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.....:	140900434SHA-001
Date of issue .....:	2014/11/10
Total number of pages.....:	153
CB Testing Laboratory.....:	Intertek Testing Services Shanghai
Address .....:	Building No.86, 1198 Qinzhou Road (North), 200233 Shanghai, China
Applicant's name.....:	GlobTek, Inc.
Address .....:	186 Veterans Dr. Northvale, NJ 07647 USA
Test specification:	
Standard .....:	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	CB Scheme
Non-standard test method……..:	N/A
Test Report Form No.....:	IEC60601_1J
Test Report Form Originator.....:	UL(US)
Master TRF.....:	2014-07

Copyright © 2014 Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE), Geneva, Switzerland. All rights reserved.
This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.
If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.
This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:
The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description .....:	Medical Power Supply
Trade Mark .....:	GlobTek
Manufacturer.....:	Same as applicant
Model/Type reference.....:	GT*43007-***** (Refer to page 6 for details.)
Ratings .....:	Input: 100-240V~, 50-60Hz, 1.5A;
	Output: Refer to page 6 for details.

Testing procedure and testing location:		
☒ CB Testing Laboratory:		
Testing location/ address ..... :	Intertek Testing Services Shanghai Building No.86, 1198 Qinzhou Road (North), 200233 Shanghai, China	
☐ Associated CB Testing Laboratory:		
Testing location/ address ..... :		
Tested by (name + signature)..... :	Jason Gong	Jason Gong
Approved by (name + signature) ..... :	Jamie Wu	Jamie Wu
☐ Testing procedure: TMP/CTF Stage 1:		
Testing location/ address ..... :		
Tested by (name + signature)..... :		
Approved by (name + signature) ..... :		
☐ Testing procedure: WMT/CTF Stage 2:		
Testing location/ address ..... :		
Tested by (name + signature)..... :		
Witnessed by (name + signature) ..... :		
Approved by (name + signature) ..... :		
☐ Testing procedure: SMT/CTF Stage 3 or 4:		
Testing location/ address ..... :		
Tested by (name + signature)..... :		
Witnessed by (name + signature) ..... :		
Approved by (name + signature) ..... :		
Supervised by (name + signature)..... :		

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

Photo of EUT: Page 124-125

Circuit Diagram / Layout: Page 126-129

National difference: Page 130-153

Summary of testing

Tests performed (name of test and test clause):	**Testing location:**
4.11 POWER INPUT	Intertek Testing Services Shanghai
5.7 HUMIDITY PRECONDITIONING	Building No. 86, 1198 Qinzhou Road (North), 200233 Shanghai, China
7.1.2 LEAGIBILITY OF MARKING	
7.1.3 DURABILITY OF MARKING	
8.4.3 VOLTAGE OR CHARGE LIMITATION	
8.5.4 WORKING VOLTAGE MEASUREMENT	
8.7.4 EARTH LEAKAGE, TOUCH CURRENT	
8.8.3 DIELECTRIC VOLTAGE WITHSTAND	
8.8.4.1 BALL PRESSURE	
8.9.4 CREEPAGE AND CLEARANCE	
9.3 SURFACES, CORNERS AND EDGES	
11.1 EXCESSIVE TEMPERATURE	
13.2 ABNORMAL OPERATION	
15.3.2 PUSH	
15.3.3 IMPACT	
15.3.4 DROP TEST	
15.3.6 MOLD STRESS RELIEF	
15.5.1.2 & 15.5.1.3 TRANSFORMER OVERLOAD AND SHORT	
15.5.2 TRANSFORMER DIELECTRIC	

Summary of compliance with National Differences

List of countries addressed:

Canada, USA, Switzerland, Korea, Japan

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

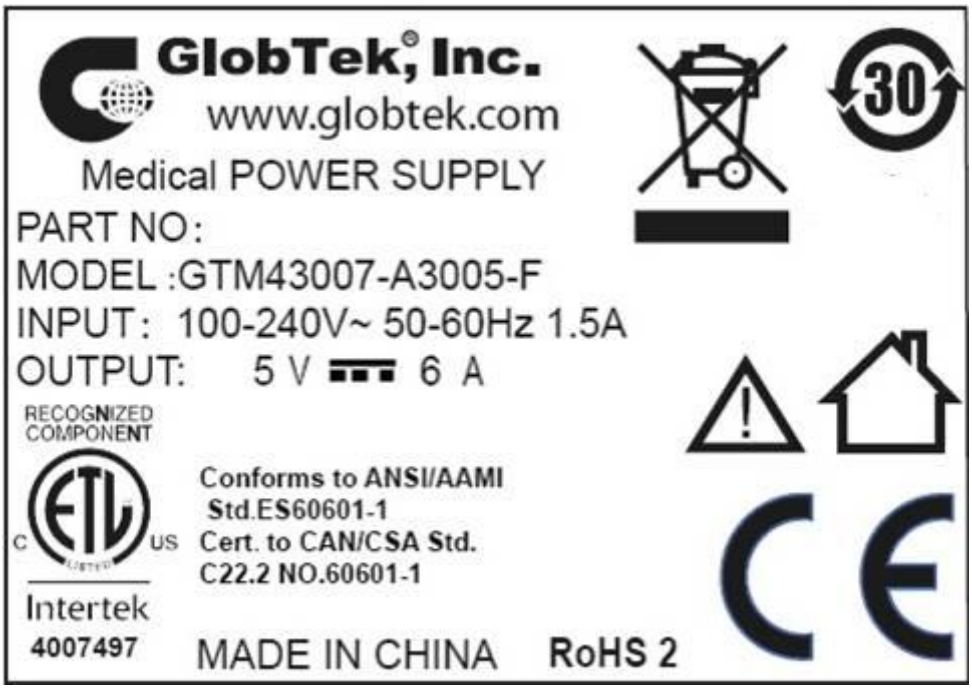
☒ The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012.

