



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......: 161100155SHA-001

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CB Testing Laboratory.....: Intertek Testing Services Shanghai

Address: Building No.85 and 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.....: N/A

Test Report Form No......: IEC60601_1K

Test Report Form Originator.....: UL(US)

Master TRF: 2015-11

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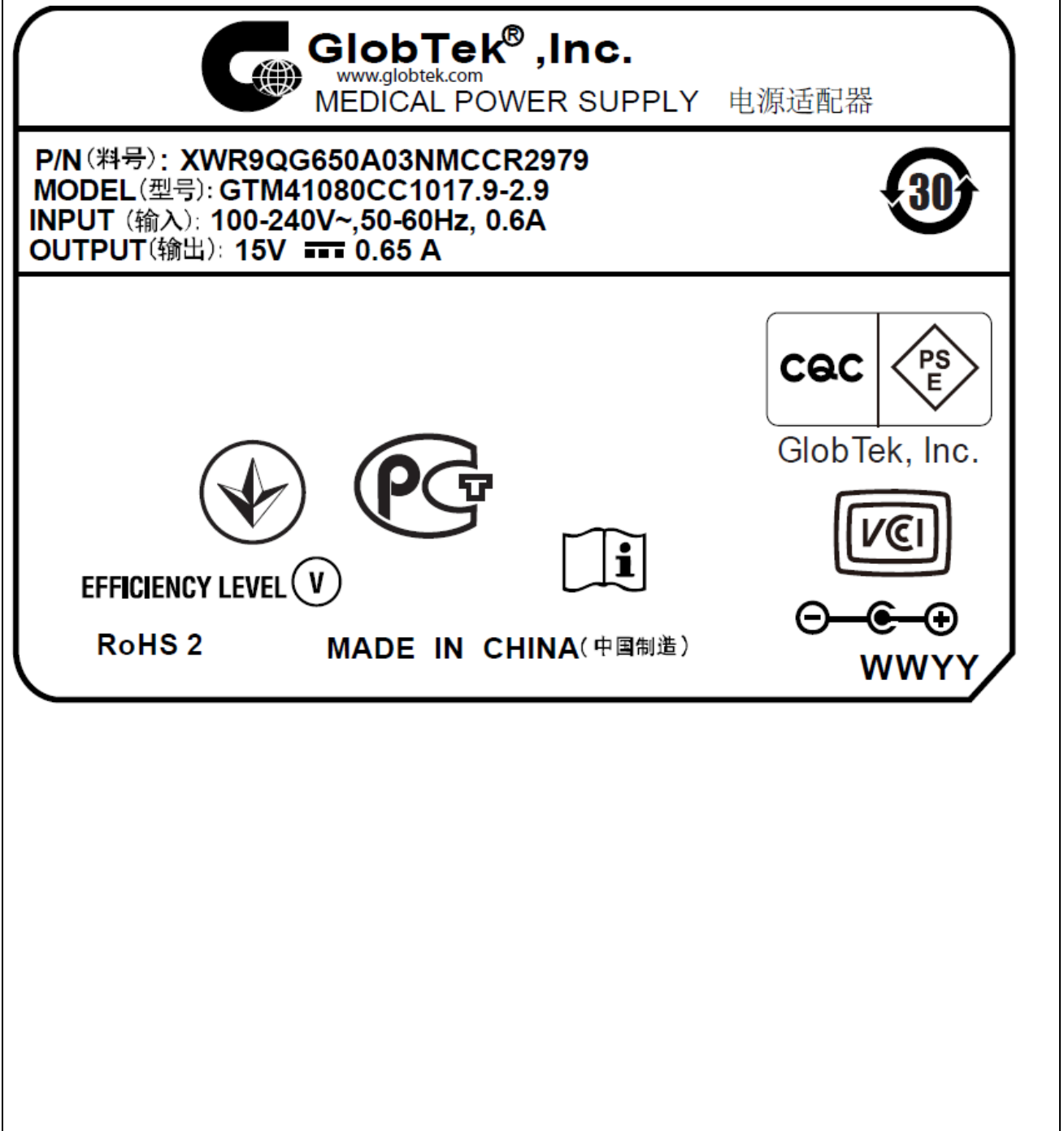
Test item description	Medical Power Supply	
Trade Mark	GlobTek	
Manufacturer	GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 USA	
Model/Type reference.....	GT*41080***** (Refer to page 7 for details.)	
Ratings.....	Input: 100-240V~, 50-60Hz, 0.6A; Output: Refer to page 7 for details.	
Testing procedure and testing location:		
<input checked="" type="checkbox"/> CB Testing Laboratory:	Intertek Testing Services Shanghai	
Testing location/ address	Building No.85 and 86, 1198 Qinzhou Road (North), 200233 Shanghai, China	
<input type="checkbox"/> Associated CB Testing Laboratory:		
Testing location/ address		
Tested by (name, function, signature)	Jason Gong (Engineer)/ Francis Cai (Engineer)	<i>Jason Gong Francis Cai</i>
Approved by (name, function, signature) ..	Justin Yu (Mandated Reviewer)	<i>Justin Yu</i>
<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 136-146</p> <p>Circuit Diagram / Layout: Page 147-151</p> <p>USA national difference: Page 152-153</p> <p>Switzerland national difference: Page 154</p> <p>Plug evaluation: Page 155-181</p>	
Summary of testing	
Tests performed (name of test and test clause): 4.11 Power Input 5.7 Humidity Preconditioning 5.9.2 Accessible Parts 7.1.2 Legibility of Markings 7.1.3 Durability of Markings 8.4.3 Plug Voltage and/or Energy 8.5.4 Working Voltage Measurement 8.7.4 Leakage Current Test 8.8.3 Dielectric Strength Means 8.8.4.1 Ball Pressure Test 8.9.4 Creepage & Clearance Measurements 11.1 Excessive Temperature 13.2 Single Fault Conditions 15.3.2 Push Test 15.3.4 Drop Test 15.3.6 Moulding Stress Relief 15.5.1.2 Transformer Short-Circuit 15.5.1.3 Transformer Overload 15.5.2 Transformer Dielectric Strength <p>Most of the test results were copied from 130100653SHA-001 dated 2013-02-28, modified on 2014-11-28, which was already evaluated with 3.0 edition of IEC60601-1.</p>	Testing location: Intertek Testing Services Shanghai Building 86, 1198 Qinzhou Road (North), Shanghai, China, 200233
Summary of compliance with National Differences	
<p>List of countries addressed:</p> <p>Canada, USA, Switzerland</p> <p>Group- and national differences for the CENELEC countries according to EN 60601-1:2006</p> <p><input checked="" type="checkbox"/> The product fulfils the requirements of IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)</p>	

Copy of marking plate

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

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



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use	transportable / portable / stationary / mobile / fixed / permanently installed / hand-held, body-worn Direct plug-in type for power adapter model; Final determination in end product evaluation for open frame model.
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location) :	PSU (external power adapter or internal power supply board)
Mode of operation	Continuous / non-continuous
Supply connection	internally powered / permanently installed / appliance coupler / non-detachable cord Direct plug-in type for power adapter model; Final determination in end product evaluation for open frame model.
Accessories and detachable parts included.....	Plug (Evaluated as attachment)
Other options include	None
Testing	
Date of receipt of test item(s)	2016-11-2
Dates tests performed	2016-11-2 to 2017-01-06
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:

"(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.

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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.

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

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Manufacturer's Declaration per sub-clause 4.2.5 of IEC 60335-1:2012

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: ☒ Yes ☐ Not applicable

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

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

Factory 1

GlobTek, Inc.

186 Veterans Dr. Northvale, NJ 07647 USA

Factory 2

GlobTek (Suzhou) Co., Ltd

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

General product information:

Product covered by this report is medical power supply module, which can be used as a part of medical equipment. The different models are corresponding to two structure types respectively.

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

The other one is open frame power supply board which also provides a protective earth bonding terminal on the PCB board. The installation and use for the insulation construction shall be finally determined in the end product.

Two transformer types are alternative, which are identical in same construction except different routing of secondary lead wires.

The medical power supply module can also be divided into constant voltage model and constant current model. The two models have the same primary circuit, critical components and output rating parameters. The only difference is the secondary circuit.

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

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

Model Similarity:

GT*41080*****

The 1st “*” part can be ‘M’ or ‘-’ or ‘H’ for market identification and not related to safety.

The 2nd “*” part can be “-” or “CC”, “-” = Constant Voltage Model, CC = Constant Current Model.

The 3rd “*” part denotes the rated output wattage designation, which can be “01” to “18”, with interval of 1.

The 4th “*” part denotes the standard rated output voltage designation, which can be “07”, “11” “17.9”, “30”, “38” and “48”. Each standard rated output voltage designation corresponds to a transformer model. Each transformer model is identical in insulation construction including clearance and creepage except number of turns per coil.

The 5th “*” part is optional, which can be “-0.1” to “-12.0” with interval of 0.1 to denote voltage deviation or blank to indicate no voltage different. The result by subtracting the deviation value from the standard rated output voltage denotes the rated output voltage, with a range of 5 - 48 volts.

The 6th “*” part is also optional, which can be “-F” to denote open frame power supply model series or blank to denote direct plug-in power adapter model series.

For the CV model, test performed on 5Vdc/3A output adapter model and 48Vdc/0.375A output adapter model as worst condition, and also performed on other output models for reference. Although ME equipment installation and use type are not specified, mechanical strength tests including push test, 1 m height drop test and mould stress relief test are performed considering the usage for adapter model. For open frame model, final determination shall be made in end product.

For the CC model, test performed on GTM41080CC1017.9-2.9 for reference.

Model list

Model	Rated output voltage range	Max. rated output current	Max. rated output power	Transformer model	Structure type
GT*41080**07*	5-7Vdc	3.6A	18W	XF00514	Power adapter with interchangeable plug portion, Class II
GT*41080**11*	7.1-11Vdc	2.53A	18W	XF00550	
GT*41080**17.9*	11.1-17.9Vdc	1.62A	18W	XF00579	
GT*41080**30*	18-30Vdc	1.0A	18W	XF00590	
GT*41080**38*	30.1-38Vdc	0.60A	18W	XF00682A	
GT*41080**48*	38.1-48Vdc	0.47A	18W	XF00682	
GT*41080**07*-F	5-7Vdc	3.6A	18W	XF00514	Open frame module without enclosure.
GT*41080**11*-F	7.1-11Vdc	2.53A	18W	XF00550	
GT*41080**17.9*-F	11.1-17.9Vdc	1.62A	18W	XF00579	
GT*41080**30*-F	18-30Vdc	1.0A	18W	XF00590	
GT*41080**38*-F	30.1-38dc	0.60A	18W	XF00682A	
GT*41080**48*-F	38.1-48Vdc	0.47A	18W	XF00682	

Technical Considerations:

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

- **Clause 7.5 (Safety Signs),**
- **Clause 7.9 (Accompanying Documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end**

product level.),

- **Clause 8.11.5 (Mains Fuse with High Breaking Capacity),**
- **Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,**
- **Clause 10 (Radiation),**
- **Clause 11.7 (Biocompatibility),**
- **Clause 14 (PEMS),**
- **Clause 16 (ME Systems)**
- **Clause 17 (EMC),**

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

TABLE: INSULATION DIAGRAM									
Pollution degree				2					—
Overvoltage category				II					—
Altitude.....				3000m					—
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}					
A	MOOP	IIIb	240	--	2.5	2.3 ⁴	3.9	3.9	Opposite polarity of mains part
A*	2MOOP	IIIb	240	340	5.0	4.6 ⁴	5.6	5.6	Accessible part to plug pin when the connector is plugged in the socket without the power supply correctly attached.
B	2MOOP	IIIb	240	340	5.0	4.6 ⁴	9.2	9.2	Mains part (plug portion) to outer enclosure (accessible position during normal use) (for adapter model only)
C	MOOP	IIIb	240	340	2.5	2.3 ⁴	3.7	3.7	Mains part to PE bonding terminal (On PCB trace) (for open frame model only)
D	2MOOP	IIIb	240	340	5.0	4.6 ⁴	5.2	5.2	Internal mains part to accessible outer enclosure (for adapter model only)

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Clause	Requirement + Test					Result - Remark			Verdict
E	2MOPP	IIIb	240 ¹	--	7.9 ²	5.0	8.0 ³	8.0 ³	Mains part to secondary circuits (Optocoupler)
F	2MOPP	IIIb	276 ¹	--	8.6 ²	7.0	9.0	9.0	Mains part to secondary circuits (Transformer)
G	MOPP (Each x 2)	IIIb	240 ¹	--	4.0 ²	2.5	4.1	4.1	Mains part to secondary circuits (Y capacitor x 2)
H	2MOPP	IIIb	240 ¹	--	7.9 ²	5.0	8.6/8.5 ⁵	8.6/5.2 ⁵	Mains part to secondary circuits (On PCB trace)
I	2MOPP	IIIb	--	Max. 48	--	--	--	--	Accessible part per 8.4.2 c)

Note:

- 1) The working voltage is highest measured value which acquired by testing all the models listed in the report at the rated input voltage, but not less than the rated input voltage.
- 2) Linear interpolation is applied to the determination of required creepage.
- 3) The minimum creepage and clearance is selected from all the types of optocouplers.
- 4) Multiplication factor for MOOP: 1.14; Multiplication factor for MOPP: 1.00.
- 5) The same area is evaluated in CC Model.

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		P
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: < Risk Management Plan for Device GTM41080> Cl. 1.3	P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		N/A
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		N/A
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.		N/A
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 identified 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:	Risk Management Report 6.1.19 10years	P
4.5	Alternative RISK CONTROL methods utilized:		N/A

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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 methods utilized	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 part	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)	No such part	N/A
	Assessment identified the APPLIED PART TYPE requirements..... :	No such part	N/A
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2..... :	Risk remained acceptable	P
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested.....: (ISO 14971 Cl. 4.2-4.4)	RISK ANALYSIS reference: <Risk management report > Section 6, EL6 (ISO 14971 Cl. 4.2-4.4)	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		N/A
	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 SUCH CONDITION	N/A
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION....:	NO SUCH CONDITION	N/A
	Components determined to be acceptable where used as a MEANS OF PROTECTION:	NO SUCH CONDITION	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		N/A
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately..... :	No such component	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)	No such component	N/A
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:	No such component	N/A
4.10	Power supply		
4.10.1	ME EQUIPMENT is suitable for connection to indicated power source (select applicable).....:	Supply mains Separate power supply Internally powered	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:		P
	- 250 V for HAND-HELD ME EQUIPMENT (V)..... :	Not hand-held ME equipment	N/A
	- 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	P
	- 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	No such condition All applicable test 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)	No such condition	N/A
5.3	Tests conducted within the environmental conditions specified in technical description		P
	Temperature (°C), Relative Humidity (%) :	0-40°C, 20%-80%RH	—
	Atmospheric Pressure (kPa) :	700-1060hPa (3000m altitude)	—
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) :	90/264V considered	P
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :	60Hz considered	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..... :	90/264V, 60Hz considered	P
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered..... :	No such condition	P
	e) ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions..... :	No alternative accessory	P
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	No separate power supply used	P
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..... :	Humidity precondition performed before leakage current test and dielectric strength test	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 = 26°C Time – 120 h	—
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		P
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS :	No applied part	N/A
5.9.2	ACCESSIBLE PARTS		P
5.9.2.1	Accessibility determined using standard test finger of Fig. 6	See Appended Table 5.9.2	P

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Clause	Requirement + Test	Result - Remark	Verdict
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s	Test hook can't insert any 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	Final determination in the end product for open frame model.	N/A
	CLASS II ME EQUIPMENT, externally powered	For adapter model, Class II only Final determination in the end product for open frame 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	No applied part	N/A
	TYPE CF APPLIED PART	No applied part	N/A
	DEFIBRILLATION-PROOF APPLIED PARTS	No applied part	N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529 :	IP20 for adapter model Final determination in the end product for open frame model.	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	P

7	ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS		P
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6 :	See Appended Table 7.1.2	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	See attached copy of Marking Plate	P
	– the date of manufacture or use by date		N/A
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	No detachable component	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)	No detachable component	N/A
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and	No detachable component	N/A
	– a MODEL OR TYPE REFERENCE	No detachable component	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		P
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	No such safety sign used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and..... :	No accessory	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	Component; Final determination to be performed in the end product	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..... :	Alternating current	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
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT..... :	Symbol 9 is used for adapter model.	P
7.2.7	RATED input in amps or volt-amps, (A, VA)..... :	RATED input in amps: 0.6A	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

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Clause	Requirement + Test	Result - Remark	Verdict
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than $\pm 10\%$ of the mean value of specified range (A, VA,W)..... :	No such range provided	N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)..... :	No such range provided	N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)..... :	No such range provided	N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W)	No such range provided	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	No MSO	N/A
	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... :	Ordinary	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 in power supply	N/A
	TYPE B APPLIED PARTS with symbol 19 of Table D.1	No applied part in power supply	N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1	No applied part in power supply	N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1	No applied part in power supply	N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1	No applied part in power supply	N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART	No applied part in power supply	N/A
	Safety sign 2 of Table D.2 placed near relevant outlet	No applied part in power supply	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	No applied part in power supply	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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..... :	No accessible fuse-holder	—
	Voltage (V) and Current (A) rating.....:	No accessible fuse-holder	—
	Operating speed (s) and Breaking capacity.....:	No accessible fuse-holder	—
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..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.3)	Component, to be determined as part of end product.	N/A
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1	No such high voltage terminal device	N/A
7.2.15	Requirements for cooling provisions marked .. :	Component, to be determined as part of end product.	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..... :	Component, to be determined as part of end product.	N/A
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK.: (ISO 14971 Cl. 4.2-4.4, 5, 6.3-6.4)	Component, to be determined as part of end product.	N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	Component, to be determined as part of end product.	N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, 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

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Clause	Requirement + Test	Result - Remark	Verdict
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	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.....	No battery	N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK	No battery	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)	No battery	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	No battery	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
	Voltage (V) and Current (A) rating	T 1.6A/250V	—
	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	Protective bonding terminal is provided on PCB for open frame model.	P
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		P

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Clause	Requirement + Test	Result - Remark	Verdict
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)	RMF Reference to specific RISKS: <RISK MANAGEMENT REPORT> SECTION 6, EL3 (ISO14971 Cl. 4.3)	P
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	Marking on EUT	N/A
	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 supply	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	No such high temperature	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
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	– status indicated by other unambiguous means		N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	No such device	N/A
	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)	No such device	N/A
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE	No such device	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	No numeric indications of parameters	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	Component, to be determined as part of end product.	N/A
	RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR		N/A
	(ISO 14971 Cl. 4.2-4.4, 5, 6.3)		
	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

