	Equipment shall not emit flames, molten metal, poisonous or ignitable gas in hazardous amounts.		N/A
	Enclosure shall not deform to such an extent that compliance is impaired.		N/A
	Temperature rises shall not exceed the values in table 8.15.10		N/A
	After tests, the insulation of equipment other than Class III, shall withstands the electric strength test in clause 8.4 with the test voltage:		—
	(a) basic insulation: 1000V		N/A
	(b) supplementary insulation: 2750V		N/A
	(c) reinforced insulation: 3750V		N/A
A	Annex A; SECTION 6: RESISTANCE TO HEAT, FIRE AND TRACKING		P
A 6.1	Resistance to fire		P
A 6.1.1	General requirements for compliance of solid insulating materials and non metallic enclosures:		P
	Compliance of solid insulating materials and non metallic materials of electrical accessories is checked by A 6.1.2 to A 6.1.7.		P
	Burning droplets or glowing particles do not escape from the equipment and ignite the tissue paper or scorch the particle board underlay.		P
A 6.1.2	Materials and tests		P
	Tests are carried out on solid insulating materials and non metallic enclosure whilst assembled on a complete end product.		P
	Tests are not carried out on decorative trims, insulation of wires, knobs and other small parts unlikely to be ignited or to propagate flames originating from inside the equipment.		P
A 6.1.3	Glow-wire tests on relevant parts		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Relevant parts, other than those in A 6.1.4 are subjected to the glow-wire test of AS/NZS 60695.2.11 at 650 °C; unless		N/A
	Otherwise specified in relevant product standard.		N/A
	Glow-wire test is not carried out on material classified at least HB40 for correct thickness.		N/A
A 6.1.4	Glow-wire tests on retaining parts		P
	Parts of insulating material retaining current carrying parts carrying more than 0.2A, subjected to the glow-wire test at temperature 'T' specified	(see appended table in annex)	P
	Temperature 'T'	750°C (for enclosure, performed on the delivered samples only, it will be checked with end appliance with various materials in main test report)	—
	Parts tested withstand the glow-wire test, but produce a flame that persists for longer than 2 s, consequential needle flame test of A 6.1.5 applies.		N/A
A 6.1.5	Consequential needle flame test		N/A
	a) Needle-flame test of A 6.1.7 is applied to all parts of non-metallic material likely to be ignited by and positioned within a distance of 50 mm of those parts that flamed during the glow-wire test of A 6.1.4.		N/A
	b) Needle-flame test of A 6.1.7 is applied to those parts contacted by the flame, outside the 50mm, subjected to burning droplets or glowing particles during the glow-wire test of A 6.1.4.		N/A
	c) Needle-flame test of A.6.1.7 is applied to those parts contacted by the flame or subjected to burning droplets or glowing particles during the needleflame test of A 6.1.5 b).		N/A
	Needle-flame test is not carried out on parts of material classified as V-0 or V-1 provided that the test sample was no thicker than the relevant part.		N/A
A 6.1.6	Needle flame tests on printed circuit boards		N/A
	Base material of printed circuit boards is subjected to the needle-flame test of A 6.1.7.		N/A
	The test is not carried out:		—
	i) on printed circuit boards in a metal enclosure that confines flames or burning droplets;		N/A
	ii) if the material is classified as V-0 for correct thickness.		N/A
A 6.1.7	Needle-flame test method		NOTED
A 6.2	Temperatures of surfaces to be handled		N/A
	The temperature rise shall not exceed the values specified in Table 5.7.	It should be checked with end product in main test report	N/A
A 6.3	Resistance to tracking		N/A

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

	Insulating material shall have adequate resistance to tracking, taking into account the severity of its duty conditions.		N/A
	For parts of insulating material used under severe duty conditions, the test voltage is 175 V.		N/A
	For parts of insulating material used under extra-severe duty conditions, the test voltage is 250 V.		N/A

APPENDED TABLES OF RESULTS OF AS/NZS 3100:

8.15.8	TABLE: Equipment incorporating electronic components fault tests		N/A
	Test voltage:		
	component	fault	result

8.15.10	TABLE: abnormal operation, temperature rise measurements		N/A
	Measured part	Measured (K)	Allowed (K)

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

INSULATING MATERIALS TEST IN ACCORDANCE WITH AS 3121: 2002		
7.1	General	COMPLIED
7.2	<p>Resistance to heat test</p> <p>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°C.</p> <p>The temperature of the oven during this period shall not vary by more than $\pm 5^{\circ}\text{C}$. The moulding shall show no physical or chemical change likely to impair the safety of the equipment of which it forms a part.</p>	COMPLIED
7.3	<p>Water absorption test</p> <p>The complete moulding shall be immersed in water at $20^{\circ}\text{C} \pm 5^{\circ}\text{C}$ for 48 h. The moulding shall not swell, 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>	COMPLIED
7.4	<p>Resistance to white spirit test</p> <p>sample shall be immersed in white spirit at room temperature for 2 min.</p> <p>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>	COMPLIED

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

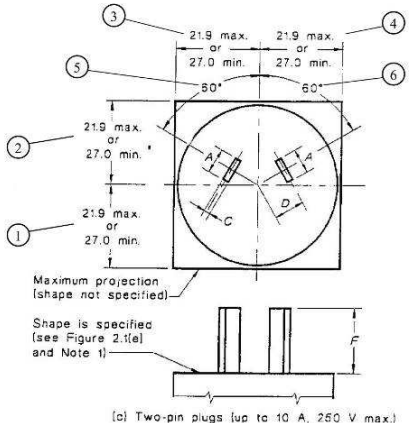
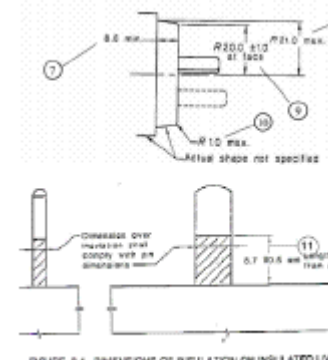
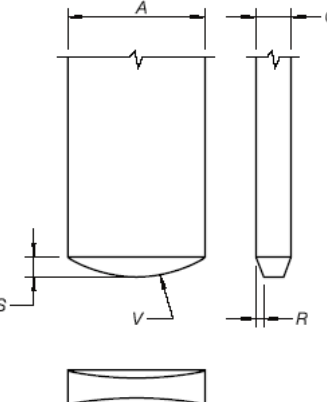
TEST RESULTS:

AS/NZS 3112:2011+A1:2012+A2:2013+A3:2016

ANNEX 1

CHECKING OF DIMENSIONS

Dimensions checked by gauge and measurement

<div> <div> <p>Standard sheet Figure 2.1 (c)</p>  <p>(c) Two-pin plugs (up to 10 A, 250 V max.)</p> </div> <div> <p>Standard sheet Figure 2.1 (e)</p>  <p>FIGURE 2.4 DIMENSIONS OF INSULATION ON INSULATED LIVE</p> </div> <div> <p>Standard sheet Figure 2.1 (h)</p>  </div> </div>			
Position	Required(mm)	By Measurement (mm)	By the gauge shown in Figure A1
A	6.35±0.15	6.38	-
B	6.35±0.15	-	N/A
C	1.63 ^{+0.15} _{-0.05}	1.65	-
D	7.92	-	OK
E	10.31	-	OK
F	17.06±0.4	17.13	-
G	19.94±0.8	-	N/A
P	4.75±0.05	-	-
R	0.35±0.05	0.36	-
S	0.90±0.10	0.95	-
T	≥0.60	-	-
V	6	-	OK
1	21.9 max. or 27.0 min.	9.0	-
2	21.9 max. or 27.0 min.	15.6	-
3	21.9 max. or 27.0 min.	19.9	-
4	21.9 max. or 27.0 min.	19.9	-
5	60°	-	OK
6	60°	-	OK
7	8.6 min.	>8.6	-
8	21.0 max.	<21.0	-
9	20.0±1.0	-	N/A
10	1.0 max	<1.0	-
11	8.7±0.5	8.7	-
Live pin to the edge of the mouldings	9min	>9.0	-

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

TEST RESULTS:

AS/NZS 3112:2011+A1:2012+A2:2013+A3:2016

ANNEX 2

RESULTS OF INSULATION RESISTANCE TEST AND HIGH VOLTAGE TEST

Tested parts	Insulation Resistance at 500V d.c. (required $\geq 5 \text{ M}\Omega$)	High voltage	
		Test voltage (V a.c.)	Failure?
(a) Between all poles of the plug, taken in pairs.	> 199M Ω	1000	No
(b) Between live poles and any external metal, all live poles being connected together.	N/A	N/A	N/A
(c) Between live poles and earthing terminal metal of exposed metal, all live poles being connected together.	N/A	N/A	N/A
(d) Between live poles and accessible insulating part, all live poles being connected together.	> 199M Ω	3500	No
(e) For insulated pin plugs, between live poles and a metal foil applied around the insulation on each live pin for a distance of approximately 4 mm from plug face, all live poles being connected.	> 199M Ω	1250	No