Copy of marking plate

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

Note:

The marking plates of the other models listed in this report are identical with below except model name and output parameter. The below marking is complying with the minimum requirements required by the safety standard. For the final production samples, the additional markings which do not give rise to misunderstanding may be added.



For Class I model

For Class II model

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use ..... :	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 (internal power supply board)
Mode of operation ..... :	Continuous
Supply connection.....	Final determination in end product evaluation for open frame model
Accessories and detachable parts included ..... :	None
Other options include ..... :	None
Testing	
Date of receipt of test item(s)..... :	2014-10-21
Dates tests performed ..... :	2014-10-21 ~ 2014-11-10
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.	- single fault condition.....: S.F.C.
- means of Operator protection ..... : MOOP	- means of Patient protection ....: MOPP

General remarks:

Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "J" of TRF for IEC for 60601-1 3rd edition with Amendment 1.

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

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

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012	
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 installation and use for the insulation construction shall be finally determined in the end product.

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

The product is designed to be operated at max. 5000m above sea level.

The insulation between primary and secondary circuits of EUT is evaluated as 2MOPP in this report as customer's request.

Model similarity:

GT*43007-*****

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

The 2nd "*" is A, B, or C and is related to PCB size: A= 2"x3", B=2"x4", C=3"x5". The different PCB sizes are only for installation purpose in end product with no safety spacing modification.

The 3rd "*" denote the rated output wattage designation, which can be "01" to "60", with interval of 1.

The 4th "*" denote the standard rated output voltage designation, which can be "05", "07", "09", "12", "15", "18", "24", "36" or "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 "*" is optional deviation, subtracted from standard output voltage, which can be "-0.1" to "-11.9" with interval of 0.1, or blank to indicate no voltage different.

The 4th and 5th asterisks together denote the output voltage with a range of 5-48 volts.

The 6th "*" can be "-F" or "-FW". "-F" represents Class I model and "-FW" represents Class II model.

Model list

Model	Output Voltage	Max. output current	Max. output power	Transformer
GT*43007-**05*	5	6A	30W	TF024 for 5-6.5Vdc TF025 for 6.6-8.9Vdc TF026 for 9-13Vdc TF027 for 13.1-17Vdc TF028 for 17.1-24.9Vdc TF029 for 25-34.9Vdc TF032 for 35-48Vdc
GT*43007-**07**	5.1-7V	6A	30W	
GT*43007-**09**	7.1-9V	5A	45W	
GT*43007-**12**	9.1-12V	5.0A	45W	
GT*43007-**15**	12.1-15V	5.0A	60W	
GT*43007-**18**	15.1-18V	4.0A	60W	
GT*43007-**24**	18.1-24V	3.31A	60W	
GT*43007-**36**	24.1-36V	2.50A	60W	
GT*43007-**48**	36.1-48V	1.66A	60W	

Technical Considerations:

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

a) Clause 7.9 (Accompanying Documents of power adapter model are provided for some critical issue like technical data, safety warnings, necessary information to set up. Further evaluation is needed for both power adapter model and open frame model on end product level.),

b) Clause 8.11.5 (Mains Fuse with High Breaking Capacity),

c) Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,

d) Clause 10 (Radiation),

e) Clause 11.7 (Biocompatibility),

f) Clause 14 (PEMS),

g) Clause 16 (ME Systems),

h) Clause 17 (EMC)