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Clause	Requirement + Test	Result - Remark	Verdict
7.6	Symbols		P
7.6.1	Meanings of symbols used for marking described in instructions for use	IFU checked	P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable	No such symbol	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 provided	N/A
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations	No PE conductor provided	N/A
7.7.3	Green and yellow insulation identify only following conductors:	No such following conductor	N/A
	– PROTECTIVE EARTH CONDUCTORS		N/A
	– conductors specified in 7.7.2		N/A
	– POTENTIAL EQUALIZATION CONDUCTORS		N/A
	– FUNCTIONAL EARTH CONDUCTORS		N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue”	No power supply cord	N/A
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	No power supply cord	N/A
7.8	Indicator lights and controls		N/A
7.8.1	Red indicator lights used only for Warning	No indicator light, no control	N/A
	Yellow indicator lights used only for Caution	No indicator light, no control	N/A
	Green indicator lights used only for Ready for use	No indicator light, no control	N/A
	Other colours: Meaning other than red, yellow, or green (colour, meaning)	No indicator light, no control	N/A
7.8.2	Red used only for emergency control	No indicator light, no 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.	N/A
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to		N/A
	– MODEL OR TYPE REFERENCE.....		N/A
	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		N/A
7.9.2.1	– use of ME EQUIPMENT as intended by the MANUFACTURER:		N/A
	– frequently used functions,		N/A
	– 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		N/A
	– MODEL OR TYPE REFERENCE		N/A
	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		N/A
	Instructions for use are in a language acceptable to the intended operator		N/A
7.9.2.2	Instructions for use include all warning and safety notices		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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		N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference		N/A
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided		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
	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 :		N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided..... :		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 :		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		N/A
	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		N/A
	APPLIED PARTS specified		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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		N/A
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
	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		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		N/A
	Other equipment providing power to ME SYSTEM sufficiently described		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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)		N/A
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 ____	N/A
7.9.3	Technical description		N/A
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		N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT		N/A
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and		N/A
	a unique version identifier	Version ____	N/A
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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		N/A

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	The following needs to be considered in the end product: - interruption of any one power-carrying conductor - unintended movement of a component - accidental detachment of conductors and connectors	P
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION : (ISO 14971 Cl. 4.3)	Final determination in the end-product	N/A
8.2	Requirements related to power sources		P
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	Connection to supply 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

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Clause	Requirement + Test	Result - Remark	Verdict
	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	Connection to supply mains only	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 identified	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
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT :	No patient connection	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	P
	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:		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. Open frame model shall be determined in end product evaluation	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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	No opening for adapter model. Open frame model shall be determined in end product evaluation	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	No such part for adapter model. Open frame model shall be determined in end product evaluation	N/A
	A TOOL is required when it is possible to prevent the devices from operating		N/A
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one 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

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Clause	Requirement + Test	Result - Remark	Verdict
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	No PE connection is provided	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
	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. :	No such condition	N/A
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Two capacitors used in series	P
	Voltage Total Working (V) and C Nominal (μF) :	Each 250V, 2200pF	—
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		P
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		P
	– dielectric strength test :	See appended Table 8.8.3	P
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		P
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		P
	– limits of Tables 13 to 16 (inclusive); or		P
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		P
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6	No PE connection is provided	N/A
	– or with requirements and tests of IEC 60950-1 for protective earthing..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION :	No such component	N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION :	No such component	N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A
	Voltage 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..... :	No such part identified	N/A
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION :		P
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 connection	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

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Clause	Requirement + Test	Result - Remark	Verdict
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 :	No patient connection	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
	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 :	No patient lead or cable	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

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Clause	Requirement + Test	Result - Remark	Verdict
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V) :	240Vac	P
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V)..... :	See Insulation Diagram and Insulation Table	P
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V)..... :	See Insulation Diagram and Insulation Table	P
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth		P
	– 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 part	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 such condition	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	No applied part	N/A
8.5.5.1	Classification “DEFIBRILLATION-PROOF APPLIED PART” applied to one APPLIED PART in its entirety		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

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Clause	Requirement + Test	Result - Remark	Verdict
8.6.1	Requirements of 8.6.2 to 8.6.8 applied	Only protective bonding terminal is provided on PCB for open frame model. Final determination in end product.	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..... :	Final determination in end product for open frame model.	N/A
	Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL		N/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside :		N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		N/A
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing		N/A
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part,	Final determination in end product for open frame model.	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..... :	Final determination in end product for open frame model.	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 :		N/A
8.6.5	Surface coatings		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact	Final determination in end product for open frame model.	N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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	Final determination in end product for open frame model.	N/A
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		N/A
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	Final determination in end product for open frame model.	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	Final determination in end product for open frame model.	N/A
8.6.9	Class II ME EQUIPMENT		N/A
	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	Final determination in end product for open frame model.	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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)	Final determination in end product for open frame model.	N/A
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time	Final determination in end product for open frame model. So earth leakage current was not measured.	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		P
	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	P
	c) TOUCH CURRENT did not exceed 100 μA in NORMAL CONDITION and 500 μA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})..... :	See appended Table 8.7	P
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}) :	Final determination in end product for open frame model. So earth leakage current was not measured.	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 :		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

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Clause	Requirement + Test	Result - Remark	Verdict
	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 :	No FE conductor provided	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
	Insulation exempted from test (complies with clause 4.8)		P
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	No such part	N/A
8.8.2	Distance through solid insulation or use of thin sheet material		P
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	See appended Table 8.10	P
	a) 0.4 mm, min, distance through insulation, or	Enclosure is 2.0mm thick	P
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		P
	– at least two layers of material, each passed the appropriate dielectric strength test..... :	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

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Clause	Requirement + Test	Result - Remark	Verdict
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	Certified triple insulated wire is used.	P
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer		N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded		N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded		P
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values		N/A
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension		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	Final determination in the end-product	N/A
	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)	RMF Reference to specific RISKS: <Risk management report> Section 6, EL4 (ISO 14971 Cl. __)	P
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat	No evidence provided	N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat	Ball pressure test performed	P
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at $125\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ or ambient indicated in technical description $\pm 2^{\circ}\text{C}$ plus temperature rise determined during test of 11.1 of relevant part, if higher ($^{\circ}\text{C}$) :	See appended Table 8.8.4.1	P
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION	No such material	N/A
8.8.4.2	Resistance to environmental stress		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	No such material	N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No heating conductor	N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of $2.1\text{ MPa} \pm 70\text{ kPa}$, with an effective capacity of at least 10 times volume of samples	No such material	N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at $70\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ for 96h, and afterwards, left at room temperature for at least 16h	No such material	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 part	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	P
8.9.3	Spaces filled by insulating compound		P
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound	Certified optocoupler	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Thermal cycling, humidity preconditioning, and dielectric strength tests	Certified optocoupler has conformed to these tests.	P
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage) :	Certified optocoupler.	P
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur	Certified optocoupler has conformed to these tests.	P
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint	No such construction	N/A
	A winding of solvent-based 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 transvers 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..... :	Except open frame model, all the other models have been checked by inspection. No evidence of such risk is found. Final determination in the end-product for open frame model.	P
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components : (ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)	RMF Reference to specific RISKS: <Risk management report> Section 6, EL3 (ISO 14971 Cl.____)	P

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Clause	Requirement + Test	Result - Remark	Verdict
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment..... :	Except open frame model, all the other models have been checked by inspection. No evidence of such risk is found. Final determination in the end-product for open frame model.	P
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS	No such construction	N/A
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 :	No such cord	N/A
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N/A
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION	No cord connected hand-held control device, no cord connected foot-operated control device.	N/A
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	No cord connected hand-held control device, no cord connected foot-operated control device.	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		P
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges :	Except open frame model, all the other models have been checked by inspection. No evidence of such risk is found. Final determination in the end-product for open frame model.	P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS	Except open frame model, all the other models have been checked by inspection. No evidence of such risk is found. Final determination in the end-product for open frame model.	P
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..... :	No insulating sleeve.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics	No such condition.	N/A
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C :	No such high temperature is acquired by test indicated in 11.1.	N/A
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 :	Plug	P
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	Not permanently installed.	N/A
	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		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description :	Plug is incorporated in EUT.	P
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV :	No mains switch	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	No mains switch	N/A
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	No mains switch	N/A
	f) A suitable plug device 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

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Clause	Requirement + Test	Result - Remark	Verdict
	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
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No multiple socket-outlets.	N/A
8.11.3	POWER SUPPLY CORDS		N/A
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	No power supply cord.	N/A
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53)... :	No power supply cord.	N/A
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °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..... :	No power supply cord.	N/A
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6..... :	No power supply cord.	N/A
8.11.3.5	Cord anchorage		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	No power supply cord.	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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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	No power supply cord.	N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components	No power supply cord.	N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals	No power supply cord.	N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	No power supply cord.	N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 :	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	No power supply cord.	N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D ² gram attached to the free end of cord (g) :	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

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Clause	Requirement + Test	Result - Remark	Verdict
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. Final determination in the end-product for open frame model.	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
	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	No mains terminal device. Final determination in the end-product for open frame model.	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	No mains terminal device.	N/A
8.11.4.4	Terminals with clamping means for a rewirable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened	No mains terminal device.	N/A
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewirable POWER SUPPLY CORD to allow for connection of conductors	No mains terminal device.	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 :	Fuse is provided for each lead.	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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	Fuse is provided for each lead.	N/A
	Protective devices have adequate breaking capacity to interrupt the max. fault current :	See appended Table 8.10	P
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		N/A
	Justification for omission of fuses or OVER-CURRENT RELEASES documented :	Fuse is provided for each lead.	N/A
8.11.6	Internal wiring of the MAINS PART		P
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable :	No 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	P

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 :	Final determination in the end product.	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 :		N/A
	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

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Clause	Requirement + Test	Result - Remark	Verdict
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:		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
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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
	- 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

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Clause	Requirement + Test	Result - Remark	Verdict
	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
	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

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Clause	Requirement + Test	Result - Remark	Verdict
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered	Final determination in the end product for open frame model. No rough surface / sharp edge on the other models.	P
9.4	Instability HAZARDS		N/A
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	Component, to be determined as part of end product	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

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Clause	Requirement + Test	Result - Remark	Verdict
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
	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)	RMF Reference to specific RISKS: (ISO 14971 Cl. __)	N/A
	All identified RISKS associated with expelled parts mitigated to an acceptable level	No such parts	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

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Clause	Requirement + Test	Result - Remark	Verdict
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity		N/A
	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	RMF Reference to specific RISKS: (ISO 14971 Cl.____)	N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum	No such parts	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 kPaL	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
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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	Component, to be determined in the end product.	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
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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
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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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	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	Not applicable to component power supply	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 (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	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
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

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Clause	Requirement + Test	Result - Remark	Verdict
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 Open frame model shall be reevaluated in the end product.	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)	Component, to be determined in end-product evaluation.	N/A
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 part	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. :	No applied part	N/A
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:		N/A
	Maximum Temperature :		—
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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)	Test conducted Acceptability of obtained values to be determined in the end product.	N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	TEST CORNER USED	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)	Component, to be determined in end-product evaluation.	N/A
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE :	NO ALTERNATIVE METHODS USED	N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No such guards	N/A
11.2	Fire prevention		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
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 :	Component, not evaluated for use with Oxygen Rich Environment	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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	Component, not evaluated for use with 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	Component, not evaluated for use with Oxygen Rich Environment	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
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)..... :	Component, not evaluated for use with Oxygen Rich Environment	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

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Clause	Requirement + Test	Result - Remark	Verdict
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 :	Final determination to be competed in the end product for open frame model.	N/A
	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)	Constructional requirements were met	N/A
	Justification, when requirement not met :	Constructional requirements were met	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	UL94 approved	N/A
	b) Fire ENCLOSURE met following:		P
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh $\leq 2 \times 2$ 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	Not evaluated for use in the presence of flammable anesthetics.	N/A
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		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)	Not evaluated for use in the presence of flammable agent.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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.....:	Final determination to be competed in the end product	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 :	Final determination to be competed in the end product	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
	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	Final determination to be competed in the end product	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)..... :	Final determination to be competed in the end product. EUT is ordinary.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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 :	Final determination to be competed in the end product.	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..... :	Final determination to be competed in the end product.	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
11.6.8	RISKS associated with compatibility of substances used with FME EQUIPMENT addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	Final determination to be competed in the end product.	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	Component, to be determined in end-product evaluation.	N/A
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	Component, to be determined in end-product evaluation.	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)	Not applicable to component power supply	N/A
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING..... :	Not applicable to component power supply	N/A
12.3	MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. :	Not applicable to component power supply	N/A
12.4	Protection against hazardous output		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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)	Not applicable to component power supply	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)	Not applicable to component power supply	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)	Not applicable to component power supply	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)	Not applicable to component power supply	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	Final determination to be competed in the end product.	N/A
	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..... :	Final determination to be competed in the end product.	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)	Final determination to be competed in the end product.	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)	Final determination to be competed in the end product.	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)	Final determination to be competed in the end product.	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		P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24..... :	See appended Table 11.1.1	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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	Fuse only	P
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed..... :	See appended Table 8.7	P
	– 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)	NO SUCH CONDITION	N/A
	RISK MANAGEMENT FILE defines the appropriate test conditions..... :	No such condition	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, or 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

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Clause	Requirement + Test	Result - Remark	Verdict
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests	No Heating Elements provided	N/A
	a 3) other ME EQUIPMENT with heating elements met test	No Heating Elements provided	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
	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) :	No Heating Elements provided	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	No Heating Elements provided	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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	No motors provided in power supply	N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT	No motors provided in power supply	N/A
	b) Motor met running overload protection test of this clause when:	No motors provided in power supply	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	No motors provided in power supply	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

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Clause	Requirement + Test	Result - Remark	Verdict
	Motor winding temperatures did not exceed values in 13.2.10 :		N/A
	Insulation Class :		—
	Maximum temperature measured (°C)..... :		—

14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		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	Component, to be determined in end-product evaluation.	N/A
	- when application of RISK MANAGEMENT showed that failure of PEMS does not lead to unacceptable RISK..... :		N/A
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PEMS: (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 PEMS		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 :	Component, to be determined in end-product evaluation.	N/A
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan	Component, to be determined in end-product evaluation.	N/A
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	Component, to be determined in end-product evaluation.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/A
	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	Component, to be determined in end-product evaluation.	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..... :	Component, to be determined in end-product evaluation.	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 :	Component, to be determined in end-product evaluation.	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)	Component, to be determined in end-product evaluation.	N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems : (ISO 14971 Cl. 6.3)	Component, to be determined in end-product evaluation.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
14.9	Design is broken up into sub systems and descriptive data on design environment documented :	Component, to be determined in end-product evaluation.	N/A
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)	Component, to be determined in end-product evaluation.	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 :	Component, to be determined in end-product evaluation.	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	Component, to be determined in end-product evaluation.	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 :	Component, to be determined in end-product evaluation.	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		N/A
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS..... :	Final determination to be competed in the end product.	N/A
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance	Final determination to be competed in the end product.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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 Final determination to be competed in the end product for open frame model.	P
	No damage resulting in an unacceptable RISK sustained		P
15.3.3	Impact test conducted..... :	Impact test was not performed on adapter model. Final determination to be competed in the end product for open frame model.	N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.4	Drop test		P
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested :	ME equipment type is not specified. Considered the usage of adapter model, 1m height drop test is performed. See Appended Table 15.3 Final determination to be competed in the end product for open frame model.	P
	No unacceptable RISK resulted	No damage	P
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	N/A
	No damage resulting in an unacceptable RISK sustained		N/A
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..... :	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 :	70°C	P
	No damage resulting in an unacceptable RISK	No damage	P
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT	Component, to be determined in end product evaluation.	N/A
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK	Component, to be determined in end product evaluation.	N/A
15.4	ME EQUIPMENT components and general assembly		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)	Final determination to be competed in the end product.	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, :		N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection :		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)	NO SUCH PART	N/A
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT	NO SUCH PART	N/A
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided : (ISO 14971 Cl. 4.2-4.4)	NO SUCH PART	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)	NO SUCH PART	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	NO SUCH PART	N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests	NO SUCH PART	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)	NO SUCH PART	N/A
	Battery compartments designed to prevent accidental short circuiting		N/A
15.4.3.2	Means provided to prevent incorrect connection of polarity	Final determination to be competed in the end product.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries : (ISO 14971 Cl. 4.2-4.4)	Final determination to be competed in the end product.	N/A
15.4.3.3	Overcharging of battery prevented by virtue of design :	Final determination to be competed in the end product.	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries : (ISO 14971 Cl. 4.2-4.4)	Final determination to be competed in the end product.	N/A
15.4.3.4	Primary lithium batteries comply with IEC 80086-4	Final determination to be competed in the end product.	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 :	Final determination to be competed in the end product.	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 :	Final determination to be competed in the end product.	N/A
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,		N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational		N/A
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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)	No such part in power supply.	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	No such part in power supply.	N/A
	b) Controls secured so that the indication of any scale always corresponds to the position of the control	No such part in power supply.	N/A
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL	No such part in power supply.	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	No such part in power supply.	N/A
	Torque values in Table 30 applied	No such part in power supply.	N/A
	No unexpected change of the controlled parameter when tested	No such part in power supply.	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	No such part in power supply.	N/A
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage	No such part in power supply.	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	No such part in power supply.	N/A
	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	No such part in power supply.	N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.... :	No such part in power supply.	N/A
15.4.8	Aluminium wires less than 16 mm² in cross-sectional area are not used	No such wire.	N/A
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed	No such parts in power supply	N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	No such parts in power supply	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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	No such parts in power supply	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		N/A
15.5.1.3	Multiple overload tests conducted on windings	No more than one protective device	N/A
15.5.2	Transformers operating at a frequency above 1kHz tested according to clause 8.8.3.....		P
	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

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Clause	Requirement + Test	Result - Remark	Verdict
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
	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	Component power supply; compliance determined in the end product	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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
	– 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

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Clause	Requirement + Test	Result - Remark	Verdict
	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	Component power supply; compliance determined in the end product	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 \leq voltage in 8.4.2 c)	Component power supply; compliance determined in the end product	N/A
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	Component power supply; compliance determined in the end product	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 μA..... :	Component power supply; compliance determined in the end product	N/A
	TOUCH CURRENT did not exceed 500 μA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR :	Component power supply; compliance determined in the end product	N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA.... :	Component power supply; compliance determined in the end product	N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values :	Component power supply; compliance determined in the end product	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16.7	ME SYSTEM complied with applicable requirements of Clause 9..... :	Component power supply; compliance determined in the end product	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	Component power supply; compliance determined in the end product	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 :	Component power supply; compliance determined in the end product	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
16.9.2	MAINS PARTS, components and layout	Component power supply; compliance determined in the end product	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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
	– 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