ANNEX 3

RESULT OF TUMBLING BARREL TEST (also refers to Appendix J)

Requirement	Test result		
	Sample 1	Sample 2	Sample 3
After 1000 times of falls, the sample shall show no damage within the meaning of this standard.	N/A	N/A	N/A
(a) Live parts shall not have become exposed to the standard test finger.	N/A	N/A	N/A
(b) For earthing pin, the resistance of the plug/socket-outlet circuit shall be such that compliance with Clause 3.14.7 is maintained.	N/A	N/A	N/A
(c) Any other function affecting safety shall not be impaired.	N/A	N/A	N/A
(d) No live part shall have become detached or loosened, to the extent that a hazardous situation is created.	N/A	N/A	N/A
(e) The pins shall be inspected with normal, or corrected to normal, vision. Insulation may be removed if necessary. Pins shall not be broken or show cracking.	OK	OK	OK

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

TEST RESULTS:

AS/NZS 3112:2011+A1:2012+A2:2013+A3:2016

ANNEX 4

PIN BENDING TEST

Test condition: bend the pins with 20 cycles according to standard			
Requirement	Test result		
	Sample 1	Sample 2	Sample 3
After the tests the pins shall be inspected with normal or corrected to normal vision. The pin shall not be broken off.	OK	OK	OK

ANNEX 5

RESULT OF TEMPERATURE RISE TEST

Test current ($1.1 \times I_n$): N/A	
Tested part	Test result
Temperature rise on termination 1 (K):	
Temperature rise on termination 2 (K):	

ANNEX 6

MOVEMENT OF PINS

Test condition: Preconditioned at 40°C for 1 h; Applied a force of 18 N gradually in 10 s and maintained for 10 s.	
Requirement	Test result
The maximum deflection shall not exceed 2.0 mm.	< 1 mm
The plug can still be inserted in the standard gauge shown in Appendix A.	OK

ANNEX 7

FIXING OF PINS

Test condition: Heated to 50°C for 1 h; Applied a force of 60 N gradually in 10 s and maintained for 10 min.			
Requirement	Test result		
	Pin 1	Pin 2	Earthing Pin

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

TEST RESULTS:

AS/NZS 3112:2011+A1:2012+A2:2013+A3:2016

Any pin shall not be displaced relative to the adjacent material of the body by more than 2.4 mm at any time during these tests	< 1 mm	< 1 mm	N/A
Any pin shall return to within 0.8 mm of its nominal length specified in Figure 2.1 (a1) within 5 min of the removal of the test force	< 0.6 mm	< 0.6 mm	N/A

ANNEX 8

GLOW WIRE TEST

Tested parts	Test temperature (°C)	Ignition of tissue paper?	Scorching of pinewood board?	Visible flame?	Extinguish within 30 s after removal of the glow wire?
Enclosure	750	No	No	No	-

ANNEX 9

RESULT OF PRESSURE TEST AT HIGH TEMPERATURE

Test condition: heating at 160°C for 2h, applied a force of 2.5N through the blade to the specimen			
Requirement	Test result		
	Before test	After test	verdict
The thickness within the area of impression shall be not less than 50% of the thickness measured before the test.	0.30mm	0.25mm	OK
No cracks on the insulation material.	OK	OK	OK
The dimension of the insulating material shall not have changed below the minimum size shown in fig2.4	1.65mm/ 6.38mm /8.7mm	1.61mm/ 6.34mm /8.4mm	OK

ANNEX 10

STATIC DAMP HEAT TEST

Test condition: two damp heat cycles (12+12h), 95% relative humidity, Lower temperature 25±3°C and upper temperature 40°C	
Requirement	Test result
after this treatment and after recovery to room temperature, this specimen shall be subjected to-	
(a) the insulation resistance test	OK

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

TEST RESULTS:

AS/NZS 3112:2011+A1:2012+A2:2013+A3:2016

(b) high voltage test	OK
(c) abrasion test	OK

ANNEX 11
LOW TEMPERATURE TEST

Test condition: maintained at $-15 \pm 2^{\circ}\text{C}$ for 24h and returned to room temperature	
Requirement	Test result
after this treatment and after recovery to room temperature, this specimen shall be subjected to-	
(a) the insulation resistance test	OK
(b) high voltage test	OK
(c) abrasion test	OK