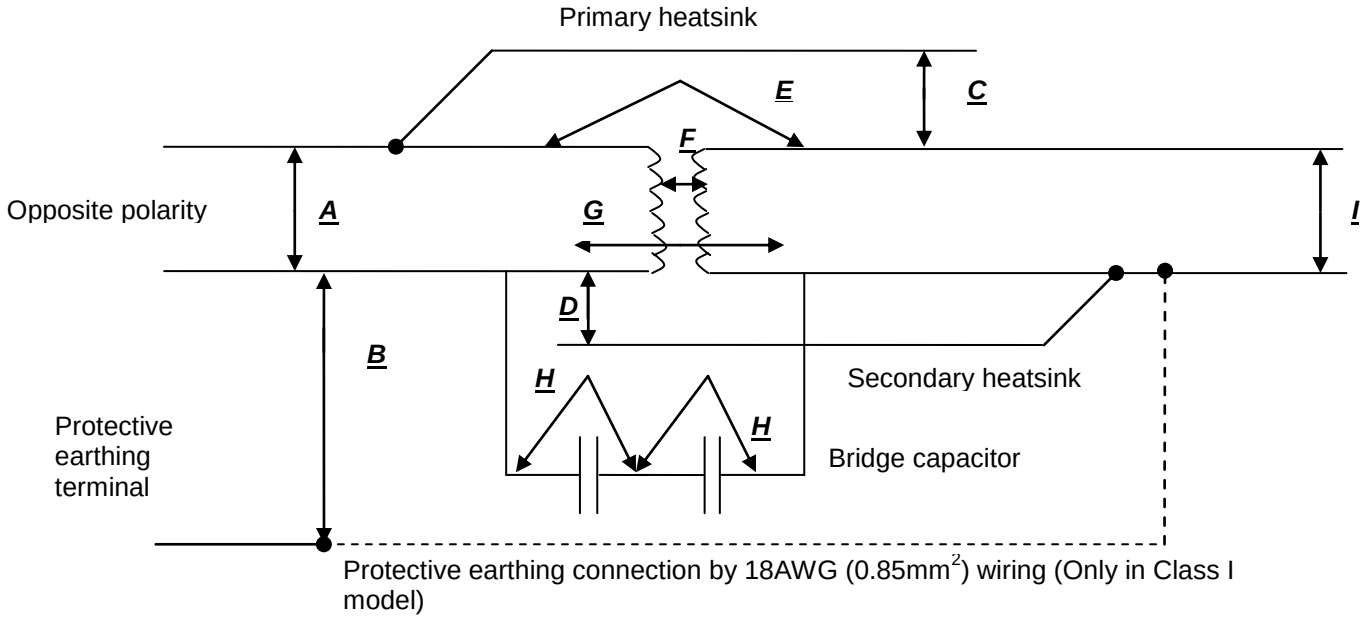
Open frame model

• Suitability of the enclosure should be evaluated when installed in the end product including access to energized parts, clearance & creepage distance measurement and mechanical strength.

• Temperature Testing should be performed on this component when installed in the end product.

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

INSULATION DIAGRAM



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

TABLE: Insulation diagram (measured values)		P
Pollution degree:	2	—
Overvoltage category:	II	—
Altitude:	5000m	—
Additional details on parts considered as applied parts:	☒ None ☐ Areas _____ (See Clause 4.6 for details)	—

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
A	MOOP	IIIb	240	340	3.0	3.0[2]	3.2	3.2	Opposite polarity of mains part
B	MOPP	IIIb	240	--	4.0	3.3[2]	4.2[3]	3.8	Mains parts to PE terminal (Along PCB trace)
C	2MOPP	IIIb	240[1]	--	8.0	6.5[2]	10.0[4]	10.0[4]	Primary heatsink to secondary circuit
D	2MOPP	IIIb	240[1]	--	8.0	6.5[2]	10.0[4]	10.0[4]	Primary circuit to secondary heatsink
E	2MOPP	IIIb	240[1]	--	8.0	6.5[2]	10.0[3]	7.7	Primary side to secondary side (Optocoupler)
F	2MOPP	IIIb	324[1]	--	10.0	9.0[2]	11.0[5]	11.0	Primary side (including ferrite) to secondary pin-out (Transformer)
G	2MOPP	IIIb	240[1]	--	8.0	6.5[2]	10.0[3]	7.7	Mains parts to secondary parts (Nearest points along PCB trace)
H	MOPP (Each) x 2	IIIb	240[1]	--	4.0+4.0	3.3+3.3[2]	5.0+5.0[3]	4.5+4.5	Primary side to secondary side (Y capacitor x 2)
I	--	IIIb	Max. 48Vdc	--			--	--	Accessible parts per 8.4.2 c)

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

Note:

1) The working voltage is highest measured value which acquired by testing all the models listed in the report at the rated input voltage, but not less than the rated input voltage.
2) Multiplication factor for MOOP: 1.48; Multiplication factor for MOPP: 1.29.
3) There is a slot wide > 1 mm between these two parts.
4) Two layers of insulating tape or 0.4mm thickness insulating tube wrap around the heatsink.
5) The whole ferrite core is wrapped around 2 layers of insulating tape.