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Clause	Requirement + Test	Result - Remark	Verdict
17	ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS		N/A
	Risks associated confirmed by review :	Not applicable to component power supply system; to be determined in the end product	N/A
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS :		N/A
	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/A
	– 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/A

ANNEX G	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES		N/A
G.2	Locations and basic requirements		
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	Not evaluated for use with Flammable Anesthetics Mixture	N/A
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH	Not evaluated for use with Flammable Anesthetics Mixture	N/A
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE	Not evaluated for use with Flammable Anesthetics Mixture	N/A
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5	Not evaluated for use with Flammable Anesthetics Mixture	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	Not evaluated for use with Flammable Anesthetics Mixture	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		N/A
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked “APG” (symbol 23 in Table D.1)..... :	Not evaluated for use with Flammable Anesthetics Mixture	N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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)..... :	Not evaluated for use with Flammable Anesthetics Mixture	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	Not evaluated for use with Flammable Anesthetics Mixture	N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts	Not evaluated for use with Flammable Anesthetics Mixture	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	Not evaluated for use with Flammable Anesthetics Mixture	N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N/A
G.4.1	a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION	Not evaluated for use with Flammable Anesthetics Mixture	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		N/A
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL	Not evaluated for use with Flammable Anesthetics Mixture	N/A
	b) ENCLOSURE complies with..... :	Not evaluated for use with Flammable Anesthetics Mixture	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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	Not evaluated for use with Flammable Anesthetics Mixture	N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures	Not evaluated for use with Flammable Anesthetics Mixture	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	Not evaluated for use with Flammable Anesthetics Mixture	N/A
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components		N/A
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	Not evaluated for use with Flammable Anesthetics Mixture	N/A
	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.....	Not evaluated for use with Flammable Anesthetics Mixture	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:	Not evaluated for use with Flammable Anesthetics Mixture	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

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Clause	Requirement + Test	Result - Remark	Verdict
	Measured $I_{\max} \leq I_{zL}$ with L_{\max} and a $U_{\max} \leq 24 \text{ V}$ as in Fig G.3	$I_{\max} = __ \text{ A}$ $I_{zL} = __ \text{ A}$ $L_{\max} = __ \text{ mH}$	N/A
	– Combinations of currents and corresponding voltages within the limitations $I_{zR} \cdot U_{zR} \leq 50 \text{ W}$ 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 $C/2U^2 \leq 1.2 \text{ mJ}$ 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 $L/2I^2 \leq 0.3 \text{ mJ}$ 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
	– 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		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:	Not evaluated for use with Flammable Anesthetics Mixture	N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR removed by ventilation before EQUIPMENT energized,		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:	Not evaluated for use with Flammable Anesthetics Mixture	N/A
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing		N/A
	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		N/A
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	Not evaluated for use with Flammable Anesthetics Mixture	N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test	Not evaluated for use with Flammable Anesthetics Mixture	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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..... :	Not evaluated for use with Flammable Anesthetics Mixture	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..... :	Not evaluated for use with Flammable Anesthetics Mixture	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
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5... :	$U_{max} = __\text{V}$ $U_c = __\text{V}$ $C_{max} = __\mu\text{F}$	N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 :	$I_{max} = __\text{A}$ $I_{zR} = __\text{A}$ $U_{zR} = __\text{V}$	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24\text{ V}$ as in Fig G.6 :	$I_{max} = __\text{A}$ $I_{zL} = __\text{A}$ $L_{max} = __\text{mH}$	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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
	- 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 :	Not evaluated for use with Flammable Anesthetics Mixture	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	Not evaluated for use with Flammable Anesthetics Mixture	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	Approved TIW is used in mains transformer.	N/A
L.2	Wire construction		N/A
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component	Approved TIW is used in mains transformer.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A
L.3	Type Test		N/A
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified	Approved TIW is used in mains transformer.	N/A
	Temperature (°C)..... :		—
	Humidity (%)..... :		—
L.3.1	Dielectric strength		N/A
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:	Approved TIW is used in mains transformer.	N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 6000 V for REINFORCED INSULATION (V) :		N/A
L.3.2	Flexibility and adherence		N/A
	Sample subjected to flexibility and adherence	Approved TIW is used in mains transformer.	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		N/A
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3	Approved TIW is used in mains transformer.	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) :		N/A
	Oven temperature based on Table L.2 (°C)..... :		—
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm²)..... :		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
L.3.4	Retention of electric strength after bending		N/A
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests	Approved TIW is used in mains transformer.	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) :		N/A
	Test voltage applied between the shot and conductor		N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm²) :		N/A
L.4	Tests during manufacture		N/A
L.4.1	Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3:	Approved TIW is used in mains transformer.	N/A
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:	Approved TIW is used in mains transformer.	N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V).....:		N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V):		N/A
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)	Approved TIW is used in mains transformer.	N/A
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:		N/A
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION..... :		N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
3.1	<GTQPR05000> A.2 _section 5	—	Risk Management Process (excluding production and post-production)	P
3.2	<GTQPR05000> A.2 _section 5	—	Adequate Resources	P
3.2	<GTQPR05000> A.2 _section 5	—	Assignment of qualified personnel	P
3.2	<GTQPR05000> A.2 _section 5	—	Policy for determining criteria for risk acceptability	P
3.3	—	<GT-RM2013-003> A.2 _section 2	Qualification of personnel	P
3.4a	—	<GT-RMPLAN2013-003> A.2_Clause 1.1	Scope of risk management activities/identification and description of device/ applicable life-cycles	P
3.4b	—	<GT-RMPLAN2013-003> A.2_Clause 1.2	Assignment of responsibilities and authorities	P
3.4c	—	<GT-RMPLAN2013-003> A.2_Clause 1.2	Requirement for review of risk management activities	P
3.4d	—	<GT-RMPLAN2013-003> A.2_Clause 1.3	Criteria for risk acceptability	P
3.4e	—	<GT-RMPLAN2013-003> A.2_Clause 1.5	verification activities	P
3.5	—	<Risk management plan GT-RMPLAN2013-003> version A.2 <Risk management procedure GTQPR05000 > Version A. 2 <Risk Management Report GT-RM2013-003> Version A.2	RMF	P
4.1	—	<GTQPR05000> A.2 _section 6	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	—	<GT-RM2013-003> A.2_Clause 6.1	Identification of characteristics	P
4.3	—	<GT-RM2013-003> A.2_Clause 6.2	Hazard identification	P
4.4	—	<GT-RM2013-003> A.2 Clause 6.4	Risk estimation	P

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Clause	Requirement + Test		Result - Remark	Verdict
4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
5	—	<GT-RM2013-003> A.2_section 7	Risk evaluation	P
6.2	—	<GT-RM2013-003> A.2_Clause 8.1	Risk control options	P
6.3	—	<GT-RM2013-003> A.2_Clause 8.1	Implementation/effectiveness of risk control	P
6.4	—	<GT-RM2013-003> A.2_Clause 8.2	Residual risk evaluation	P
6.5	—	<GT-RM2013-003> A.2_Clause 8.3	Risk/Benefit analysis	P
6.6a	—	<GT-RM2013-003> A.2_Clause 8.1	Introduction of new risks due to risk control	P
6.6b	—	<GT-RM2013-003> A.2_Clause 8.1	Estimation of previously risk due to risk control	P
6.7	—	<GT-RM2013-003> A.2_Clause 8.1	Completeness of risk control	P
7	—	<GT-RM2013-003> A.2_section 10	Overall residual risk evaluation	P
8	—	<Risk Management Report GT-RM2013-003> Version A.2	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 (W or VA)	Power factor (cos ϕ)
For Model GTM41080-1507-2.0, with 5Vdc/3A output						
Normal condition		90	50/60	0.327	19.5	<0.9
Normal condition		100	50/60	0.302	19.3	<0.9
Normal condition		240	50/60	0.146	19.5	<0.9
Normal condition		264	50/60	0.137	20.0	<0.9
For Model GTM41080-1811-2.0, with 9Vdc/2A output						
Normal condition		90	50/60	0.380	22.6	<0.9
Normal condition		100	50/60	0.362	22.4	<0.9
Normal condition		240	50/60	0.162	22.5	<0.9
Normal condition		264	50/60	0.154	22.6	<0.9
For Model GTM41080-1817.9-5.9, with 12Vdc/1.5A output						
Normal condition		90	50/60	0.384	22.7	<0.9
Normal condition		100	50/60	0.365	22.6	<0.9
Normal condition		240	50/60	0.164	22.4	<0.9
Normal condition		264	50/60	0.163	22.5	<0.9
For Model GTM41080-1830-6.0, with 24Vdc/0.75A output						
Normal condition		90	50/60	0.379	22.4	<0.9
Normal condition		100	50/60	0.357	22.3	<0.9
Normal condition		240	50/60	0.158	22.2	<0.9

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Clause	Requirement + Test		Result - Remark		Verdict
Normal condition	264	50/60	0.150	22.2	<0.9
For Model GTM41080-1838-2.0, with 36Vdc/0.5A output					
Normal condition	90	50/60	0.371	22.1	<0.9
Normal condition	100	50/60	0.329	22.0	<0.9
Normal condition	240	50/60	0.155	22.2	<0.9
Normal condition	264	50/60	0.149	22.1	<0.9
For Model GTM41080-1848, with 48V/0.375A output					
Normal condition	90	50/60	0.358	21.9	<0.9
Normal condition	100	50/60	0.314	21.4	<0.9
Normal condition	240	50/60	0.162	21.8	<0.9
For Model GTM41080CC1017.9-2.9, with 15Vdc/0.65A output					
Normal condition	90	50/60	0.238	12.11	<0.9
Normal condition	100	50/60	0.218	12.11	<0.9
Normal condition	240	50/60	0.114	12.47	<0.9
Normal condition	264	50/60	0.107	12.67	<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 lx	Clearly legible
Inside Markings (Clause 7.3)		-	N/A
Controls & Instruments (Clause 7.4)		-	N/A
Safety Signs (Clause 7.5)		-	N/A
Symbols (Clause 7.6)		-	N/A
Supplementary information: Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) 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 :	See Table 8.10	Pass	
Ink/other printing material or process..... :	See Table 8.10	Pass	
Material (composition) of Warning Label :	-	N/A	
Ink/other printing material or process..... :	-	N/A	
Other..... :	-	N/A	
Marking Label Tested:		Remarks	
Marking label		Clearly legible	
Printing material		Clearly legible	
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/60Hz	
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. 276Vrms	--	--	--	--	For all models
Optocoupler primary to secondary	Max. 240Vrms	--	--	--	--	For all models
Y capacitor primary to secondary	Max. 240Vrms	--	--	--	--	For all models
Secondary output connector	--	<60Vdc	<10%	--	--	For all models
Supplementary Information:						
1)The input supply voltage to the ME EQUIPMENT 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										
48Vdc/0.375A model	9	3	7	12	6	8	9	9	1	12
24Vdc/0.75A model	1	6	2	5	1	10	9	1	4	3
5Vdc/3A model	4	1	7	6	8	4	3	2	4	3
Plug pin 1 and plug earth pin										
Plug pin 2 and plug earth pin										
Plug pin 1 and enclosure										
Plug pin 2 and enclosure										
Maximum allowable stored charge when measured voltage exceeded 60 v (μc)									45	
Calculated stored charge (μc)										

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Clause	Requirement + Test					Result - Remark				Verdict
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										
Supplementary information:										

8.4.4	TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT			N/A
Maximum allowable residual voltage (V) :			60 V	
Maximum allowable stored charge when residual voltage exceeded 60 V..... :			45 μC	
Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)		Measured residual voltage (V)	Calculated stored charge (μC)	Remarks
Supplementary information:				

8.5.5.1a	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:						

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Clause	Requirement + Test		Result - Remark	Verdict
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:				

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)

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Clause	Requirement + Test	Result - Remark	Verdict
Supplementary information: PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩ ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 mΩ 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 mΩ 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 mΩ			

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
NC	264	60	6.8	For all models, from L/N to accessible enclosure
SFC, interrupt one conductor	264	60	8.7	
SFC, one Y1 capacitor is short circuited.	264	60	10.4	
NC	264	60	60.8	For all models, from L/N to output terminal (+)
SFC, interrupt one conductor	264	60	86.3	
SFC, one Y1 capacitor is short circuited.	264	60	152	
NC	264	60	58.8	For all models, from L/N to output terminal (-)
SFC, interrupt one conductor	264	60	90.7	
SFC, one Y1 capacitor is short circuited.	264	60	144	

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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
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 external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	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. 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; 100 μA 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; 100 μA 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	—	—	—	Maximum allowed values: Type B & BF: 1000 μA

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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
together with external voltage on metal Accessible Part not Protectively Earthed				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;				
Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7				
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.				
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).				
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	

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.		
B/D (Mains part to outer accessible part) (for adapter model only)	2 MOOP	340	--	3000	No breakdown
C (Mains part to protective bonding terminal) (for open frame model only)	1 MOOP	340	--	1500	No breakdown
E (Mains part to secondary circuits) (On optocoupler)	2 MOPP	340	--	4000	No breakdown
F (Mains part to secondary circuits) (On transformer)	2 MOPP	340	--	4000	No breakdown

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Clause	Requirement + Test			Result - Remark	Verdict
G (Mains part to secondary circuits) (On 2 bridge Y capacitor)	2 MOPP	340	--	4000	No breakdown
H (Mains part to secondary circuits) (On PCB trace)	2 MOPP	340	--	4000	No breakdown
Supplementary information: ¹ Alternatively, per the Table (i.e., ___dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used. ² A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).					

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts		P
	Allowed impression diameter (mm)	≤ 2 mm	—
	Force (N)	20	—
Part/material		Test temperature (°C)	Impression diameter (mm)
Enclosure			
SE1X (pass 125degC ball pressure test)		--	--
C2950		75	1.1
CX7211		75	1.1
LN-1250P		75	1.0
PA-765A		75	1.1
EXCY0098		75	1.0
LN-1250G		75	1.0
Blade holder			
SE1X		125	1.0
Bobbin of Mains transformer			
T375J		125	1.3
PM-9820		125	1.3
CP-J-8800		125	1.4
Supplementary information:			

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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 ± 2 °C = ____ °C ¹⁾			
	1 h at 25 °C ± 2 °C			
	2 h at 0 °C ± 2 °C			
	1 or more h at 25 °C ± 2 °C			
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 ± 2 °C = ____ °C ¹		
		2 - 1 h at 25 °C ± 2 °C		
		3 - 2 h at 0 °C ± 2 °C		
		4 - 1 or more h at 25 °C ± 2 °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.				

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	TABLE: List of critical components					P
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity ¹⁾	
PCB	WALEX ELECTRONIC (WUXI)CO LTD	T2 T2A T2B T4	Min 1.6 mm thickness, min. V-0, 130°C	UL 796	UL E154355	
Alt.	DONGGUAN HE TONG ELECTRONICS CO LTD	CEM1	Min 1.6 mm thickness, min. V-0, 130°C	UL 796	UL E243157	
Alt.	CHEERFUL ELECTRONIC	02 03 03A	Min 1.6 mm thickness, min. V-0, 130°C	UL 796	UL E199724	
Alt.	DONGGUAN DAYSUN ELECTRONIC CO LTD	DS2	Min 1.6 mm thickness, min. V-0, 130°C	UL 796	UL E251754	
Alt.	SUZHOU CITY YILIHUA ELECTRONICS CO LTD	YLH-1, YLH-2	Min 1.6 mm thickness, min. V-0, 130°C	UL 796	UL E251781	
Alt.	SHANGHAI AREX PRECISION ELECTRONIC CO LTD	02V0, 04V0	Min 1.6 mm thickness, min. V-0, 130°C	UL 796	UL E186016	
Alt.	BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A DGV0-3A	Min 1.6 mm thickness, min. V-0, 130°C	UL 796	UL E177671	
Alt.	SHENZHEN TONGCHUANGX IN ELECTRONICS CO LTD	TCX	Min 1.6 mm thickness, min. V-0, 130°C	UL 796	UL E177671	
Alt.	PACIFIC WIN INDUSTRIAL LTD	PW-02 PW-03	Min 1.6 mm thickness, min. V-0, 130°C	UL 796	UL E177671	
Alt.	Interchangeable	Interchangeable	Min 1.6 mm thickness, min. V-0, 130°C	UL 796	UL E177671	
Fuse (FS1, FS2)	Conquer Electronics Co., Ltd.	MST	T1.6A, 250V, Rated breaking capacity 100A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40017118 UL E82636	

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Clause	Requirement + Test		Result - Remark		Verdict
Alt.	Ever Island Electric Co., Ltd. and Walter Electric	2010	T1.6A, 250V, Rated breaking capacity 130A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40018781 UL E220181
Alt.	Bel Fuse Ltd.	RST	T1.6A, 250V, Rated breaking capacity 100A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40011144 UL E20624
Alt.	Cooper Bussmann LLC	SS-5	T1.6A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40015513 UL E19180
Alt.	Walter Electronic Co. Ltd.	ICP series	T1.6A, 250V, Rated breaking capacity 50A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40012824 UL E56092
Alt.	Das & Sons International Ltd.	385T series	T1.6A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40008524 UL E205718
Alt.	Shenzhen Lanson Electronics Co. Ltd.	SMT T1,6A250V	T1.6A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40012592 UL E221465
Alt.	Sun Electric Co.	5H	T1.6A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40012592 UL E221465
X capacitor (CX1) (optional)	Cheng Tung Industrial Co., Ltd.	CTX	Max.0.22uF, 310V, 110°C, type X1 or X2	IEC/EN 60384-14 UL 1414	VDE 40022642 UL E193049
Alt.	Tenta Electric Industrial Co. Ltd.	MEX	Max.0.22uF, 250V, 110°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 119119 UL E222911
Alt.	Ultra Tech Xiphi Enterprise Co. Ltd.	HQX	Max.0.22uF, 275V, 100°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40022642 UL E183780
Alt.	Okaya Electric Industries	RE series	Max.0.22uF, 250V, 110°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40028657 UL E47474
Alt.	VISHAY Capacitors Belgium NV	F1772	Max.0.22uF, 310V, 110°C, type X1 or X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40005079 UL E354331