ANNEX 12

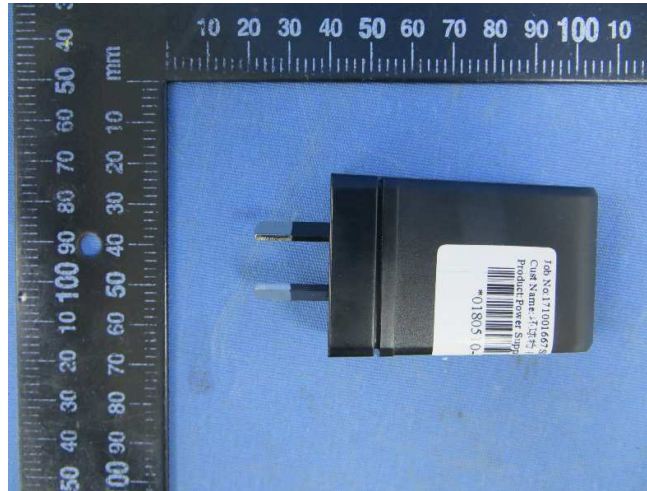
IMPACT TEST AT LOW TEMPERATURE

Test condition Test temperature ($^{\circ}\text{C}$): -15 Duration: 24 hours	Test result
Requirement	
After the test the specimen shall show no damage within the meaning of this standard	OK

ANNEX 13
ABRASION TEST

Test condition: 20000 movements, 30 movements per min.	
Requirement	Test result
After the test,	
The pins shall show no damage which may affect safety or impair the further use of the plug	OK
The insulating sleeve shall not have punctured or rucked up.	OK

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



Overall view of end appliance



Lateral view of end appliance



Rear view of end appliance

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



Plug pins



Riveted connection for plug portion

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

Appendix: Equipment combined with NEMA 1-15 plug portion.

KEY:

√	= Complies.	G	= General comment
E	= Further evaluation required	N/A	= Not applicable
E√	= Once "E" is found acceptable	T	= Testing required
F	= Non-compliance	TF	= Test failed

Section	Key	Comment
FORWARD		
Introduction		
1		Scope
1.1-1.4	G	The device under evaluation is an integrated plug for model GT*41134-***-*** input rating 100-240V~, 50-60Hz, 0.6A and model GT-41134-0606-W2-TAB input rating 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

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

Section	Key	Comment
		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
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

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

Section	Key	Comment
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
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

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

Section	Key	Comment
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
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

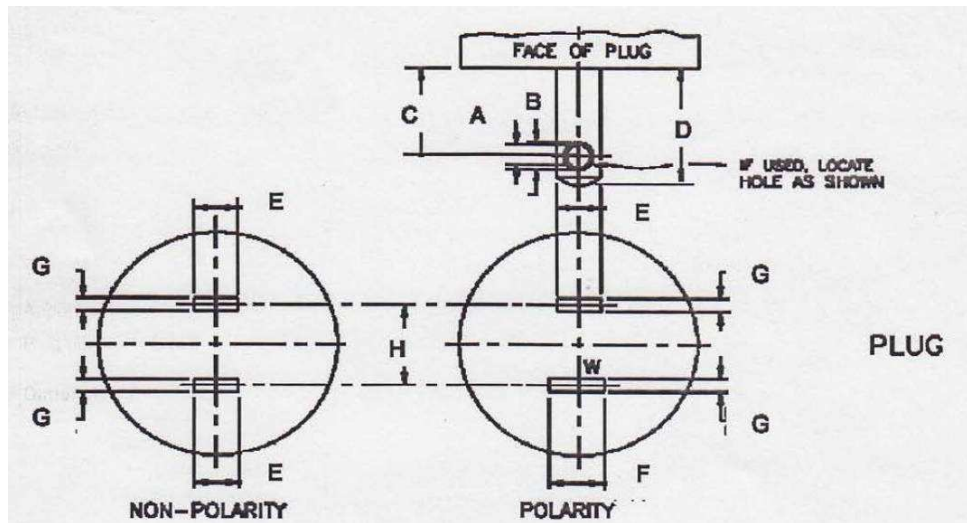
IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
Section	Key	Comment		
62		Insulation Resistance Test		
62.1-62.6	T	Refer to data sheet		
63		Conductor Secureness Test		
63.1-63.2	N/A	No wire leads provided.		
64		Tightening Torque Test		
64.1-64.2	N/A	Not provide any wire-binding screw		
	N/A	ATTACHMENT PLUGS		
65		General		
65.1	G	Noted.		
66		Security of blades test		
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				