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

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

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

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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
4	**GENERAL REQUIREMENTS**		
4.1	**Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse**		P
4.2	**RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS**		
4.2.2	**General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007) .....:**	See Appended RM Results Table 4.2	P
4.2.3	**Evaluating RISK**		
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: Report No.GT-RMPLAN2014-002	P
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.		P
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.		P
4.2.3.2	**MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.**		P
4.3	**Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.**	No essential performance	N/A
	- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.		N/A
	- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated		N/A
	- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE.....:		N/A
	- RISK CONTROL measures implemented		N/A
	- Methods used to verify the effectiveness of RISK CONTROL measures implemented		N/A
4.4	**EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE .....:**	5 years	P
4.5	**Alternative RISK CONTROL methods utilized:**		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No alternative risk control method.	N/A
	Alternative means based scientific data or clinical opinion or comparative studies .....:		N/A
4.6	**RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10.....:**	No such parts.	N/A
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient ....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		N/A
	Assessment identified the APPLIED PART TYPE requirements.....:		N/A
4.7	**ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2.....:**	GT-RM2014-002 Cl. 6.3 No.3, 5	P
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested.....: **(ISO 14971 Cl. 4.2-4.4)**	GT-RM2014-002 Cl. 6.3 No.3, 5	P
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically .....:	See Appended Table 13.2 for simulated physical test.	P
4.8	**All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ....:**	All components and wiring used according to applicable rating.	P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS		P
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings .....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No components used outside their ratings.	N/A
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION...:	See Table 8.10 b.	P
	Components determined to be acceptable where used as a MEANS OF PROTECTION .....:	See Table 8.10 b.	P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following		P
	a) Applicable safety requirements of a relevant IEC or ISO standard		P
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		P
4.9	**A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately.....:**	No COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS.	N/A
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:		N/A
4.10	**Power supply**		
4.10.1	**ME EQUIPMENT is suitable for connection to indicated power source** (select applicable)**.....:**	Suitable for connection to a SUPPLY MAINS.	P
4.10.2	**Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:**	Not hand-held equipment.	N/A
	- 250 V for HAND-HELD ME EQUIPMENT (V)..... :	100-240Vac, single phase, less than 4KVA	P
	– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V)..... :	100-240Vac, single phase, less than 4KVA	N/A
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS		N/A
4.11	**Power input**		
	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**		
5.1	**Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods .....:**	RM not provided: All the applicable tests were conducted.	P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. (ISO 14971 Cl. 4.2-4.4)		N/A
5.3	**Tests conducted within the environmental conditions specified in technical description**		P
	Temperature (ºC), Relative Humidity (%) .....:	0-40ºC, 20%-80%RH	—
	Atmospheric Pressure (kPa) .....:	540-1060hPa	—
5.5	**a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V) .....:**	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..... :	Not for d.c. supply connection.	N/A
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions..... :	No alternative accessory	N/A
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	No separate power supply used	N/A
5.7	**ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3..... :**	See table 8.7 and 8.8.3.	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	Pre-condition performed: 26°C, 93%RH for 168 h according to client's request.	—
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		
5.9.1	**APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ..... :**	No such parts.	N/A
5.9.2	**ACCESSIBLE PARTS**		
5.9.2.1	**Accessibility determined using standard test finger of Fig. 6**	Final determination in end product.	N/A