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Clause	Requirement + Test		Result - Remark		Verdict
Alt.	Winday Electronic Industries Co., Ltd.	MPX	Max.0.22uF, 310V, 110°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40018071 UL E302125
Alt.	Dain Electronics Co., Ltd.	MPX, MEX and NPX	Max.0.22uF, 250V, 110°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40018798 UL E147776
Alt.	Sinhua Electronics (Huzhou) Co., Ltd.	MPX	Max.0.22uF, 300V, 110°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40014686 UL E237560
Alt.	Shunde Da Hua Electric Co., Ltd.	HD-MKP	Max.0.22uF, 250V, 105°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40001126 UL E227157
Alt.	Foshan Shunde Chuang Ge	MKP-X2	Max.0.22uF, 275V, 105°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40008922 UL E308832
Alt.	Hongzhi Enterprises Ltd.	MPX	Max.0.22uF, 250V, 100°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40023936 UL E192572
Alt.	Jiangsu Xinghua Huayu Co., Ltd.	MPX	Max.0.22uF, 250V, 100°C, type X2	IEC/EN 60384-14	VDE 40022417
Y-Capacitor (CY1, CY2) (optional)	TDK-EPC CORPORATION	CD	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 138526 UL E37861
Alt.	SUCCESS ELECTRONICS CO LTD	SE SB	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40008996 UL E114280
Alt.	MURATA MFG CO LTD	KX	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40002831 UL E37921

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
Alt.	WALSIN TECHNOLOGY CORP	AH	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40001804 UL E146544
Alt.	JYA-NAY CO LTD	JN	Type Y1, max. 2200pF, min. 250V min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40001831 UL E201384
Alt.	HAOHUA ELECTRONIC CO	CT7	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40003902 UL E233106
Alt.	HONGZHI ENTERPRISES LTD	Y	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40004354 UL E192572
Alt.	JERRO ELECTRONICS CORP	JX-series	Type Y1, max. 2200pF, min. 250V, min. 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40032158 UL E333001
Varistor (MOV1) (optional)	JOYIN CO LTD	07N471K 10N471K 14N471K	300Vac	IEC 61051-2 UL 1449	VDE 005937 UL E325508
Alt.	CENTRA SCIENCE CORP	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40008220 UL E316325
Alt.	THINKING ELECTRONIC INDUSTRIAL CO LTD	TVR07471K TVR10471K TVR14471K	300Vac	IEC 61051-2 UL 1449	VDE 005944 UL E314979
Alt.	SUCCESS ELECTRONICS CO LTD	SVR07D471K SVR10D471K SVR14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40030401 UL E330256
Alt.	CERAMATE TECHNICAL CO LTD	GNR07D471K GNR10D471K GND14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40031745 UL E315429
Alt.	BRIGHTKING (SHENZHEN) CO LTD	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40027827 UL E327997
Alt.	LIEN SHUN ELECTRONICS CO LTD	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40005858 UL E315524

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Clause	Requirement + Test			Result - Remark	Verdict
Alt.	HONGZHI ENTERPRISES LTD	HEL-7D471K HEL-10D471K HEL-14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40008621 UL E324904
Alt.	GUANGXI NEW FUTURE INFORMATION INDUSTRY CO LTD	07D471K 10D471K 14D471K	300Vac	IEC 61051-2 UL 1449	VDE 40030322 UL E323753
Optocoupler (U1)	LITE-ON Technology Corporation	LTV-817C	2MOPP at working voltage 250Vrms, 100°C	IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007	SIQ CB Report No.T223-0437/12
Alt.	Everlight Electronics Co., Ltd.	EL817	2MOPP at working voltage 250Vrms, 100°C	IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007	SIQ CB Report No.T223-0106/13
Transformer (T1)	GlobTek HAOPUWEI HEJIA	XF00514 XF00550 XF00579 XF00590 XF00682A XF00682	Class E, with critical component listed below	IEC 60601-1:2005 + CORR.1:2006 + CORR.2:2007	Tested with appliance
-Triple-insulated wire (Secondary)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	Min.130°C	UL 2353 UL 60601-1	UL E211989
-Alt.	COSMOLINK CO LTD	TIW-M	Min.130°C	UL 2353 UL 60601-1	UL E213764
-Alt.	FURUKAWA ELECTRIC CO LTD	TEX-E	Min.130°C	UL 2353 UL 60601-1	UL E206440
-Bobbin	CHANG CHUN PLASTICS CO LTD	T375J T375HF	V-0, 150°C, thickness 0.45 mm min.	UL 94 UL 746 A/B/C/D	UL E59481
-Alt.	SUMITOMO BAKELITE CO LTD	PM-9820	V-0, 150°C, thickness 0.45 mm min.	UL 94 UL 746 A/B/C/D	UL E41429
-Alt.	HITACHI CHEMICAL CO LTD	CP-J-8800	V-0, 150°C, thickness 0.45 mm min.	UL 94 UL 746 A/B/C/D	UL E42956
-Insulating tape	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1 1350T-1	Min.130°C	UL 510	UL E17385
-Alt.	BONDTEC PACIFIC CO LTD	370S	Min.130°C	UL 510	UL E175868

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Clause	Requirement + Test		Result - Remark		Verdict
-Alt.	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ CT	Min.130°C	UL 510	UL E165111
-Alt.	JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A	Min.130°C	UL 510	UL E246950
-Alt.	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	Min.130°C	UL 510	UL E246820
Line filter (LF1)	GlobTek HAOPUWEI HEJIA	NF00001D	Class A	IEC 60601- 1:2005 + CORR.1:2006 + CORR.2:2007	Tested with appliance
Enclosure and Blade holder	SABIC INNOVATIVE PLASTICS B V	SE1X SE1 SE100	Min. V-1 at 1.5 mm thickness, 105°C	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	C2950	Min. V-0 at 1.5 mm thickness, 75°C	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	CX7211 EXCY0098	Min. V-1 at 1.25 mm thickness, 85°C	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	TEIJIN CHEMICALS LTD	LN-1250P LN-1250G	Min. V-0 at 1.5 mm thickness, 115°C	UL 94 UL 746 A/B/C/D	UL E50075
Alt.	CHI MEI Corporation	PA-765A	Min. V-1 at 1.5 mm thickness, 80°C	UL 94 UL 746 A/B/C/D	UL E56070
Alt.	CHI MEI Corporation	PC-540	Min. V-0 at 1.5 mm thickness, 70°C	UL 94 UL 746 A/B/C/D	UL E56070
Blade holder	SABIC INNOVATIVE PLASTICS B V	SE1X	Min. V-1 at 1.5 mm thickness, 105°C	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	C2950	Min. V-0 at 1.5 mm thickness, 75°C	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	SABIC INNOVATIVE PLASTICS B V	CX7211 EXCY0098	Min. V-1 at 1.25 mm thickness, 85°C	UL 94 UL 746 A/B/C/D	UL E45329
Alt.	TEIJIN CHEMICALS LTD	LN-1250P LN-1250G	Min. V-0 at 1.5 mm thickness, 115°C	UL 94 UL 746 A/B/C/D	UL E50075

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Clause	Requirement + Test		Result - Remark		Verdict
Alt.	CHI MEI Corporation	PA-765A	Min. V-1 at 1.5 mm thickness, 80°C	UL 94 UL 746 A/B/C/D	UL E56070
Alt.	CHI MEI Corporation	PC-540	Min. V-0 at 1.5 mm thickness, 70°C	UL 94 UL 746 A/B/C/D	UL E56070
Output cord	Interchangeable	Interchangeable	Min. 24AWG, min. 300V, min. 80°C	---	UL approved
Label	DONGGUAN XIANGQUAN PRINTING CO LTD	Type XQ03	Rated min 80°C Suitable for use on the plastic enclosure	UL 969	UL MH27594
Alt.	FAN JA PAPER PRINTING CO LTD	Type FJ-03-3	Rated min 80°C Suitable for use on the plastic enclosure	UL 969	UL MH19546
Alt.	FAN JA PAPER PRINTING CO LTD	Type FJ07	Rated min 80°C Suitable for use on the plastic enclosure (PC or ABS)	UL 969	UL MH19546
Alt.	DONGGUAN XIANGQUAN PRINTING CO LTD	Type XQ004-B	Rated min 80°C Suitable for use on the plastic enclosure	UL 969	UL MH47303
Alt.	E-LIN ADHESIVE LABEL CO LTD	Type EL-15	Rated min 80°C Suitable for use on the plastic enclosure	UL 969	UL MH45549
Alt.	SHENZHEN CORWIN PRINTING CO LTD	CW-01	Rated min 80°C Suitable for use on the plastic enclosure	UL 969	UL MH47077
Alt.	YUEN CHANG SPECIAL PRINTING (SHENZHEN) CO LTD	JL-08	Rated min 80°C Suitable for use on the plastic enclosure (PC or ABS)	UL 969	UL MH29752
Alt.	GlobTek	---	Engraving Silkscreen Laser printing	---	---
Switch (Output cord) (optional)	OPENWISE INDUSTRIAL LTD	303	Through-cord single-pole, rated 2A 250V	EN 61058-1 EN 61058-2-1 UL 20	VDE: 106396 UL E213260
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

8.10 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.

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		

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Clause	Requirement + Test	Result - Remark	Verdict
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:			

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:			

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Clause	Requirement + Test	Result - Remark	Verdict
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:			

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:			

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Clause	Requirement + Test	Result - Remark	Verdict
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:			

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	

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Clause	Requirement + Test	Result - Remark	Verdict
9.8.3.2	TABLE: PATIENT support/suspension system - Static forces		N/A
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:				

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./ Description ¹⁾		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			

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Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				P
Model No..... :	1	2	3	4	5
Test ambient (°C) :	21.8	23.5	23.1	21.3	20.4
Test supply voltage/frequency (V/Hz)⁴⁾.. :	See below	See below	See below	See below	See below

Model No.	Thermo-couple No.	Thermocouple location ³⁾	Max allowable temperature ¹⁾ from Table 22, 23 or 24 or RM file for AP ⁵⁾ (°C)	Max measured temperature ²⁾ , (°C)	Remarks
Input: 264V~/60HZ					
1	1	Internal secondary wire	70	51.8	8.10.7 c)
1	2	C3 body	105	73.1	T marking on capacitor body
1	3	T1 winding	95	83.7	Thermocouples are used, so the limit is to be reduced by 10°C.
1	4	T1 bobbin	105	81.7	--
1	5	T1 core	105	74.7	--
1	6	C1 body	105	65.7	T marking on capacitor body
1	7	CX1 body	100	48.3	--
1	8	LF1 winding	105	61.4	--
1	9	CY1 body	125	59.0	--
1	10	U1	100	68.7	--
1	11	PCB near BD1	130	67.2	--
1	12	Enclosure	71	43.7	Table 23 used, enclosure is not intended to be touched for 1s to 10s.
2	1	Internal secondary wire	70	51.5	8.10.7 c)
2	2	C3 body	105	77.8	T marking on capacitor body
2	3	T1 winding	95	75.7	Thermocouples are used, so the limit is to be reduced by 10°C.
2	4	T1 bobbin	105	80.2	--
2	5	T1 core	105	74.8	--
2	6	C1 body	105	63.7	T marking on capacitor body

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Clause	Requirement + Test		Result - Remark		Verdict
Model No.	Thermo-couple No.	Thermocouple location ³⁾	Max allowable temperature ¹⁾ from Table 22, 23 or 24 or RM file for AP ⁵⁾ (°C)	Max measured temperature ²⁾ , (°C)	Remarks
2	7	CX1 body	100	53.2	--
2	8	LF1 winding	105	59.7	--
2	9	CY1 body	125	60.3	--
2	10	U1	100	71.9	--
2	11	PCB near BD1	130	67.1	--
2	12	Enclosure	71	45.8	Table 23 used, enclosure is not intended to be touched for 1s to 10s.
3	1	Internal secondary wire	70	56.0	8.10.7 c)
3	2	C3 body	105	79.2	T marking on capacitor body
3	3	T1 winding	95	85.9	Thermocouples are used, so the limit is to be reduced by 10°C.
3	4	T1 bobbin	105	86.6	--
3	5	T1 core	105	80.8	--
3	6	C1 body	105	72.1	T marking on capacitor body
3	7	CX1 body	100	55.2	--
3	8	LF1 winding	105	67.3	--
3	9	CY1 body	125	62.8	--
3	10	U1	100	74.2	--
3	11	PCB near BD1	130	72.2	--
3	12	Enclosure	71	40.4	Table 23 used, enclosure is not intended to be touched for 1s to 10s.
4	1	Internal secondary wire	70	52.4	--
4	2	C3 body	105	63.7	T marking on capacitor body
4	3	T1 winding	95	79.7	Thermocouples are used, so the limit is to be reduced by 10°C.
4	4	T1 bobbin	105	79.2	--

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Clause	Requirement + Test		Result - Remark		Verdict
Model No.	Thermo-couple No.	Thermocouple location ³⁾	Max allowable temperature ¹⁾ from Table 22, 23 or 24 or RM file for AP ⁵⁾ (°C)	Max measured temperature ²⁾ , (°C)	Remarks
4	5	T1 core	105	74.8	--
4	6	C1 body	105	65.5	T marking on capacitor body
4	7	CX1 body	100	51.9	--
4	8	LF1 winding	105	61.6	--
4	9	CY1 body	125	56.6	--
4	10	U1	100	66.0	--
4	11	PCB near BD1	130	65.3	--
4	12	Enclosure	71	47.8	Table 23 used, enclosure is not intended to be touched for 1s to 10s.
5	1	Internal secondary wire	70	51.8	--
5	2	C3 body	105	73.1	T marking on capacitor body
5	3	T1 winding	95	83.7	Thermocouples are used, so the limit is to be reduced by 10°C.
5	4	T1 bobbin	105	81.7	--
5	5	T1 core	105	74.7	--
5	6	C1 body	105	65.7	T marking on capacitor body
5	7	CX1 body	100	48.3	--
5	8	LF1 winding	105	61.4	--
5	9	CY1 body	125	59.0	--
5	10	U1	100	68.7	--
5	11	PCB near BD1	130	66.8	--
5	12	Enclosure	71	43.7	Table 23 used, enclosure is not intended to be touched for 1s to 10s.
Input: 90V~/60HZ					
1	1	Internal secondary wire	70	55.3	--
1	2	C3 body	105	71.9	T marking on capacitor body

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Clause	Requirement + Test		Result - Remark		Verdict
Model No.	Thermo-couple No.	Thermocouple location ³⁾	Max allowable temperature ¹⁾ from Table 22, 23 or 24 or RM file for AP ⁵⁾ (°C)	Max measured temperature ²⁾ , (°C)	Remarks
1	3	T1 winding	95	84.5	Thermocouples are used, so the limit is to be reduced by 10°C.
1	4	T1 bobbin	105	83.1	--
1	5	T1 core	105	80.5	--
1	6	C1 body	105	82.4	T marking on capacitor body
1	7	CX1 body	100	62.5	--
1	8	LF1 winding	105	94.3	--
1	9	CY1 body	125	63.3	--
1	10	U1	100	70.1	--
1	11	PCB near BD1	130	96.2	--
1	12	Enclosure	71	42.5	Table 23 used, enclosure is not intended to be touched for 1s to 10s.
2	1	Internal secondary wire	70	53.8	--
2	2	C3 body	105	77.6	T marking on capacitor body
2	3	T1 winding	95	86.2	Thermocouples are used, so the limit is to be reduced by 10°C.
2	4	T1 bobbin	105	85.2	--
2	5	T1 core	105	79.3	--
2	6	C1 body	105	90.0	T marking on capacitor body
2	7	CX1 body	100	81.7	--
2	8	LF1 winding	105	103.0	--
2	9	CY1 body	125	65.7	--
2	10	U1	100	75.9	--
2	11	PCB near BD1	130	107.1	--
2	12	Enclosure	71	47.6	Table 23 used, enclosure is not intended to be touched for 1s to 10s.

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Clause	Requirement + Test		Result - Remark		Verdict
Model No.	Thermo-couple No.	Thermocouple location ³⁾	Max allowable temperature ¹⁾ from Table 22, 23 or 24 or RM file for AP ⁵⁾ (°C)	Max measured temperature ²⁾ , (°C)	Remarks
3	1	Internal secondary wire	70	58.2	--
3	2	C3 body	105	79.6	T marking on capacitor body
3	3	T1 winding	95	91.4	Thermocouples are used, so the limit is to be reduced by 10°C.
3	4	T1 bobbin	105	92.2	--
3	5	T1 core	105	85.5	--
3	6	C1 body	105	96.1	T marking on capacitor body
3	7	CX1 body	100	79.6	--
3	8	LF1 winding	105	104.3	--
3	9	CY1 body	125	67.7	--
3	10	U1	100	78.8	--
3	11	PCB near BD1	130	102.1	--
3	12	Enclosure	71	43.3	Table 23 used, enclosure is not intended to be touched for 1s to 10s.
4	1	Internal secondary wire	70	52.2	--
4	2	C3 body	105	63.5	T marking on capacitor body
4	3	T1 winding	95	80.3	Thermocouples are used, so the limit is to be reduced by 10°C.
4	4	T1 bobbin	105	80.3	--
4	5	T1 core	105	75.0	--
4	6	C1 body	105	86.7	T marking on capacitor body
4	7	CX1 body	100	74.6	--
4	8	LF1 winding	105	103.3	--
4	9	CY1 body	125	57.5	--
4	10	U1	100	68.5	--
4	11	PCB near BD1	130	112.4	--
4	12	Enclosure	71	51.1	Table 23 used,

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Clause	Requirement + Test	Result - Remark	Verdict

Model No.	Thermo-couple No.	Thermocouple location ³⁾	Max allowable temperature ¹⁾ from Table 22, 23 or 24 or RM file for AP ⁵⁾ (°C)	Max measured temperature ²⁾ , (°C)	Remarks
					enclosure is not intended to be touched for 1s to 10s.
5	1	Internal secondary wire	70	54.1	--
5	2	C3 body	105	76.4	T marking on capacitor body
5	3	T1 winding	95	86.6	Thermocouples are used, so the limit is to be reduced by 10°C.
5	4	T1 bobbin	105	84.1	--
5	5	T1 core	105	76.8	--
5	6	C1 body	105	81.3	T marking on capacitor body
5	7	CX1 body	100	65.5	--
5	8	LF1 winding	105	92.6	--
5	9	CY1 body	125	61.4	--
5	10	U1	100	72.8	--
5	11	PCB near BD1	130	98.7	--
5	12	Enclosure	71	51.6	Table 23 used, enclosure is not intended to be touched for 1s to 10s.

Supplementary information:

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

² Max temperature determined in accordance with 11.1.3e)

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

⁴ Supply voltage:

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

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

⁶ Model No.1 represents 48Vdc/0.375A output model; Model No.2 represents 36Vdc/0.5A output model; Model No.3 represents 24Vdc/0.75A output model; Model No.4 represents 9Vdc/2A output model; Model No.5 represents 5Vdc/3A output model.