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

Section	Key	Comment
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
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			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix: Dimensions of NEMA 1-15 plug portion



Symbol	Requirement (inch)	Measured (inch)	Symbol	Requirement (inch)	Measured (inch)
A	0.120 – 0.130	0.123	E	0.240 – 0.260	0.248
B	0.151 – 0.161	0.157	F	0.307 – 0.322	--
C	0.449 – 0.479	0.466	G	0.055 – 0.065	0.057
D	0.625 – 0.718	0.656	H	0.495 – 0.505	0.498
Perimeter faces to the plug blades shall not be less than 7.9 mm (intended for use with children's toys) or 5.1 mm from any point of either blade					12.39

For model GT-41134-0606-W2-TAB

Symbol	Requirement (inch)	Measured (inch)	Symbol	Requirement (inch)	Measured (inch)
A	0.120 – 0.130	0.124	E	0.240 – 0.260	0.251
B	0.151 – 0.161	0.159	F	0.307 – 0.322	--
C	0.449 – 0.479	0.465	G	0.055 – 0.065	0.058
D	0.625 – 0.718	0.676	H	0.495 – 0.505	0.498
Perimeter faces to the plug blades shall not be less than 7.9 mm (intended for use with children's toys) or 5.1 mm from any point of either blade					9.9

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

Appendix: Photos for NEMA 1-15 plug portion.



The connector conduct part can't be touched by test finger. CI & CR are measured according to table 2.10.3 & 2.10.4.

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

Appendix: Equipment combined with BS-plug portion

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

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

Clause	Requirement - Test	Result-Remark	Verdict
	For non-solid pins, compliance shall be checked by 12.11.4.2.		N/A
	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 \pm 10% for 60 \pm 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 \pm 5/0 S to a pull of 100 \pm 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°C \pm 5°C 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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
Clause	Requirement - Test	Result-Remark	Verdict
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
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 $1\text{N.m} \pm 10\%$ 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

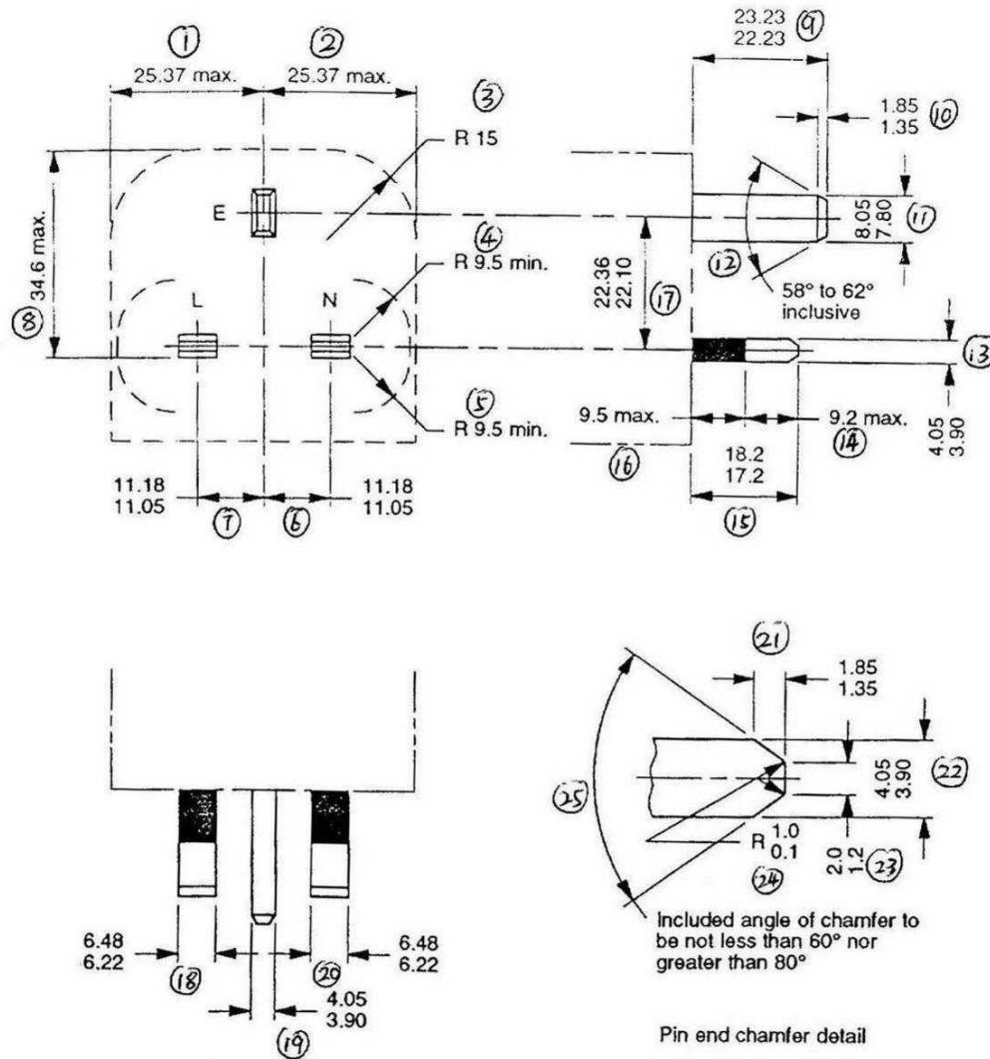
IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix: Dimensions of BS1363 plug portion