IEC 60601-1			
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**		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 ..... :**		N/A
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL.....:		N/A
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		
6.2	**CLASS I ME EQUIPMENT, externally powered**	Final determination in the end product for open frame model.	P
	CLASS II ME EQUIPMENT, externally powered	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 ..... :**	Final determination in the end product for open frame model.	N/A
6.4	**ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use..... :**	No sterilization required	N/A
6.5	**ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2**	Power supply not investigated for OXYGEN RICH ENVIRONMENT	N/A
6.6	**CONTINUOUS or Non-CONTINUOUS OPERATION ..... :**	Continuous operation	P
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		
7.1.2	**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**		
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:**		
	– the name or trademark and contact information of the MANUFACTURER	See attached copy of Marking Plate	P
	– a MODEL OR TYPE REFERENCE		P
	– a serial number or lot or batch identifier; and		P
	– the date of manufacture or use by date		P
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or		N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.4)		N/A
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and		N/A
	– a MODEL OR TYPE REFERENCE		N/A
	Software forming part of a PEMS identified with a unique identifier.....:	No PEMS	N/A
7.2.3	**Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS**	No such safety sign used.	N/A
	Safety sign 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted		N/A
7.2.4	**ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and .....:**	No such accessories.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- with a MODEL or TYPE REFERENCE		N/A
	– a serial number or lot or batch identifier		N/A
	– the date of manufacture or use by date		N/A
	Markings applied to individual packaging when not practical to apply to ACCESSORIES		N/A
7.2.5	**ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following**	Not receive power from other equipment.	N/A
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or		N/A
	– Table D.2, safety sign No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or		N/A
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.		N/A
7.2.6	**Connection to the Supply Mains**		
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point		P
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT	Not for permanently installed.	N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V).....:	100-240V	P
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)...:	Not so marked.	N/A
	– Nature of supply and type of current.....:	Single phase, AC.	P
	Symbols 1-5, Table D.1 (used for same parameters.....:	'~' is used.	P
	– RATED supply frequency or RATED frequency range in hertz.....:	50-60Hz or 60Hz	P
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT .....:	Symbol 9 is used for Class II model.	P
7.2.7	**RATED input in amps or volt-amps, (A, VA) .....:**	1.5A	P
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) .....:	1.5A	P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W).....:	No such range provided.	N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) .....:	No such range provided.	N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA).....:	No such 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**		
7.2.8.2	**Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment**		P
	Rated Voltage (V), Rated Current (A).....:	See model similarity	—
	Rated Power (W), Output Frequency (Hz) .....:	See model similarity	—
7.2.9	**ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for ME EQUIPMENT or parts rated IPX0....:**	Ordinary type.	N/A
7.2.10	**Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols .....:**	No Applied Parts in power supply	N/A
	TYPE B APPLIED PARTS with symbol 19 of Table D.1		N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 .....:		N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 .....:		N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 .....:		N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART .....:		N/A
	Safety sign 2 of Table D.2 placed near relevant outlet.....:		N/A
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use .....:		N/A
7.2.11	**ME EQUIPMENT suitable for CONTINUOUS OPERATION**		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time .....:	Continuous operation.	N/A
7.2.12	**Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder**	No accessible fuse-holder	N/A
	Fuse type.....:		**—**
	Voltage (V) and Current (A) rating .....:		**—**
	Operating speed (s) and Breaking capacity.....:		**—**
7.2.13	**Physiological effects – safety sign and warning statements .....:**	EUT is component power supply only, no physiological effect	N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use .....: (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.....:**	No special protective packaging measures have to be taken.	N/A
	Permissible environmental conditions marked on outside of packaging .....:		N/A
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK .....:		N/A
	RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK. .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.3-6.4)		N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization		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		
7.2.19	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL.....:**	No FE terminal.	N/A
7.2.20	**Removable protective means marked to indicate the necessity for replacement when the function is no longer needed.....:**	Component, to be determined as part of end product.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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**		
7.3.1	**Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W) .....:**	No heating element, no lamp holder.	N/A
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL		N/A
7.3.2	**Symbol 24 of Table D.1, or safety sign No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts.....:**	No such HV part.	N/A
7.3.3	**Type of battery and mode of insertion marked :**		
	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.....:		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)		N/A
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD .....:		N/A
7.3.4	**Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified .....:**	Specification adjacent to component	P
	Voltage (V) and Current (A) rating .....:	See the table 8.10	—
	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**		N/A
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made		N/A
7.3.6	**Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS**	No FE terminal.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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)		N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	Marked on EUT	N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	Not permanently installed	N/A
	Marking for connection to a 3-phase supply, complies with IEC 60445	Not 3-phase	N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		P
7.3.8	**"For supply connections, use wiring materials suitable for at least X °C" or equivalent, marked at the point of supply connections**	No such high temperature	N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	**Marking of controls and instruments**		
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
	– status indicated by other unambiguous means		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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)		N/A
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE .....:		N/A
	– or an indication of direction in which magnitude of the function changes		N/A
	Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009		N/A
7.4.3	**Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units**	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 .....:		N/A
7.5	**Safety signs**		
	Safety sign with established meaning used	No safety sign used.	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.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.3)		N/A
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		N/A
	Specified colours in ISO 3864-1 used for safety signs.....:		N/A
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		N/A
	Safety signs including any supplementary text or symbols described in instructions for use		N/A
	- and in a language acceptable to the intended OPERATOR		N/A
7.6	**Symbols**		
7.6.1	**Meanings of symbols used for marking described in instructions for use .....:**	Accompanying documents have been checked.	P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.6.3	**Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable**	No such symbol is used.	N/A
7.7	**Colours of the insulation of conductors**		
7.7.1	**PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation**		P