⁷ For open frame model, it shall be evaluated in the end product.

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Clause	Requirement + Test			Result - Remark	Verdict
11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				P
Model No. :	1(GTM41080CC1017.9-2.9)				
Test ambient (°C)	21.2	23.3			
Test supply voltage/frequency (V/Hz)⁴⁾ .. :	264V~/60HZ	90V~/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
Input: 264V~/60HZ					
1	1	PCB near D7	130	85.1	--
1	2	T1 winding	110 ³⁾	92.4	--
1	3	T1 core	120	90.0	--
1	4	C1 body	105	78.4	T marking on capacitor body
1	5	Q1	130	83.6	--
1	6	BD1	130	82.3	--
1	7	LF1	105	73.8	--
1	8	Enclosure	71	57.5	Table 23 1s<t<10s
Input: 90V~/60HZ					
1	1	PCB near D7	130	77.9	--
1	2	T1 winding	110 ³⁾	84.2	--
1	3	T1 core	120	82.1	--
1	4	C1 body	105	77.7	T marking on capacitor body
1	5	Q1	130	75.8	--
1	6	BD1	130	83.9	--
1	7	LF1	105	76.6	--
1	8	Enclosure	71	55.3	Table 23 1s<t<10s
Supplementary information: ¹⁾ Maximum allowable temperature on surfaces of test corner is 90 °C ²⁾ Max temperature determined in accordance with 11.1.3e) ³⁾ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C. ⁴⁾ Supply voltage: - ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage; - Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE. - Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage. ⁵⁾ APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use. ⁶⁾ For open frame model, it shall be evaluated in the end product.					

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Clause	Requirement + Test	Result - Remark	Verdict

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:							

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)							

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Clause	Requirement + Test	Result - Remark	Verdict
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:			

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:				

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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:	—	—
	C1 short circuit	Fuse open	No HZ
	BD1 short circuit	Fuse open	No HZ
	U1 (sec.) short circuit	No output, circuit protected.	No HZ
	U1 (pri.) short circuit	No output, circuit protected.	No HZ
	D8 (Pin 1-2) short circuit	No output, circuit protected.	No HZ
	D8 (Pin 1-3) short circuit	Normal operation.	No HZ
	ZD3 short circuit	No output, circuit protected.	No HZ
	Q1 short circuit	Fuse open	No HZ
13.2.3	Overheating of transformers per Clause 15.5:	—	—
		See 15.5	NO HZ
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
		No thermostat used	N/A
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
		No temperature limiting device	N/A
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
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

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Clause	Requirement + Test	Result - Remark	Verdict
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Simulated blocking of filters	No filter	N/A
	Flow of a cooling agent interrupted	No cooling agent used	N/A
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
		No moving part	N/A
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited ¹⁾ – Also see 13.10	—	—
		No such motor	N/A
		No such motor	N/A
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 & 13.2.9:	—	—
	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

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Clause	Requirement + Test	Result - Remark	Verdict
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
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:			

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

15.5.1.2	TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION						P
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V) ¹⁾ ... :					264Vac	—	
RATED input frequency (Hz)..... :					60Hz	—	
Winding tested	Class of insulation (A, B, E, F, or H)	Type of protective device (fuse, circuit breaker) /Ratings	Protective device operated Yes/No	Time to THERMAL STABILITY (when protective device did not operate)(Min)	Maximum allowed temp from Table 31 (°C)	Maximum winding temp measured (°C)	Ambient (°C)
XF00514	A	Fuse 1.6A	No	60min	140 ²⁾	32.1	25

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Clause	Requirement + Test			Result - Remark			Verdict
XF00550	A	Fuse 1.6A	No	60min	140 ²	31.1	25
XF00579	A	Fuse 1.6A	No	60min	140 ²	30.2	25
XF00590	A	Fuse 1.6A	No	60min	140 ²	32.2	25
XF00682A	A	Fuse 1.6A	No	60min	140 ²	30.5	25
XF00682	A	Fuse 1.6A	No	60min	140 ²	31.2	25
Supplementary information: ¹⁾ Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.							

15.5.1.3	TABLE: transformer overload test – conducted only when protective device under short-circuit test operated					P
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V) ¹⁾ :					264V	
RATED input frequency (Hz)..... :					60Hz	
Test current just below minimum current that would activate protective device 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)	
XF00514	A	Fuse 1.6A (OL current 0.402A)	140 ²	115.9	25	
XF00550	A	Fuse 1.6A (OL current 0.480A)	140 ²	104.8	25	
XF00579	A	Fuse 1.6A (OL current 0.425A)	140 ²	101.2	25	
XF00590	A	Fuse 1.6A (OL current 0.407A)	140 ²	106.1	25	
XF00682A	A	Fuse 1.6A (OL current 0.371A)	140 ²	98.9	25	
XF00682	A	Fuse 1.6A (OL current 0.467A)	140 ²	104.2	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.						

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Clause	Requirement + Test			Result - Remark	Verdict
15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				P
Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
All models	Primary & secondary windings	4000	50	No	No
All models	Secondary winding & core	4000	50	No	No
All models	Primary winding	1200	300	No	No
Supplementary information: Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details					

16.6.1	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:			

ATTACHMENT Photo of EUT

Photo 1: external view of EUT for CV model adapter



Photo 2: external view of EUT for CV model adapter



Photo 3: Internal view of EUT for CV model adapter

Photo 4: Component side view of PCB for CV model adapter

Photo 5: Soldering side view of PCB for CV model adapter

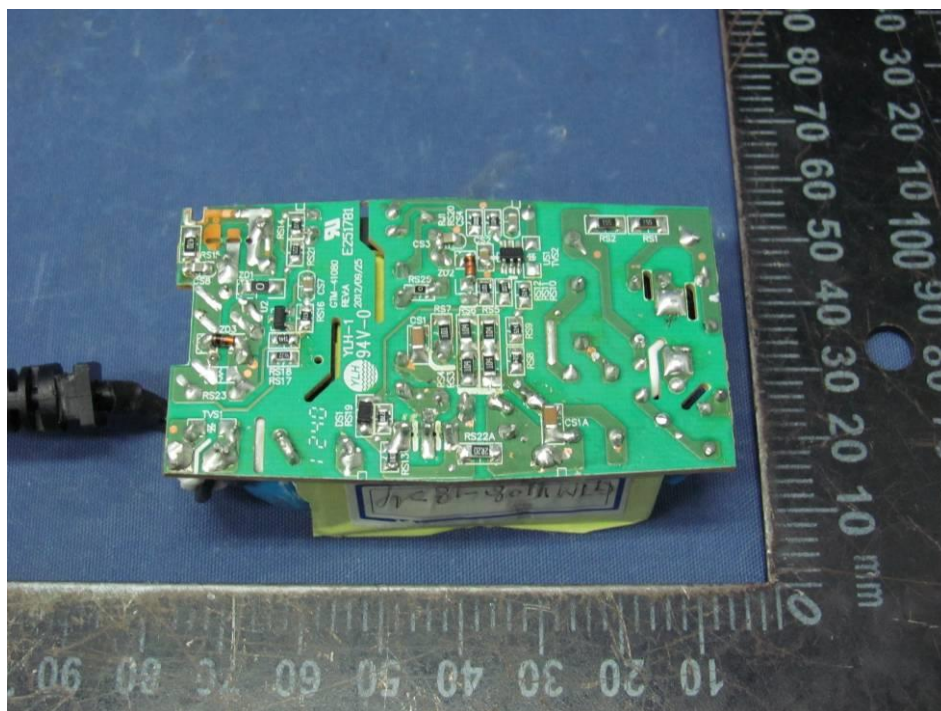


Photo 6: External view of transformer

Photo 7: Pin-out view of transformer

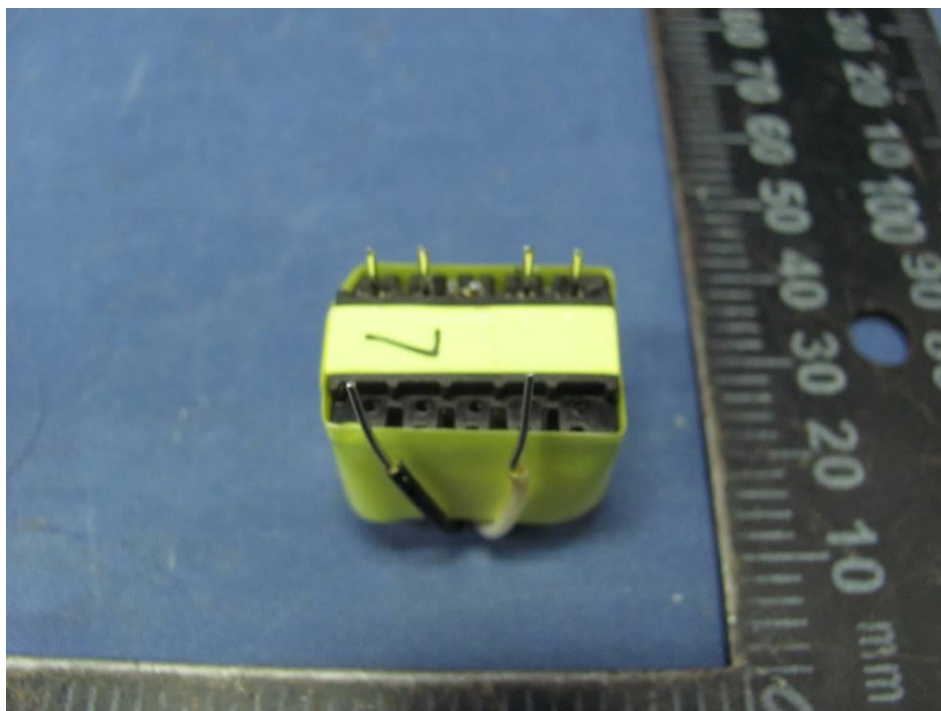


Photo 8: Primary winding view-1 of transformer

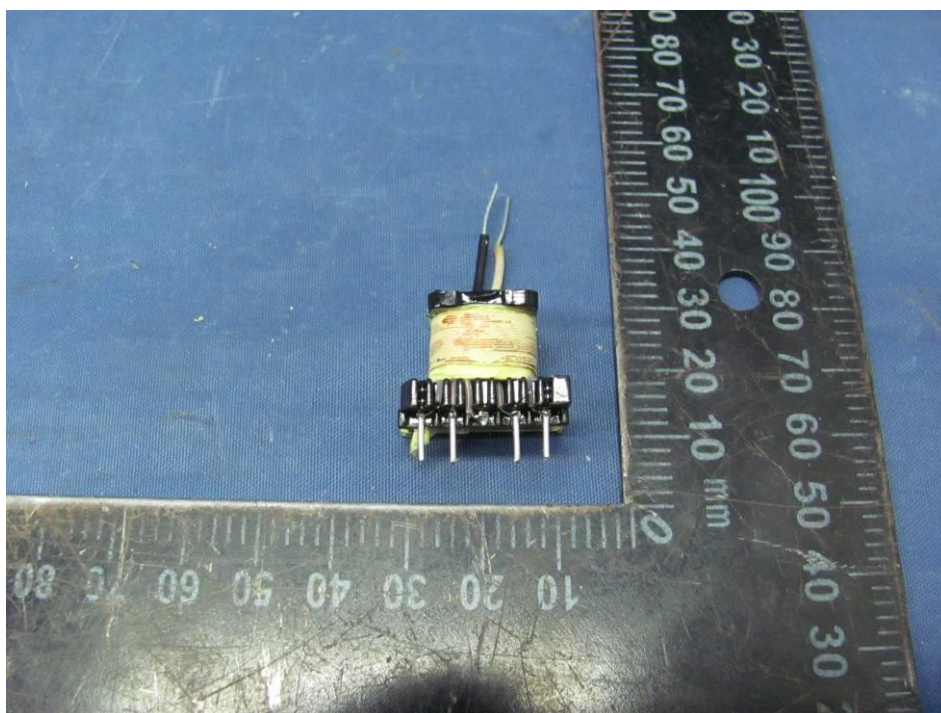


Photo 9: Primary winding view-2 of transformer

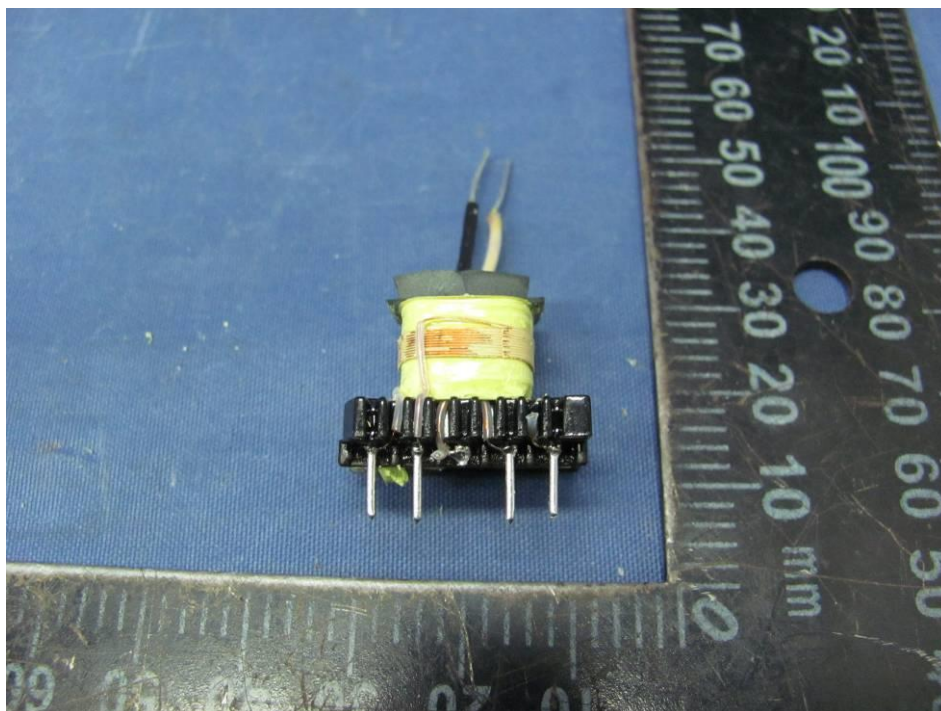


Photo 10: Secondary winding view of transformer

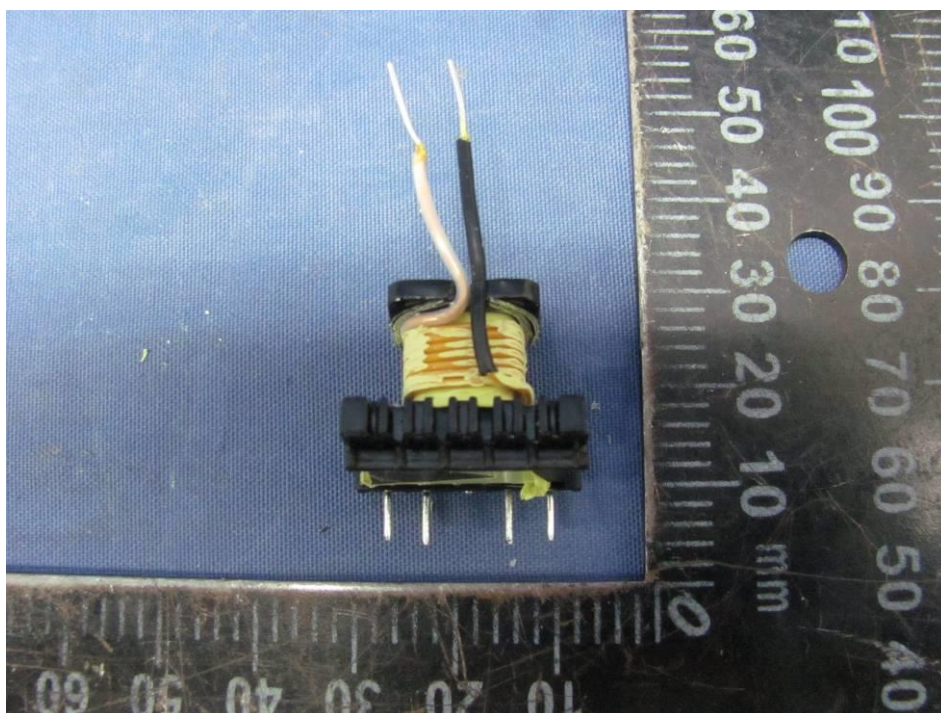


Photo 11: Primary winding view-3 of transformer

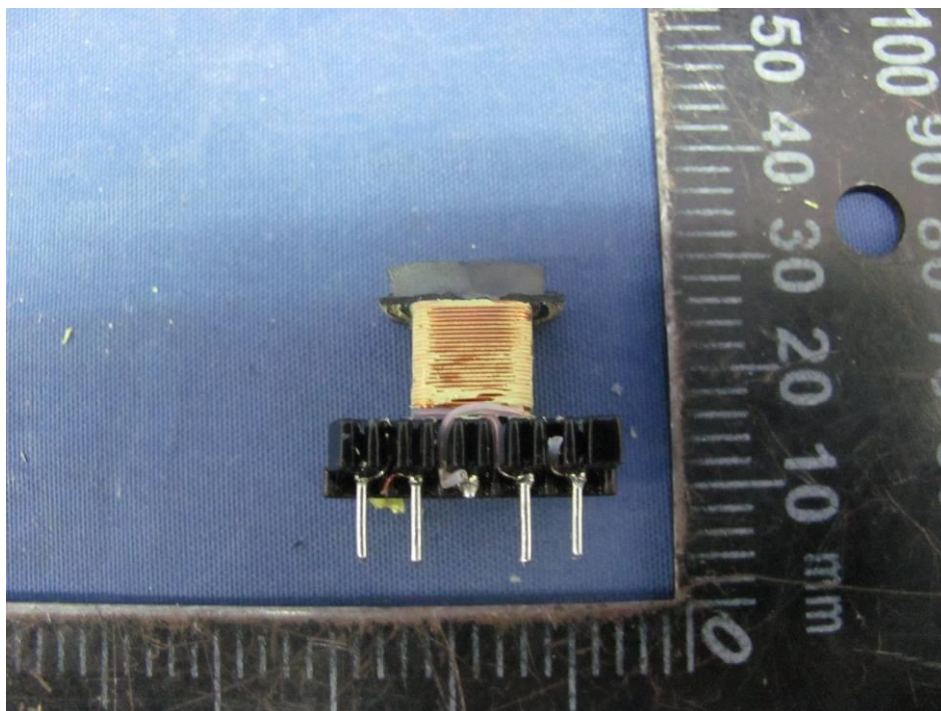


Photo 12: External view of transformer (Alternative type)