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 gauge	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°-62° inclusive	60°	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°-80° inclusive	68°	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			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix: BS1363-3 Fig 4



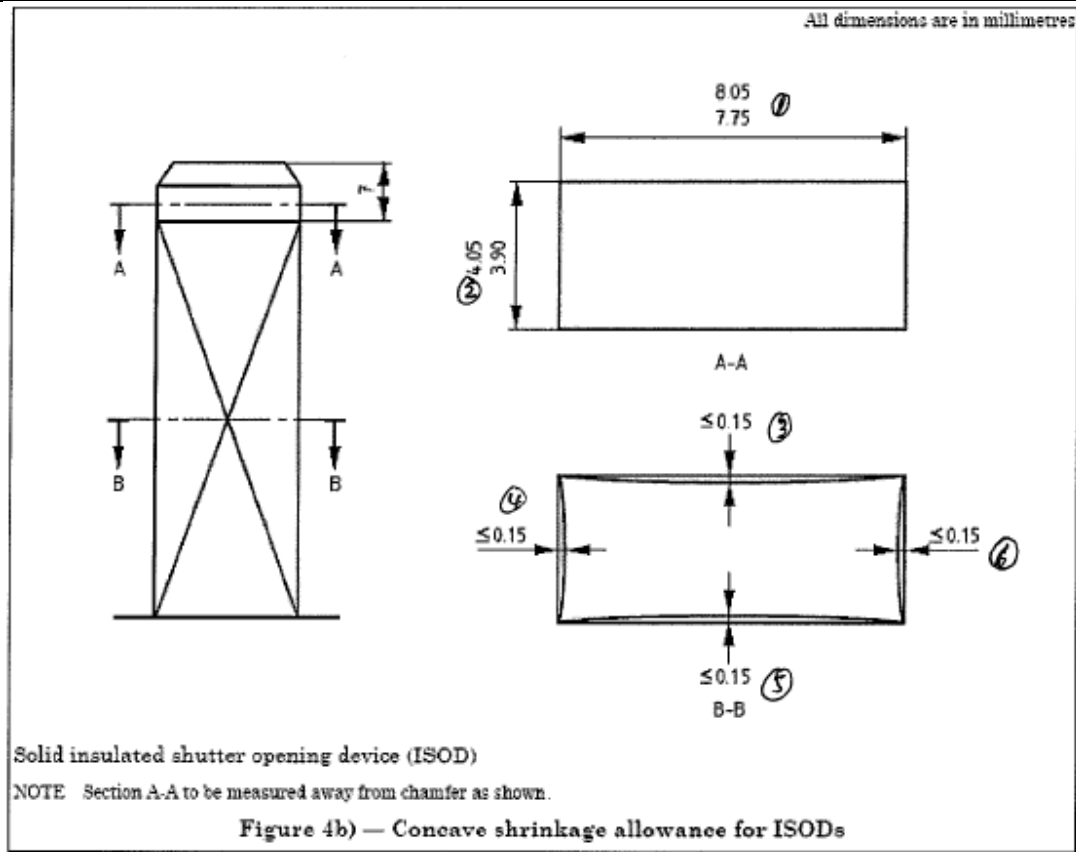
All dimensions are in millimetres.

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

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

Appendix: 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



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

Appendix: Photo for BS1363 plug



The connector conduct part can't be touched by test finger. CI & CR are measured according to table 2.10.3 & 2.10.4.