7.7.2	**Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations**		P
7.7.3	**Green and yellow insulation identify only following conductors:**		P
	– PROTECTIVE EARTH CONDUCTORS		P
	– 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**		
7.8.1	**Red indicator lights used only for Warning**		N/A
	Yellow indicator lights used only for Caution		N/A
	Green indicator lights used only for Ready for use		P
	Other colours: Meaning other than red, yellow, or green (colour, meaning) .....:		N/A
7.8.2	**Red used only for emergency control**	No such indicator light.	N/A
7.9	**ACCOMPANYING DOCUMENTS**		
7.9.1	**ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description**		P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		P
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to .....:	GlobTek, Inc.	P
	– MODEL or TYPE REFERENCE .....:	GT*43007-*****	P
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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**		
7.9.2.1	**– use of ME EQUIPMENT as intended by the MANUFACTURER:**	Power adapter.	P
	– frequently used functions,	Power supply only.	P
	– known contraindication(s) to use of ME EQUIPMENT	No contraindication.	P
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient		N/A
	– name or trademark and address of the MANUFACTURER	GlobTek, Inc.	P
	– MODEL OR TYPE REFERENCE	GT*43007-*****	P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:		N/A
	– the PATIENT is an intended OPERATOR		N/A
	– warning against servicing and maintenance while the ME EQUIPMENT is in use		N/A
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and		N/A
	–maintenance the PATIENT can perform		N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT		P
	Instructions for use are in a language acceptable to the intended operator		P
7.9.2.2	**Instructions for use include all warning and safety notices**		P
	Warning statement for CLASS I ME EQUIPMENT included	Checked on end product for open frame model	N/A
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments		P
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No MULTIPLE SOCKET-OUTLET.	N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS		N/A
7.9.2.3	**Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions**	No such connection.	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**	No such additional 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)		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..... :	No primary batteries.	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided ..... :	No INTERNAL ELECTRICAL POWER SOURCE.	N/A
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK..... :	Further evaluation is needed on end product level.	N/A
7.9.2.5	**Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE**	See “POWER SUPPLY INFORMATION” in IFU.	P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to		N/A
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	No SIP/SOP.	N/A
	APPLIED PARTS specified	No APPLIED PARTS	N/A
7.9.2.6	**Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation**	No need.	N/A
7.9.2.7	**Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device**	Further evaluation is needed on end product level.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
7.9.2.8	**Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation**	No need.	N/A
7.9.2.9	**Information provided to operate ME EQUIPMENT**	No detachable parts or ACCESSORIES.	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**	No such message.	N/A
7.9.2.11	**Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT**	Further evaluation is needed on end product level.	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**	No need for cleaning, disinfection and sterilization.	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**	Further evaluation is needed on end product level.	N/A
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT		N/A
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application		N/A
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL		N/A
7.9.2.14	**A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided**	No detachable parts or ACCESSORIES.	N/A
	Other equipment providing power to ME SYSTEM sufficiently described		N/A
7.9.2.15	**Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use ..... :**	No disposal of waste.	N/A
7.9.2.16	**Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)**		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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**	No 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**	No such need.	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.....:**	On page head	P
7.9.3	**Technical description**		
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**	See "ELECTRICAL SPECIFICATIONS" in IFU.	P
	Technical description separable from instructions for use contains required information, as follows		
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT		P
	– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and		P
	a unique version identifier.....:	On page head	P
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	No such requirements.	N/A
7.9.3.2	**The technical description contains the following required information**		
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT.....:	Not PERMANENTLY INSTALLED ME EQUIPMENT	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and		N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)		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**	No such need.	N/A
7.9.3.4	**Means used to comply with requirements of 8.11.1 clearly identified in technical description**	Further evaluation is needed on end product level.	N/A
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		
8.1	**Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS**		P
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION ..... : (ISO 14971 Cl. 4.3)	GT-RM2014-002 Cl.6.3 No.6	P
8.2	**Requirements related to power sources**		
8.2.1	**Connection to a separate power source**		
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	Connection to mains only	N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	**Connection to an external d.c. power source**		
	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 AC mains only	N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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**		
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	No APPLIED PARTS	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**		
8.4.2	**ACCESSIBLE PARTS and APPLIED PARTS**		
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT :	No PATIENT CONNECTIONS.	P
	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:	No such part.	N/A
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	Open frame model shall be determined in end product evaluation	N/A
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	Open frame model shall be determined in end product evaluation	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	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**		
8.5.1	**MEANS OF PROTECTION (MOP)**		
8.5.1.1	**Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4**		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)**		
	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		P
	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. ..... :	See appended Tables 8.8.3 and 8.10	P
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		P
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) ..... :	See appended Table 8.10	—
8.5.1.3	**MEANS OF OPERATOR PROTECTION (MOOP)**	The separation between primary and secondary circuit was evaluated by MOPP.	N/A
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– dielectric strength test ..... :		N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		N/A
	– limits of Tables 13 to 16 (inclusive); or		N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6		N/A
	– or with requirements and tests of IEC 60950-1 for protective earthing..... :		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION ..... :		N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION ..... :		N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) ..... :		—
	Points 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		N/A
	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..... :		N/A
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION .... :		N/A
8.5.2	**Separation of PATIENT CONNECTIONS**		
8.5.2.1	**PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE ..... :**	No PATIENT CONNECTIONS	N/A
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART		N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function		N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS ..... :		N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART		N/A
	LEAKAGE CURRENT tests conducted per 8.7.4 .... :		N/A
	Dielectric strength test conducted per 8.8.3.... :		N/A
	CREEPAGE and CLEARANCES measured ..... :		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