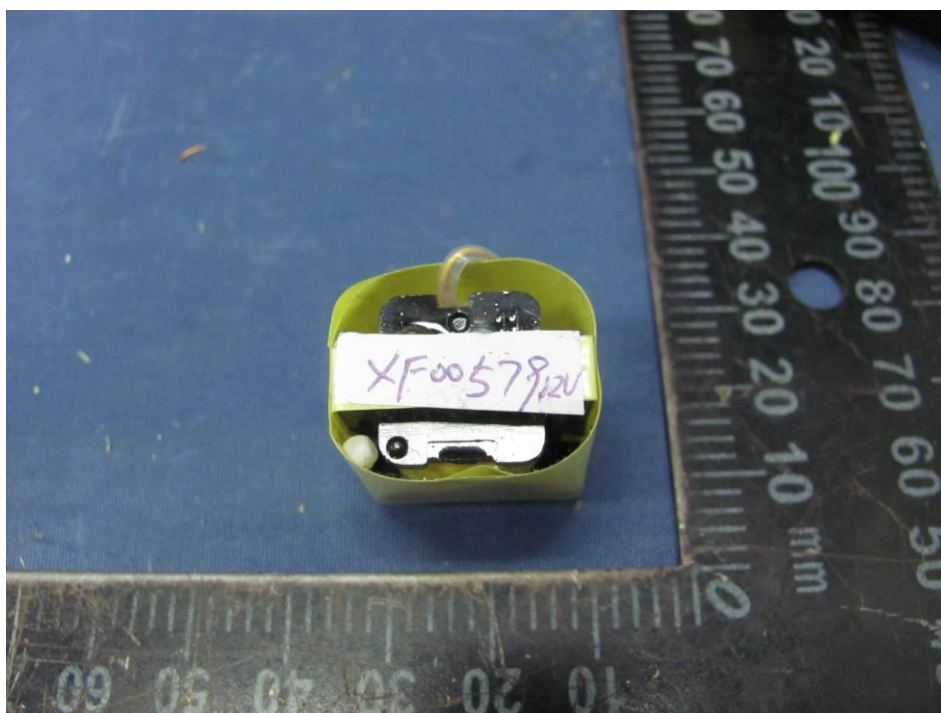


Photo 13: Pin-out view of transformer (Alternative type)

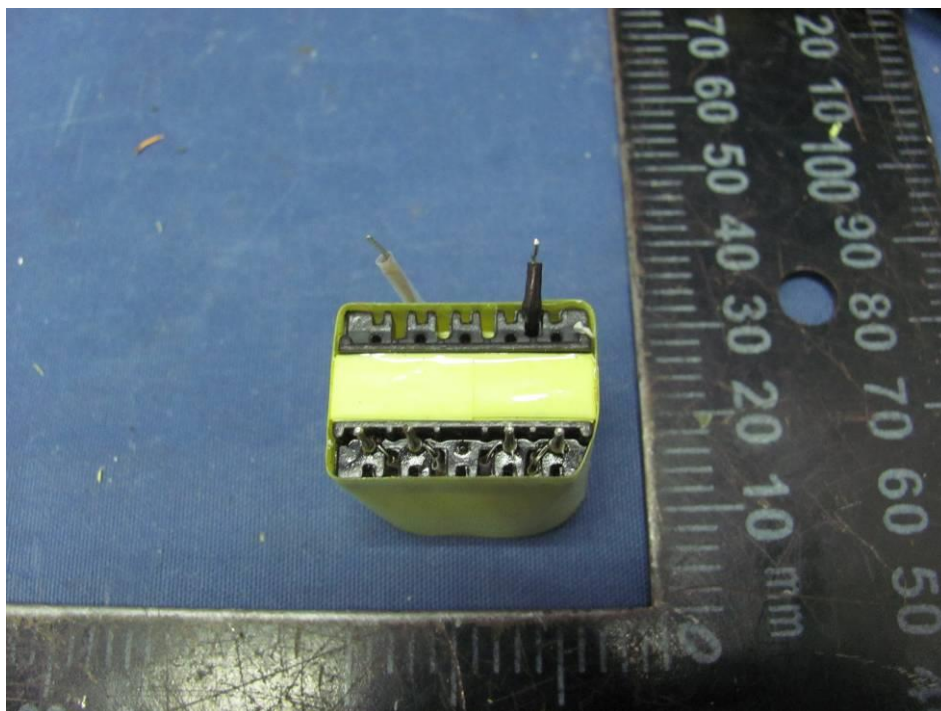


Photo 14: Component side view of open frame model

Photo 15: Soldering side view of open frame model

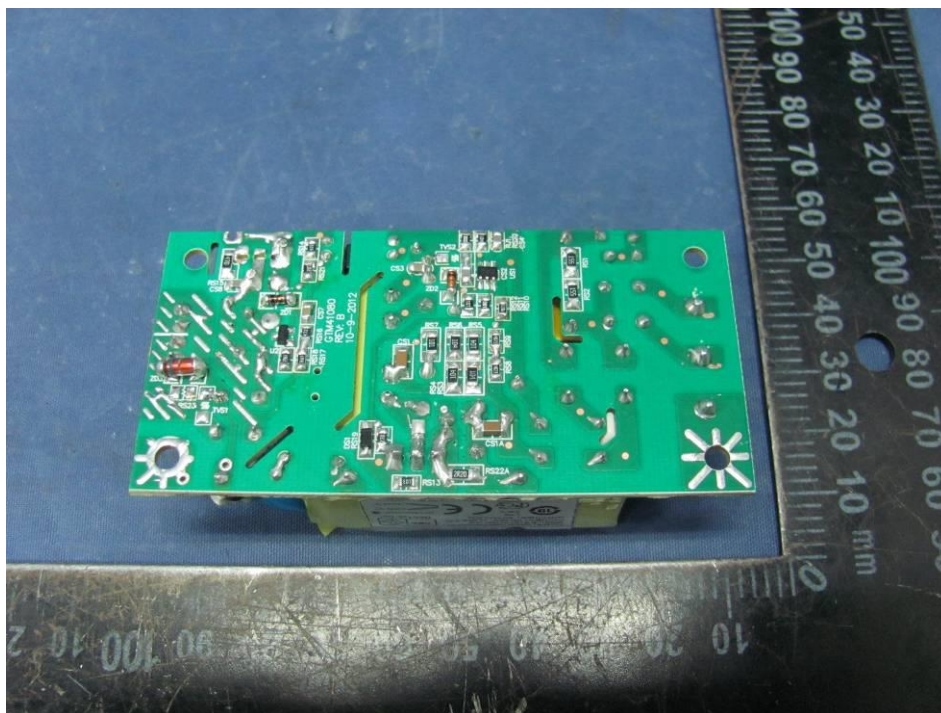


Photo 16: external view of EUT for CC model adapter



Photo 17: external view of EUT CC model adapter



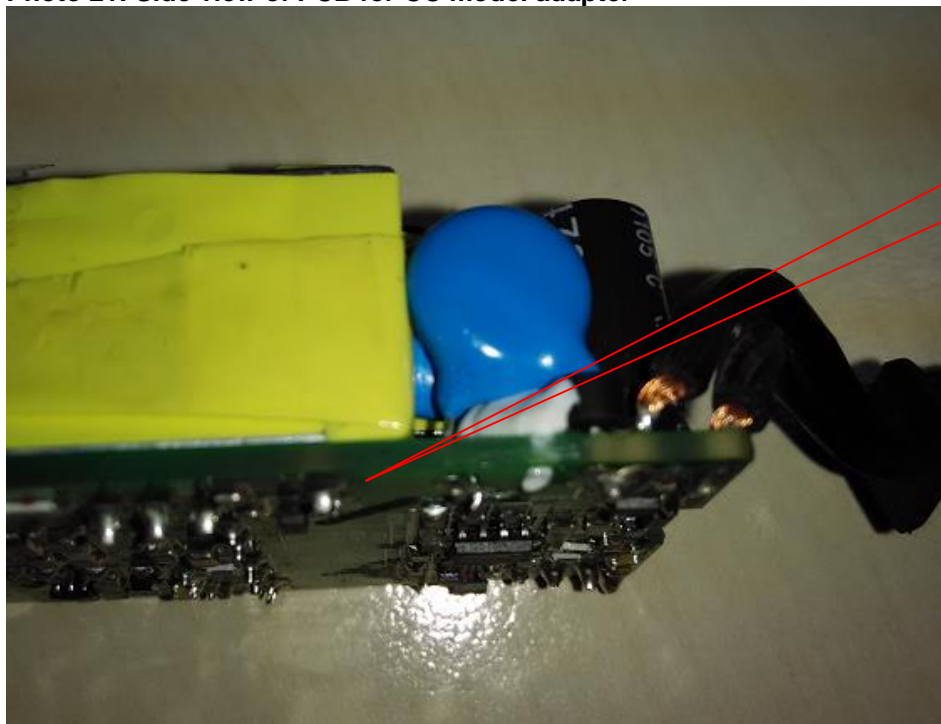
Photo 18: Internal view of EUT for CC model adapter

Photo 19: Component side view of PCB for CC model adapter

Photo 20: Soldering side view of PCB for CC model adapter

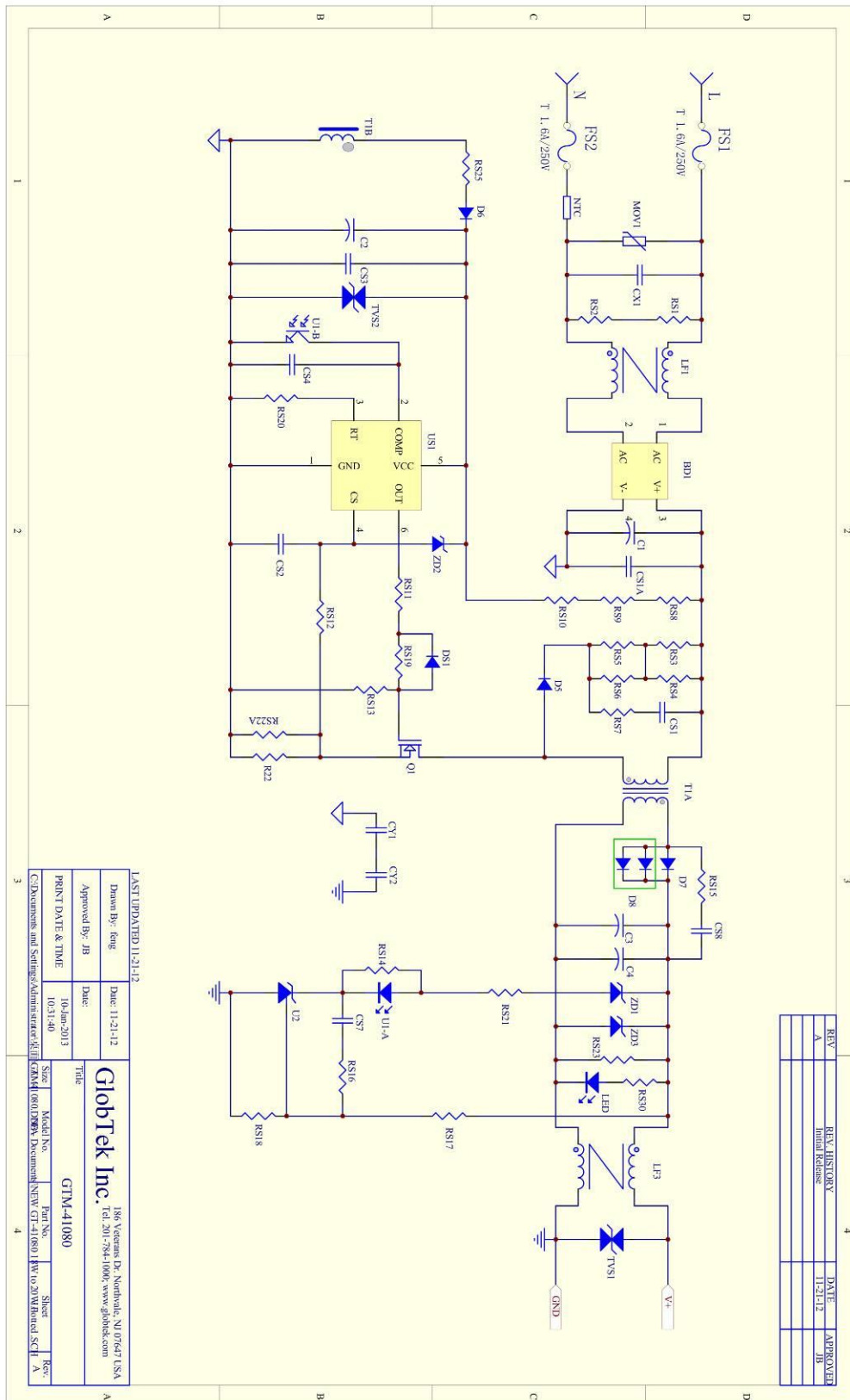


Photo 21: Side view of PCB for CC model adapter



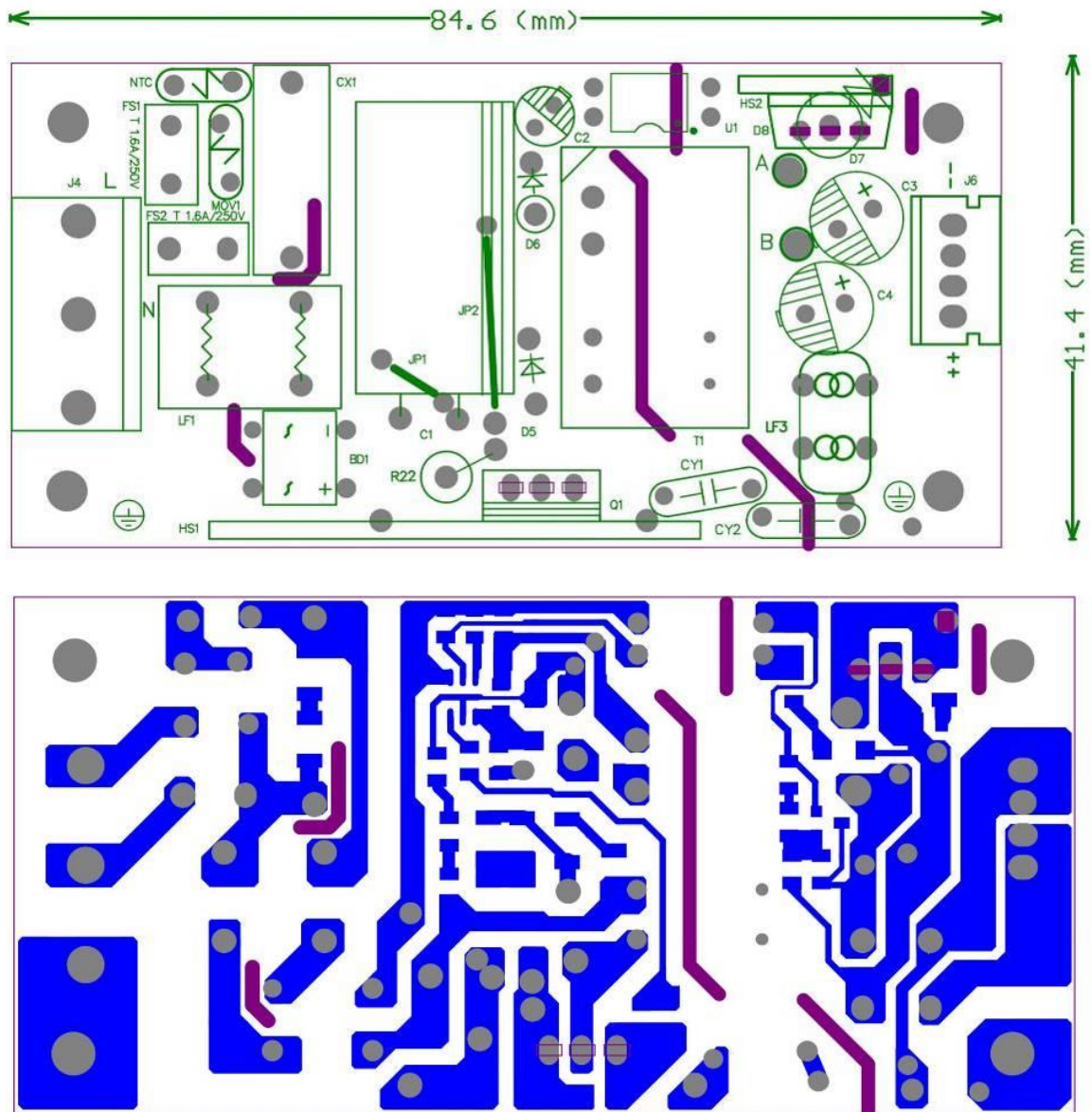
Two layers of insulation tape wrapped from the pin.