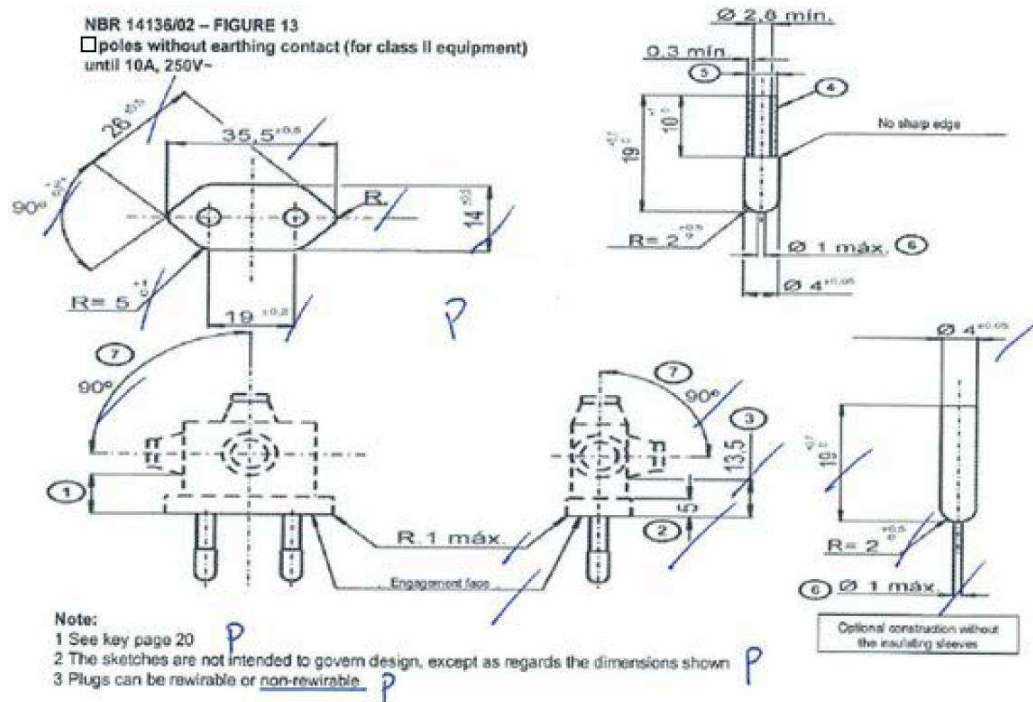
IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix: Specification of NBR 14136 plug

[illegible]

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

Appendix: Evaluation sheet of NBR 14136 Figure 13 plug



Key of page 20:

- 1– The distance between the engagement face and the cord or cord guard, if any, shall be at least 14 mm
- 2– Within this distance, the outline shall be not smaller than the engagement face.
- 3– Within this distance, the outline shall be not larger than the engagement face.
- 4– Insulating sleeves on the current-carrying pins are optional
if the insulating sleeves are separate parts, they shall enter the plug by at least 3mm measured from the engagement face.
- 5– The external diameter of the insulating sleeves shall not be larger than the diameter of the uninsulated part of the pins.
- 6– To avoid damage to shutters, the ends of the pins shall show neither sharp edges nor burrs. They shall be of rounded shape as shown.
- 7– The angle of 90° represents the maximum permissible area for the orientation of the entry of the flexible cable or cord.

Plug Marking for the 10A 250V~ Plug:

Cable section of 0.5mm² - 2.5A 250V~
Cable section of 0.75mm² - 10A 250V~
Cable section of 1mm² - 10A 250V~
Cable section of 1.5mm² - 10A 250V~
Cable section of 2.5mm² - 10A 250V~