IEC 60601-1			
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 .... :**		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 .... :		N/A
	Dielectric strength test conducted per 8.8.3.... :		N/A
	Relevant CREEPAGE and CLEARANCES measured		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)		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**		
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT ..... :	No PATIENT lead.	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) ..... :		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)		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.5.4	**WORKING VOLTAGE**		
	– 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	No PATIENT CONNECTION.	N/A
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)..... :	No APPLIED PART.	N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No DEFIBRILLATION-PROOF APPLIED PARTS.	N/A
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V)..... :	No motor.	N/A
8.5.5	**DEFIBRILLATION-PROOF APPLIED PARTS**		
8.5.5.1	**Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety**	No DEFIBRILLATION-PROOF APPLIED PARTS.	N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:		N/A
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :		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..... :		N/A
8.5.5.2	**Means provided to limit energy delivered to a 100 Ω load..... :**		N/A
8.6	**Protective and functional earthing and potential equalization of ME EQUIPMENT**		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.6.1	**Requirements of 8.6.2 to 8.6.8 applied**		P
	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..... :**	Further evaluation is needed on end product level.	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	No such construction.	N/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside..... :	No such construction.	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	No such construction.	N/A
8.6.3	**PROTECTIVE EARTH CONNECTION not used for a moving part,**	No such construction.	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)		N/A
8.6.4	**a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop.....:**	Final judgement 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**		
	Poorly conducting surface coatings on conductive elements removed at the point of contact		N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	**Plugs and sockets**		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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	Further evaluation is needed on end product level.	N/A
	- applied also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	**Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR**		
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE		N/A
	–accidental disconnection avoided in NORMAL USE		N/A
	– Terminal allows conductor to be detached without a TOOL		N/A
	– Terminal not used for a PROTECTIVE EARTH CONNECTION		N/A
	– Terminal marked with symbol 8 of Table D.1		N/A
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard		N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR		N/A
8.6.8	**FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION**		N/A
8.6.9	**Class II ME EQUIPMENT**		
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow		N/A
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.		N/A
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS		N/A
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		
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