ATTACHMENT Circuit Diagram / Layout



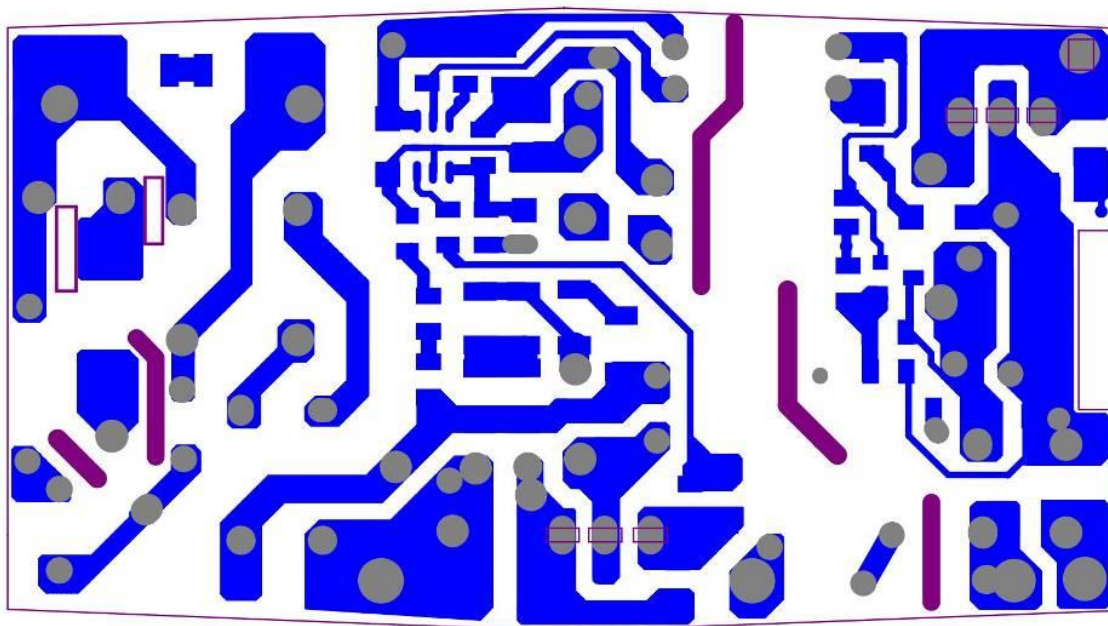
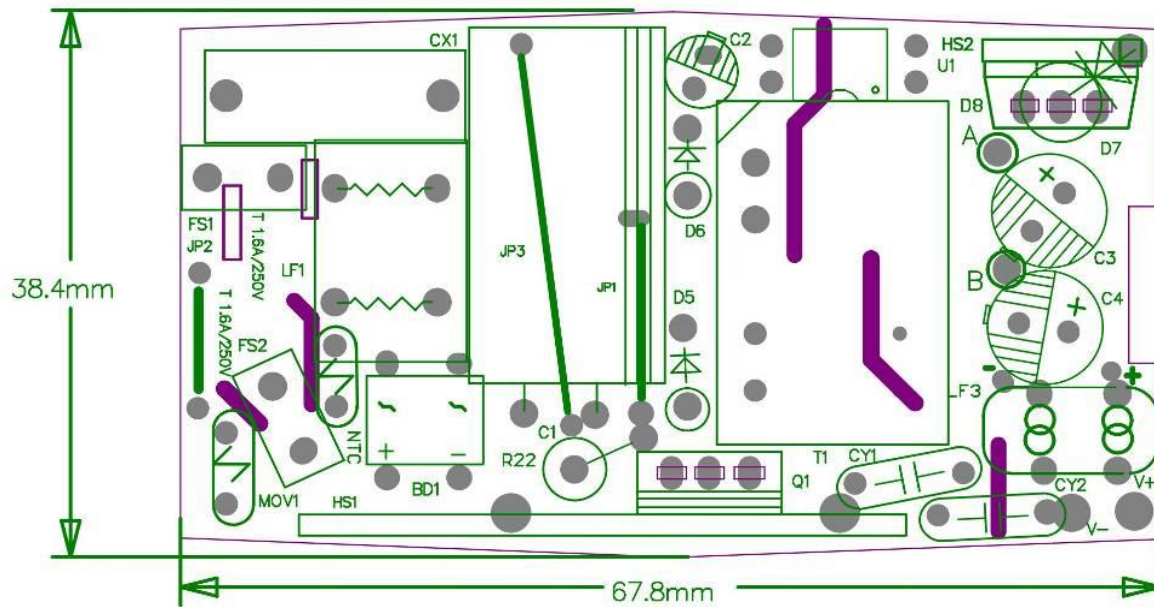
ATTACHMENT Circuit Diagram / Layout

For open frame model



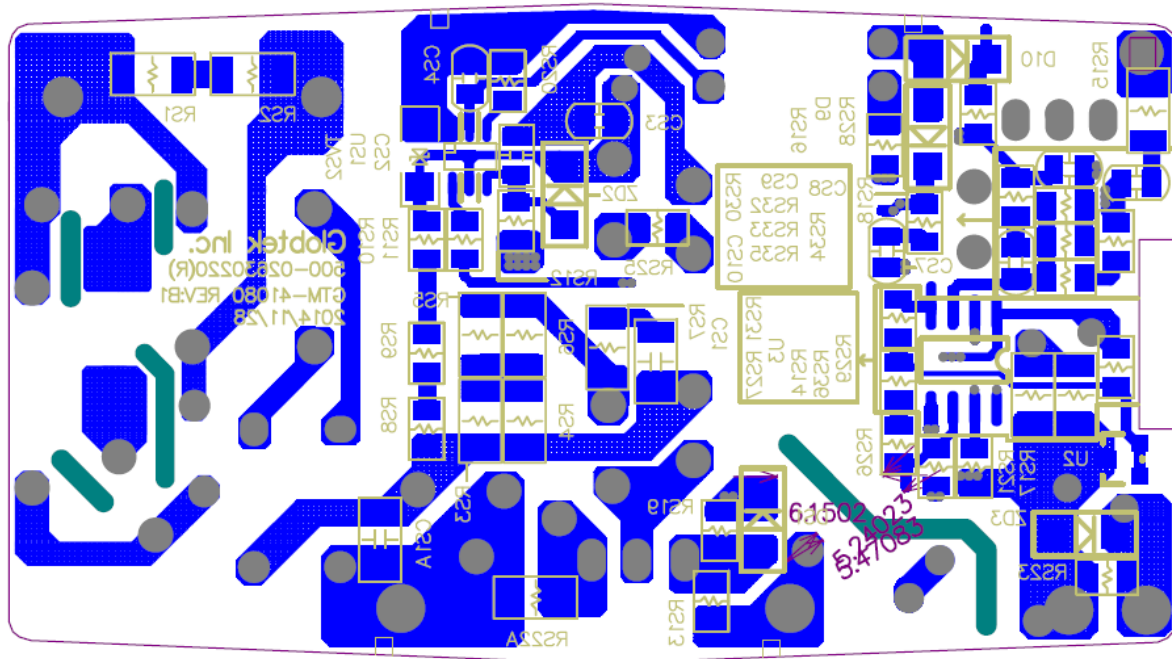
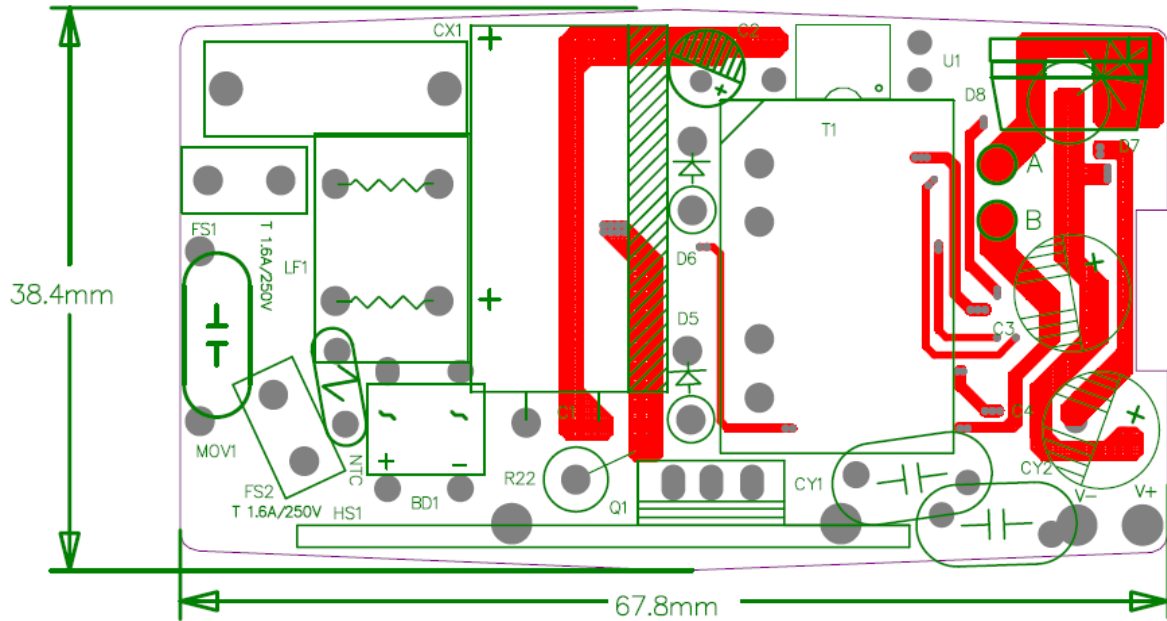
ATTACHMENT Circuit Diagram / Layout

For adapter model



[illegible]

ATTACHMENT Circuit Diagram / Layout for CC model adaptor



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

ATTACHMENT TO TEST REPORT IEC 60601-1 US NATIONAL DIFFERENCES Medical electrical equipment, Part 1: General Requirements	
Differences according to	US National standard ANSI/AAMI ES60601-1: 2005 / A2:2010
Attachment Form No.	US_ND_IEC60601_1G
Attachment Originator	Underwriters Laboratories Inc.
Master Attachment	2011-04
Copyright © 2011 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.	

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

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	National standard reference: SN EN 60601-1:2006		
4	<p>Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7, Mercury - Annex 1.7 of SR 814.81 applies for mercury.</p> <p>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</p> <p>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>	No such component.	N/A
4	<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.</p> <p>See TRF template regulatory requirements Switzerland on IECEE Website R.R. TRF templates.</p>	No supply cord.	N/A

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

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

Supplementary tests on plug portion according to EN 50075:1990

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

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict
6.2	<p>The plug is tested in a tumbling barrel. (Clause 13.2 of EN 50075, fall number is shown in test report for medical power supply) After the test, the plug shall show no damage within the meaning of this standard, in particular:</p> <ul style="list-style-type: none"> --- No part shall become detached or loosened. --- The pin shall not turn when a torque of 0.4Nm is applied. <p>Note: A section of the pin is square constructed for preventing the rotation.</p>		P
6.3	<p>The pins is held in a suitable clamp in such a position that the straight part of a steel wire (D=1+-0.02mm, U-shaped) rests on the plug pin. The plug is caused to move backwards and forwards, so that the wire rubs along the pin. The number of the movements is 20 000, and the rate of the operation is 25 movements per min. (Clause 13.3 of EN 50075)</p> <p>After the test, the pin show no damage which may effect safety or impair the further use of the plug, in particular, the insulating sleeve shall not have punctured or rucked up.</p>		P
6.4	<p>A pull force of 40N is applied for 60s on each pin in turn in the direction of the longitudinal axis of the pin. The pull is applied 60min after the plug has been placed in a heating cabinet of 70°C. After the plug cooling down to ambient temperature, any pin shall not have displaced in the body of the plug more than 1mm. (Clause 13.4 of EN 50075)</p>		P
7.	Resistance to Heat and to Ageing (Clause 14 of EN 50075)		P
8.	Current-carrying Parts and Connections (Clause 15 of EN 50075)		
8.1	<p>Connection, electrical and mechanical, shall withstand the mechanical stresses occurring in normal use, and electrical connections shall be designed that contact pressure is not transmitted through insulating material. (Clause 15.1 & 15.2 of EN 50075)</p>		P
8.2	<p>Current-carrying parts shall be of copper or an alloy containing at least 58% of copper. (Clause 15.3 of EN 50075)</p>		P
9.	Creepage Distance, Clearances, and Distances Through Insulation (Clause 16 of EN 50075)		P
10.	Resistance of Insulating Material to Abnormal Heat and to fire (Clause 17 of EN 50075)		P

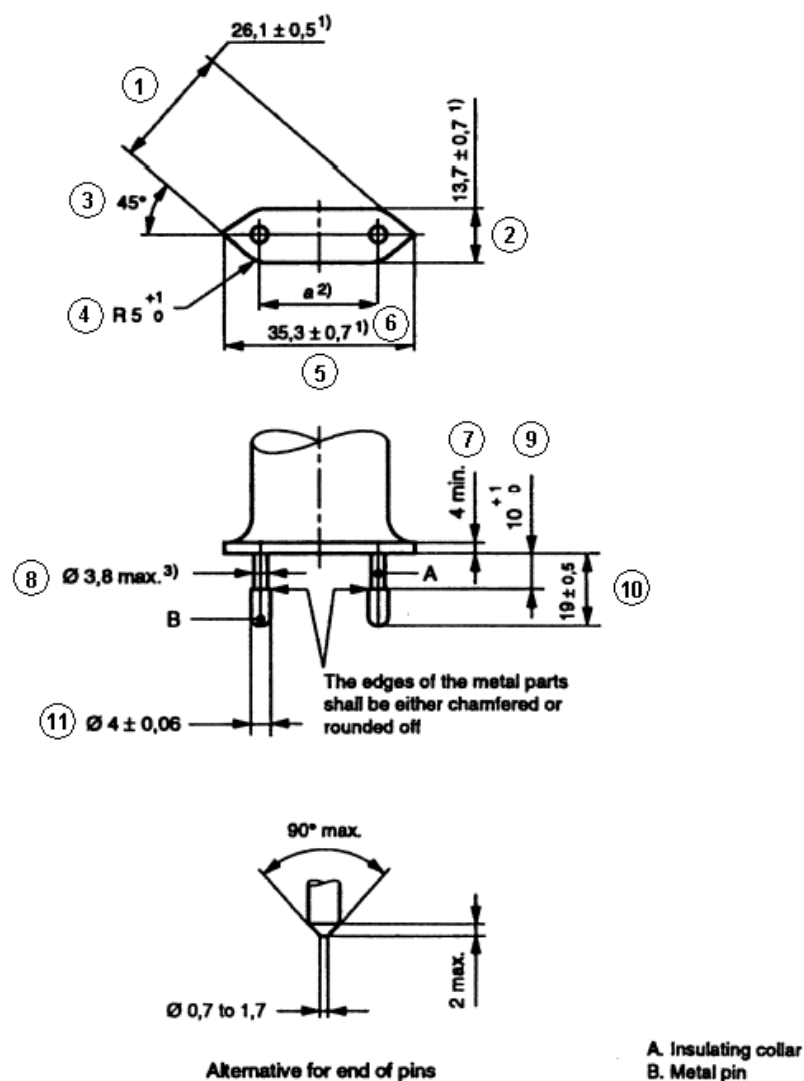
IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 2: Dimensions of integral plug

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

IEC 60601-1 Attachment

Clause	Requirement + Test	Result - Remark	Verdict
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EN50075: 1990 Standard sheet 1**Dimensions in millimetres**

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

²⁾ Dimension a is:

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

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

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

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

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

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

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



IEC 60601-1 Attachment

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

Appendix 4 Equipment's combined with Australian plug.

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

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

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict
Clause	Requirement – Test	Remark	Verdict
2.13.9.1	MOVEMENT OF PINS		P
2.13.9.2	FIXING OF PINS		P
2.13.13	ADDITIONAL TESTS ON THE INSULATION MATERIAL OF INSULATED PIN PLUGS		P

INSULATING MATERIALS TEST IN ACCORDANCE WITH AS/NZS 3121: 2002			
7.1	General		P
7.2	Resistance to heat test The moulding shall be placed in an oven and maintained for 6 h at the temperature appropriate to its class (see Clause 5) plus 10°C. 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
7.3	Water absorption test 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
7.4	Resistance to white spirit test Sample shall be immersed in white spirit at room temperature for 2 min. The moulding shall not blister, warp or show any physical or chemical change to a degree that would be liable to impair the safety of the equipment of which it forms a part.		P

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

Appendix 5 Photos of Australian plug portion



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



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

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

Section	Key	Comment
FORWARD		
Introduction		
1		Scope
1.1-1.4	G	The device under evaluation is an integral plug for medical power supply GT*41080-**** whose input rated 100-240VAC, 50-60Hz, 0.6A. The plug is evaluated according to rated input.
2		Glossary
2.1-2.38	G	Noted.
3		Components
3.1-3.4	G	Noted
4		Units of Measurement
4.1	G	Noted
5		Reference
5.1	G	Noted
CONSTRUCTION		
		ALL DEVICES
6		General
6.1	√	According to declared reasonable condition, 100-240VAC, 50-60Hz, has been considered in all following test.
6.2	√	Plug for AC use only
7		Configurations
7.1	√	1-15P plug applied.
8		Insulating Materials
8.1		General
8.1.1	√	All parts that act as the electrical insulation or enclosure are made of plastic material. See 8.2.1
8.1.2	N/A	Vulcanized fiber is not provided
8.2		Flammability
8.2.1	√	The insulating material required HB or more. For detailed parts, see report of end product)
8.3		Electrical properties
8.3.1	√	Exception No. 1: No information according to above table info. The insulating material has a CTI 3 (Required 3), so it need NOT comply with Comparative Tracking Index Test, Section 55.
8.3.2	√	Exception No. 2: The insulating material has a HWI 3, (required HWI value is 4 when material class is V-0). According to 8.1.2 (UL746D) and reasonable usage, reasonable arcing occurs in normal use. We are of the opinion that it need NOT comply with Glow Wire Test, see Section 56. Exception No. 3: The insulating material has a HAI 2. (required HWI value is 4 when material class is V-0. or check if the thickness), since no arcing in normal use, so it need not comply with High-Current Arc Resistance to Ignition Test, Section 57.
8.4		Thermal properties
8.4.1	√	All the RTI rating of the insulating materials are higher than 80 degree (C)
8.5		Vulcanized fiber

IEC 60601-1 Attachment			
Clause	Requirement + Test		Verdict
Section	Key	Comment	
8.5.1	N/A	No Vulcanized fiber is provided	
8.5.2	N/A	No Vulcanized fiber is provided	
8.6		Sealing compounds	
8.6.1-8.6.2	N/A	Sealing compound is not provided, no need to comply with relevant requirement involved in ASTM 28.	
8.7		Fuse enclosures	
8.7.1-8.7.2	N/A	Fuse is not provided	
9		Enclosure	
9.1		General	
9.1.1	√	Live parts of plug parts are protected against exposure to contact by persons when fully assembled using all essential parts. Exception no. 2: for fixed wiring.	
9.1.2-9.1.3	N/A	No accessible dead-metal parts	
9.1.4	√	The probe shown in Figure 9.1 is used to judge the accessibility of a live or dead-metal part. The applied force is not more than 13.3N.	
9.1.5-9.1.7	N/A	No such separable part	
9.2		Male faces and wire terminations	
9.2.1	N/A	Not a 15 or 20A attachment plug or current tap	
9.2.2	N/A	There is no exposed live part.	
9.2.3	N/A	No such parts	
9.2.4-9.2.5	√	Probe not access to live parts. The cover is securely fixed for all acceptable wiring.	
9.2.6	√	The face plate is secure with the back part.	
10		Current-carrying Parts	
10.1		General	
10.1.1	√	Iron or steel is not used for current-carrying parts.	
10.1.2	√	The current-carrying parts are not able to be turned by means of general tools due to the appliance shroud mounted on Evaluated appliance.	
10.1.3	N/A	No such uninsulated live parts except for female contact of connector	
10.2		Contacts (applying to the connector)	
10.2.1	N/A	Female contacts of the connector cannot be touched by the probe. Others parts are covered by exception no. 3	
11		Grounding and Dead Metal Parts	
11.1-11.10	N/A	No grounding parts	
12		Terminals	
12.1-12.4		No terminals for end user	
13		Cord Entry and Strain Relief	
13.1-13.5	N/A	Flexible cord part are considered in the end appliances.	
14		Spacings	
14.1	√	The spacing through air between uninsulated live parts of opposite polarity and between uninsulated live parts and exposed external surface is measured more than 2mm (required 3/36 inch, 1,2mm) for a device rated 250V or less.	
14.2	N/A	No such isolated dead-metal part	
15		Assembly	
15.1		General	
15.1.1	√	Pre-wired in factory	