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

Appendix: Evaluation sheet of IRAM 2063 plug

25	RESISTANCE TO HEAT		
25.2	Parts of insulating material of fixed socket-outlets necessary to retain current-carrying parts and parts of the earthing circuit in position, as well as parts of the front surface zone of 2 mm wide surrounding the phase and neutral pin entry holes: ball-pressure test at $(125 \pm 2)^\circ\text{C}$ for 1 h		P
	After the test: diameter of impression ≤ 2 mm: 0.67 mm		P
25.3	For parts not necessary to retain current-carrying parts and parts of the earthing circuit in position, even though in contact with them: ball-pressure test (1 h)		---
	Test temperature ($^\circ\text{C}$): $(70 \pm 2)^\circ\text{C}$ / $(40 \pm 2)^\circ\text{C}$ + highest temperature rise determined during the test of clause 19		---
	After the test: diameter of impression ≤ 2 mm:		---
28	RESISTANCE OF INSULATING MATERIAL TO ABNORMAL HEAT, TO FIRE AND TO TRACKING		P
28.1	Resistance to abnormal heat and to fire		P
28.1.1	Glow-wire test		
	For parts of fixed accessories necessary to retain current-carrying parts and parts of the earthing circuit in position: test temperature 850°C		P
	No visible flame and no sustained glowing		P
	Flame and glowing extinguish within 30 s:		P
	No ignition of the tissue paper		P
	For parts of fixed accessories needed to retain the earth terminal in position in a box: test temperature 650°C		---
	No visible flame and no sustained glowing		---
	Flame and glowing extinguish within 30 s:		---
	No ignition of the tissue paper		---
	For parts of portable accessories necessary to retain current-carrying parts and parts of the earthing circuit in position: test temperature 750°C		P
	No visible flame and no sustained glowing		P
	Flame and glowing extinguish within 30 s:		P
	No ignition of the tissue paper		P
	For parts not necessary to retain current-carrying parts and parts of the earthing circuit in position, even though in contact with them: test temperature 650°C		---
	No visible flame and no sustained glowing		---
	Flame and glowing extinguish within 30 s:		---
	No ignition of the tissue paper		---

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

Appendix: Evaluation sheet of IRAM 2063 plug

6.4	PLUG PINS MEASUREMENT		
	Measured in mm	Allowed in mm	Verdict
- Phase Pin:			
Length:	18.03,18.05,18.04	18,2 ± 0,2 (18.0/18.4)	P
Wide:	6.25,6.26,6.25	6,25 ± 0,1 (6.15/6.35)	P
Thickness:	1.57,1.55,1.56	1,55 ± 0,07 (1.48/1.62)	P
- Neutral Pin:			
Length:	18.10,18.09,18.08	18,2 ± 0,2 (18.0/18.4)	P
Wide:	6.23, 6.25,6.23	6,25 ± 0,1 (6.15/6.35)	P
Thickness:	1.51,1.51,1.52	1,55 ± 0,07 (1.48/1.62)	P
- Pin of earth			
Length:	---	21,4 ± 0,2 (21.2/21.6)	---
Wide:	---	6,25 ± 0,1 (6.15/6.35)	---
Thickness:	---	1,55 ± 0,07 (1.48/1.62)	---
Perimeter:	11.86.11.86, 11.85	≥ 8mm	P
Comments:	-		

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

Appendix: MECHANICAL DURABILITY TEST FOR NON-STANDARD INTERCHANGEABLE PLUG ADAPTERS ACCORDING IEC 61984: 2008

IEC 61984: 2008										
Clause	Requirement + Test	Result - Remark	Verdict							
6.14.1	MECHANICAL ENDURANCE (COC AND CBC)		P							
	A connector, either COC or CBC, shall meet the mechanical operations without load as specified in the DS or in the manufacturer's specification (preferred numbers of operating cycles are given in Table 4a).	100 cycles	P							
7.3.9	MECHANICAL OPERATION		P							
	The object of this test is to assess the mechanical operational endurance of a connector either CBC or COC in the normal operational mode without electrical load.		P							
	The test shall be carried out according to test 9a of IEC 60512, under the following conditions, unless otherwise specified.		P							
	Test conditions:		P							
	The specimens shall be engaged and disengaged by means of a device simulating normal operating conditions.		P							
	The preparation and mounting of the specimen shall be as in normal use.		P							
	The type and cross sectional area of the cable/wire bundle to be used shall be specified by the manufacturer or by the DS.		P							
	The number of operating cycles shall be specified by the manufacturer or by the DS.		P							
	Preferred values are indicated in Table 4a.	100 cycles	P							
	The speed of insertion and withdrawal shall be approximately 0,01 m/s with a rest in the unmated position of approximately 30 s.		P							
Table 4	Mechanical and electrical durability		P							
	Table 4a – Operating cycles – Preferred values		P							
	<table><tr><td>Operating cycles - Preferred values</td></tr><tr><td>10</td></tr><tr><td>50</td></tr><tr><td>100</td></tr><tr><td>500</td></tr><tr><td>1 000</td></tr><tr><td>5 000</td></tr></table>	Operating cycles - Preferred values	10	50	100	500	1 000	5 000	100 cycles	P
Operating cycles - Preferred values										
10										
50										
100										
500										
1 000										
5 000										