IEC 60601-1 Attachment				
Clause	Requirement + Test		Result - Remark	Verdict
Section	Key	Comment		
15.1.2	√	Electrical contact is reliably maintained at any point		
15.1.3	√	Live parts is protected against exposure to persons		
15.1.4	N/A	Not multiple outlet device		
15.1.5	N/A	Female contacts of the connector can be mated with the inlet in right way without exposure of the blades		
15.2		Grounding and polarization		
15.2.1-15.2.4	N/A	No grounding		
15.3		Mating and interchangeability		
15.3.1	√	The electrical continuity is automatically established.		
15.3.2-15.3.6	√	1-15P receptacles ensuring.		
15.4		Fuseholders		
15.4.1-15.4.8	N/A	Fuseholder is not provided		
15.5		Switches		
15.5.1	N/A	The switch is provided between coupler 1 and coupler 2. but it is a information		
ATTACHMENT PLUGS AND INLETS (for plug only)				
16		Insulating material		
16.1	√	The enclosure is measured min. 2.1 mm.		
17		Enclosure		
17.1		General		
17.1.1	N/A	Not a general use plug.		
17.1.2	√	Measured 44 mm.		
17.1.3	N/A	Not a 50A plug		
17.2		Grip		
17.2.1	N/A	See section 69		
17.3		Face size		
17.3.1	√	Larger than figure 17.1		
18		Current carrying parts		
18.1	N/A	Not a folded-over plug.		
18.2	√	Dimensional requirements fulfilled.		
19		Grounding and dead metal parts		
19.1-19.4	N/A	No grounding or dead metal parts.		
20		Terminals and leads		
20.1-20.5	N/A	All the assembly are pre-wired in factory		
21		Assembly		
21.1	√	The blades are held securely in place		
21.2	N/A	Not a inlet		
21.3-21.4	N/A	The device under evaluate is a plug part not inlet or surface mounting.		
21.5	N/A	Not for radio antenna or ground.		
22		Weatherproof type		
22.1-22.2	N/A	Not weatherproof type		
23-26	N/A	CONNECTORS		
27-37	N/A	RECEPTACLES		
		SELF-CONTAINED RECEPTACLES FOR USE WITHOUT A SEPARATE OUTLET BOX		

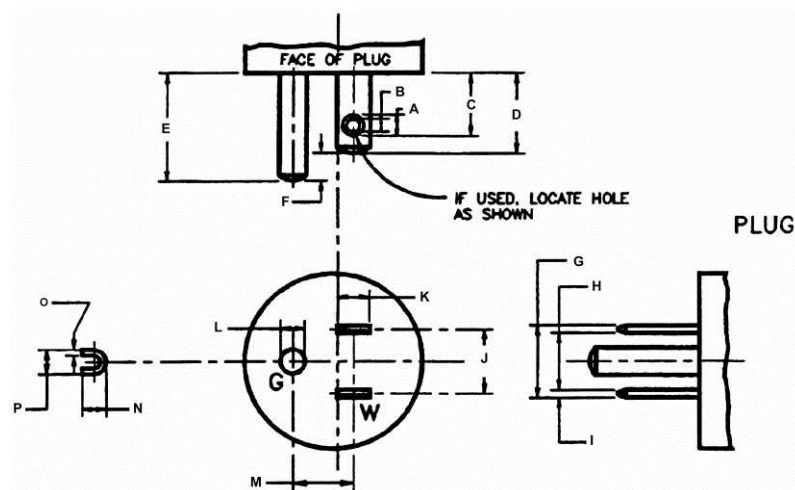
IEC 60601-1 Attachment				
Clause	Requirement + Test		Result - Remark	Verdict
Section	Key	Comment		
38-44	N/A	These sections are applicable for self-contained receptacles.		
		CURRENT TAPS		
45	N/A	The section is applicable for current taps only		
		FLATIRON AND APPLIANCE PLUGS		
46-53	N/A	These sections are applicable for flatiron and appliance plugs.		
PERFORMANCE				
		GENERAL		
54		Representative Devices		
54.1-54.7	G	Noted.		
		ALL DEVICES		
55		Comparative Tracking Index Test		
55.1	N/A	Refer to Exception No. 2 of 8.3.2. Not main tests but the test is considered		
56		Glow Wire Test		
56.1-56.2	N/A	Refer to Exception No. 2 of 8.3.2, Not main tests but the test is considered		
57		High-Current Arc Resistance to Ignition Test		
57.1-57.6	G	Refer to Exception No. 3 of 8.3.2		
58		Mold Stress Relief		
58.1-58.2	T	All devices are placed in air oven maintained at a 80oC for 7 hours. After 58.2, there is not any warpage, shrinkage or other distortion.		
58.3	T	Refer to data sheet. Repeat dielectric voltage-withstand test as described in section 60. Not required to be subjected to the humidity conditioning described in 60.1.2.		
59		Moisture Absorption Resistance		
59.1-59.2	T	Refer to data sheet		
60		Dielectric Withstand Test		
60.1-60.2	T	Refer to data sheet		
61		Accelerated Aging Tests		
61.1		General		
61.1.1	G	Exception to 8.4.1 for other material is not applicable for the devices under evaluation		
61.2		Rubber, EPDM, and TEE compounds		
61.2.1-61.2.4	N/A	Not a rubber , EPDM, and TEE compounds		
61.3		PVC compounds and copolymers		
61.3.1-61.3.2	G	See 61.1.1 shown as above		
62		Insulation Resistance Test		
62.1-62.6	T	Refer to data sheet		
63		Conductor Secureness Test		
63.1-63.2	N/A	No wire leads provided.		
64		Tightening Torque Test		
64.1-64.2	N/A	Not provide any wire-binding screw		
	N/A	ATTACHMENT PLUGS		
65		General		
65.1	G	Noted.		
66		Security of blades test		

IEC 60601-1 Attachment				
Clause	Requirement + Test		Result - Remark	Verdict
Section	Key	Comment		
66.1-66.2	T	Refer to data sheet		
67		Secureness of cover test		
67.1-67.2	T	Refer to data sheet		
68		Crushing test		
68.1-68.2	T	Refer to data sheet		
69		Attachment plug grip test		
69.1-69.9	T	Refer to data sheet		
70		Integrity of assembly test		
70.1-70.2	N/A	Cord part shall be considered in the end appliance.		
71		Self-hinge Flexing test		
71.1-71.3	N/A	Not self-hinge type		
72		Terminal temperature test		
72.1-72.4	N/A	No terminal for end user.		
73		Fuse-holder temperature test		
73.1-73.8	N/A	No fuse-holder applied.		
74-79	N/A	Pin type terminal		
80-85	N/A	INLET (applying for inlet)		
86-103	N/A	CONNECTORS		
104-150	N/A	RECEPTACLES		
		CURRENT-TAPS		
		All devices		
151-152	N/A	These sections are for current-taps		
		Flatiron and appliance plugs.		
153-161	N/A	These sections are applicable for flatiron and appliance plugs.		
RATINGS				
162		Details		
162.1	G	According to exception no. 2, rating is not required. The special-use device is not intended to ship out solely. (Note: plug is mounted in evaluated appliance).		
162.2	√	Rating of 1A 120V~ is evaluated		
162.3	√	0.5HP rated.		
162.4-162.7	N/A	Not have the specified devices		
MARKINGS AND INSTRUCTIONS				
163		General		
163.1-163.2	G	The location of the catalog number is not prohibited from appearing according to exceptions of table 163.1 and 163.2		
164		Identification and marking of terminals		
164	G	No any grounding parts and terminals		
SUPPLEMENT SA		(reserved for future use)		
SUPPLEMENT SB		ENCLOSURE TYPES FOR ENVIRONMENTAL PROTECTION		
SB1-SB7	N/A	The requirements of SB don't apply to the device under evaluation for it's intended for indoor use only (refer to SB1.1)		
SUPPLEMENT SC		MARINE SHORE POWER INLETS		

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict
Section	Key	Comment	
SC1-SC12	N/A	These sections are for marine shore power inlets	
SUPPLEMENT SD		HOSPITAL GRADE DEVICES	
SD1-SD30	N/A	These sections are for hospital grade devices	

IEC 60601-1 Attachment

Clause	Requirement + Test	Result - Remark	Verdict
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Appendix 7: Dimensions of NEMA 5-15 plug portion

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

1) $0.038^{(1)} (0.96)$ min is used on U shape, and $0.027^{(1)} (0.68)$ is used on tubular shape.

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

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



IEC 60601-1 Attachment

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

Clause	Requirement + Test	Result - Remark	Verdict
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Equipment combined with BS-plug**Supplementary tests on plug portion according to BS1363: Part 3 + Amd 9543 + Amd 14225 + Amd 14540 + Amd 17437 + Amd A4**

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

IEC 60601-1 Attachment

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

IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict
Clause	Requirement - Test	Result-Remark	Verdict
13.10	The total mass of the equipment with all specified connectors shall not exceed 800 g. The torque exerted on a socket shall not exceed 0.7 N·m. The test apparatus as Figure 37	Compliance with the main standard	N/A
	Additional: Products with torque exceeding 0.25Nm do not comply with the main standard hence full compliance with the main standard cannot be claimed		N/A
Additional test for ISODs according to BS1363: Part 1 + Amd 9541 + Amd 14539 + Amd 17435 + Amd A4			
12.9.1	All exposed surfaces of plug pins shall be smooth and free from burrs or sharp edges and other irregularities which could cause damage or excessive wear to corresponding socket contacts or shutters.		P
12.9.4	Apply a force of 1100 -10/0N at a rate not exceeding 10 mm/min. After this test the plug should fit the gauge to fig. 5.		P
	Apply a force of 400 +10/0N at a rate 10 ± 2 mm/min. Deflection shall not exceed 1.5 mm. After this test the plug should fit the gauge to fig. 5.		P
12.9.6	ISODs shall have adequate mechanical strength to ensure that they cannot be distorted by twisting. Apply a torque $1\text{N.m} \pm 10\%$ 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

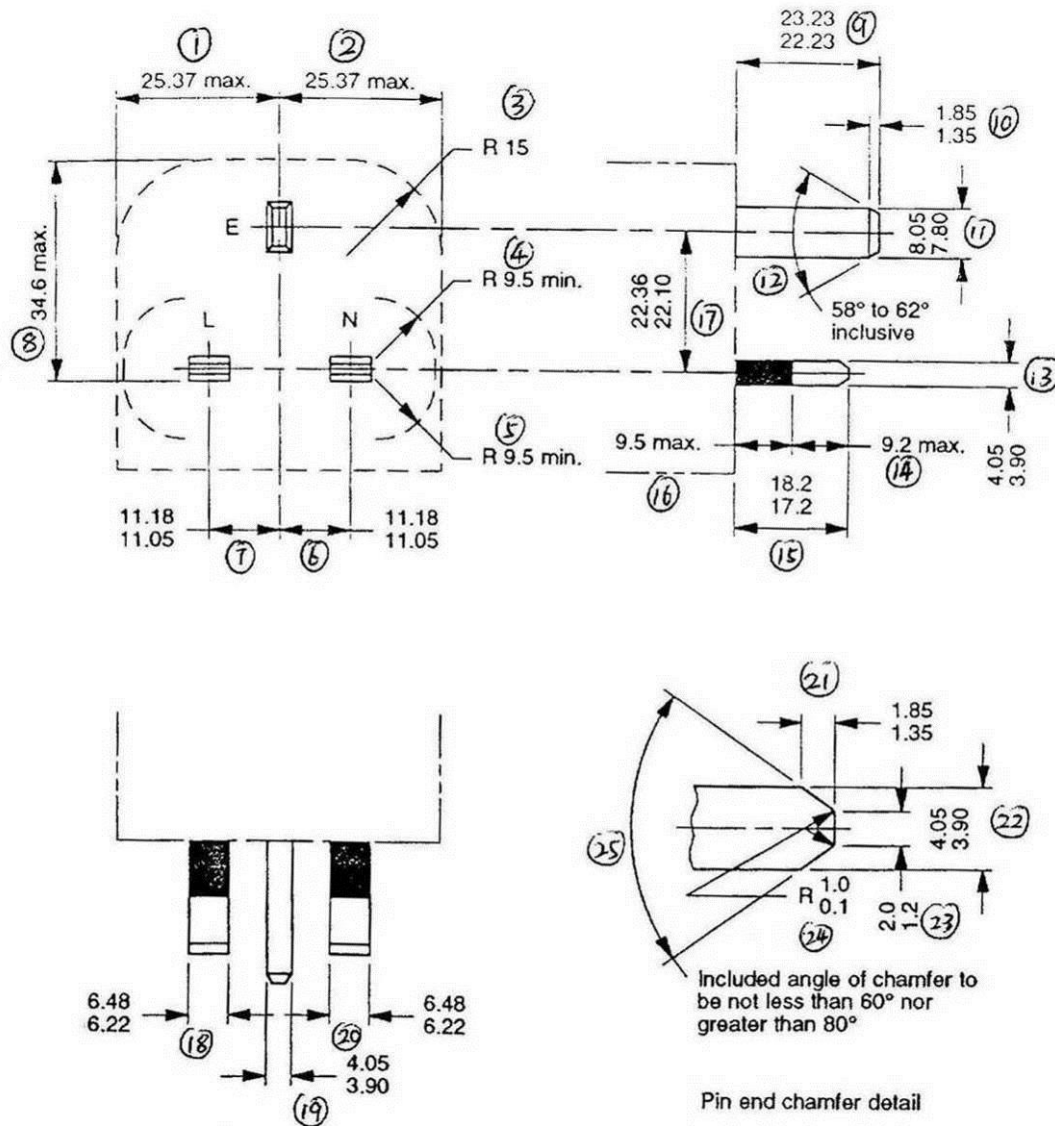
IEC 60601-1 Attachment			
Clause	Requirement + Test	Result - Remark	Verdict

Appendix 9

	Dimensions Checked by means of measurement according to BS1363-3 Fig. 4 (see appendix no. 2)		
Position	Requirement (mm)	Measured (mm)	Verdict
1.	25,37max	24.02	P
2.	25,37max	24.02	P
3.	R15min	Measured by guage	P
4.	R9,5min	9.60	P
5.	R9,5min	9.60	P
6.	11,05-11,18	11.12	P
7.	11,05-11,18	11.12	P
8.	34,6max	30.50	P
9.	22,23-23,23	22.60	P
10.	1,35-1,85	1.55	P
11.	7,80-8,05	8.03	P
12.	58°-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 Attachment

Clause	Requirement + Test	Result - Remark	Verdict
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Appendix 10: BS1363-3 Fig 4

All dimensions are in millimetres.

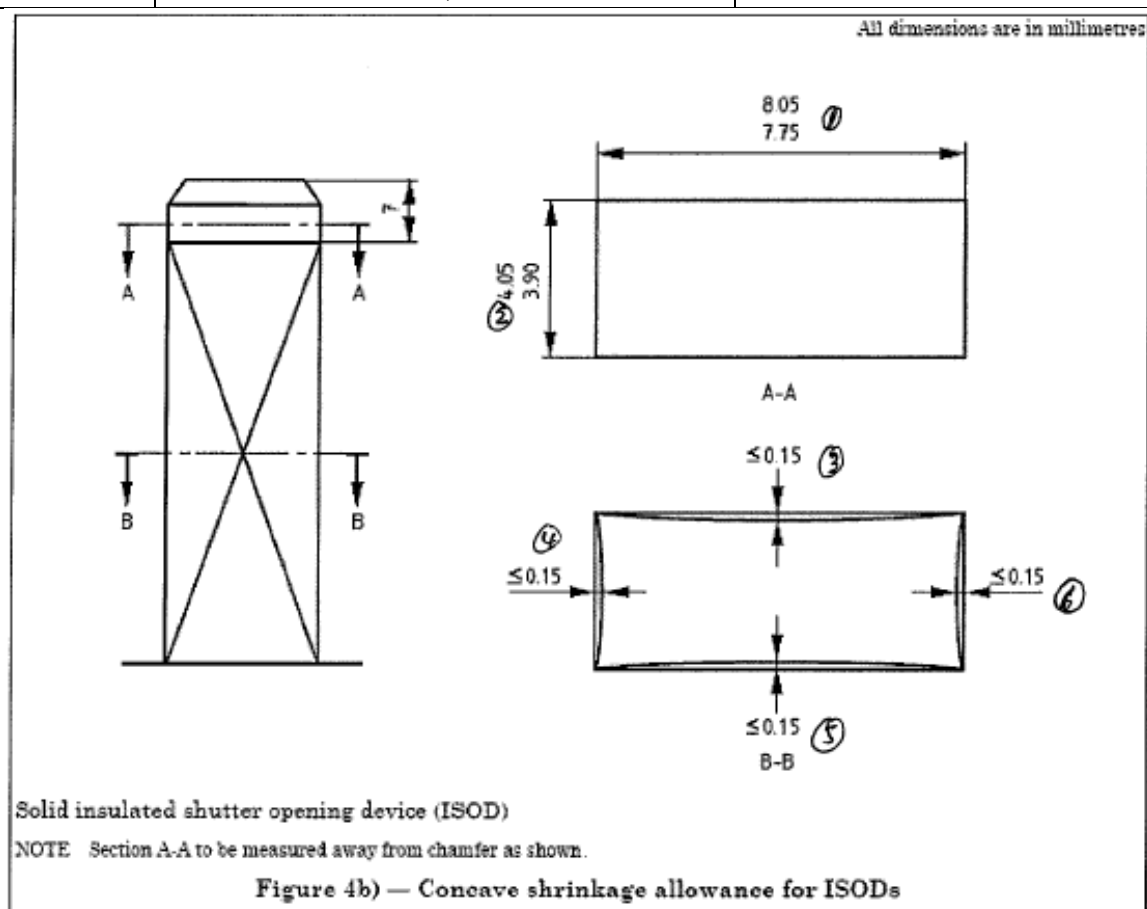
Figure 4. Dimensions and disposition of pins (see clause 12)

IEC 60601-1 Attachment

Clause	Requirement + Test	Result - Remark	Verdict
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Appendix 11: Concave shrinkable allowance for ISODs

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



IEC 60601-1 Attachment

Clause	Requirement + Test	Result - Remark	Verdict
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