IEC 60601-1			
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.	N/A
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION		P
	SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE		P
8.7.3	**Allowable Values**		
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b. :	See appended Table 8.7	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz ..... :		N/A
	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 Only secondary output was considered	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.	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

IEC 60601-1			
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 ..... :	Final determination in end product for open frame model.	N/A
8.7.4	**LEAKAGE and PATIENT AUXILIARY CURRENTS measurements ..... :**	See appended Table 8.7	P
8.8	**Insulation**		
8.8.1	**Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION 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**		
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		P
	a) 0.4 mm, min, distance through insulation, or		N/A
	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..... :		N/A
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION	See appended Table 8.8.3	P
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		N/A
	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

IEC 60601-1			
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 ..... :	Additional protection by insulating tape.	P
	Finished component complied with routine dielectric strength tests of 8.8.3 ..... :		N/A
	Tests of Annex L not repeated since material data sheets confirm compliance ..... :	See Table 8.10 and Material Information Attachment	P
8.8.3	**Dielectric Strength**		
	Solid insulating materials with a safety function withstood dielectric strength test voltages .... :	See appended Table 8.8.3	P
8.8.4	**Insulation other than wire insulation**		
8.8.4.1	**Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT**		P
	ME EQUIPMENT and design documentation examined ..... :	See the table 8.10	P
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	GT-RM2014-002 Cl. 6.3 No.4	P
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat ..... :	No evidence is provided.	N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat ..... :	Ball pressure test performed	P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus ... :	See appended Table 8.8.4.1	P
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C) ..... :	See appended Table 8.8.4.1	P
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION	No such material	N/A
8.8.4.2	**Resistance to environmental stress**		
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		P
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such material	N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No heating conductor	N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	No such material	N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °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**		
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 DEFIBRILLATION-PROOF APPLIED PARTS.	N/A
8.9.2	**a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION , min CREEPAGE and CLEARANCES not applied ..... :**	The spacing between parts of opposite polarity fulfils the values of Table 11.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.9.3	**Spaces filled by insulating compound**		
8.9.3.1	**Only solid insulation requirements applied where distances between conductive parts filled with insulating compound**	No such construction.	N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests		N/A
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) ..... :**		N/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N/A
8.9.3.3	**Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint**		N/A
	A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		N/A
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage ..... :		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
8.10	**Components and wiring**		
8.10.1	**Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely ..... :**	Securely fixed by additional means	P
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components ..... : (ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)	GT-RM2014-002 Cl. 6.3 No.3	P
8.10.2	**Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment ..... :**	GT-RM2014-002 Cl. 6.3 No.6	P
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS		P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.10.3	**Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken .....:**	No such cord.	N/A
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		
8.10.4.1	**Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION**	No cord connected hand-held control device, no cord connected foot-operated control device.	N/A
8.10.4.2	**Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3**		N/A
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3		N/A
8.10.5	**Mechanical protection of wiring**		
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges .....:	No internal moving part.	N/A
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS	No ACCESS COVERS	N/A
8.10.6	**Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead**	No guiding roller.	N/A
8.10.7	**a) Insulating sleeve adequately secured.....:**	See appended Table 8.10	P
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics	Within its rated characteristics. See the table 8.10.	P
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C .....:	No such high temperature is acquired by test indicated in 11.1.	P
8.11	**MAINS PARTS, components and layout**		
8.11.1	**a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles.....:**	Further evaluation is needed on end product level.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	Not permanently installed.	N/A
	PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position		N/A
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		P
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ..... :	Further evaluation is needed on end product level.	N/A
	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 ..... :		N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead		N/A
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447		N/A
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH ..... :		N/A
	g) A fuse or a semiconductor device not used as an isolating means		P
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		P
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	No such part.	N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage		N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N/A
	Standard test finger applied		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.11.2	**MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2**	No multiple socket-outlets.	N/A
8.11.3	**POWER SUPPLY CORDS**		
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 ..... :		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**		
	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	No power supply cord.	N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or		N/A
	– metal provided with an insulating lining affixed to cord anchorage		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components		N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 ..... :		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) ..... :		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 ..... :		N/A
8.11.4	**MAINS TERMINAL DEVICES**		
8.11.4.1	**PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection**	No mains terminal device.	N/A
	Terminals alone are not used to keep conductors in position		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.11.4.2	**Arrangement of MAINS TERMINAL DEVICES**		
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	No mains terminal device.	N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N/A
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		N/A
8.11.4.3	**Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times**		N/A
8.11.4.4	**Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened**		N/A
8.11.4.5	**Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors**		N/A
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test		N/A
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		
	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 ..... :	See appended Table 8.10	P
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not permanently installed.	N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART	No such construction	N/A
	Protective devices have adequate breaking capacity to interrupt the max. fault current ..... :	See appended Table 8.10 To be evaluated on end product	P
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		P
	Justification for omission of fuses or OVER-CURRENT RELEASES documented ..... :		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.11.6	**Internal wiring of the MAINS PART**		
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable ..... :	See appended Table 8.10 for details	P
	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**		
9.2	**HAZARDS associated with moving parts**		
9.2.1	**When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level .....:**	No moving parts.	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)		N/A
	All RISKS associated with moving parts have been reduced to an acceptable level		N/A
9.2.2	**TRAPPING ZONE**		
9.2.2.1	**ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:**	No TRAPPING ZONE.	N/A
	– Gaps in Clause 9.2.2.2, or		N/A
	– Safe distances in Clause 9.2.2.3, or		N/A
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or		N/A
	– Continuous activation in Clause 9.2.2.5		N/A
	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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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 .....:**		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 ..... :**		N/A
9.2.2.4	**GUARDS and other RISK CONTROL measures**		
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 .....:**		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**		
	Continuous activation used as a RISK CONTROL, complies with the following		N/A
	a) movement was in OPERATOR'S field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR		N/A
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or		N/A
	- the continuous activation system is SINGLE FAULT SAFE		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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**		
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....:		N/A
9.2.4	**Emergency stopping devices**		
	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)		N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)**		N/A
9.3	**Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered .....:**	No rough surface / sharp edge.	P
9.4	**Instability HAZARDS**		
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**	Final determination in end product.	N/A
9.4.2	**Instability – overbalance**		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.4.2.1	**ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested.....:**		N/A
9.4.2.2	**Instability excluding transport**		
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE, ...:		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**		
	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)		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).....:		N/A
9.4.2.4	**Castors and wheels**		
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 .....:**		N/A
9.4.2.4.3	**MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold .....:**		N/A
9.4.3	**Instability from unwanted lateral movement (including sliding)**		
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		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.4.3.2	**Instability excluding transport**		
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test .....:		N/A
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test		N/A
9.4.4	**Grips and other handling devices**		
	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 .....:		N/A
9.5	**Expelled parts HAZARD**		
9.5.1	**Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)**	No expelled parts.	N/A
	All identified RISKS associated with expelled parts mitigated to an acceptable level		N/A
9.5.2	**Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 .....:**		N/A
9.6	**Acoustic energy (including infra- and ultrasound) and vibration**		
9.6.1	**Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and**	Component, to be determined as part of end product	N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity .....:		N/A
	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)		N/A
	All identified RISKS mitigated to an acceptable level		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
9.6.2	**Acoustic energy**		
9.6.2.1	**PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE**	Component, to be determined as part of end product	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)**		N/A
9.6.3	**Hand-transmitted vibration**		
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values	No vibration.	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**		
9.7.2	**Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)**	No such parts.	N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure		N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A
	– 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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– 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 .....:**		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
	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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)		N/A
9.8	**HAZARDS associated with support systems**		
9.8.1	**ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK ...:**	No support systems.	N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD		N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK		N/A
	– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	– 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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)		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.....:		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)		N/A
9.8.3	**Strength of PATIENT or OPERATOR support or suspension systems**		
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)		N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts		N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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 .....:		N/A
9.8.3.2	**a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m^2 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 .....:		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 .....:		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**		N/A
9.8.4	**Systems with MECHANICAL PROTECTIVE DEVICES**		
9.8.4.1	**a) A MECHANICAL PROTECTIVE DEVICE provided for the support system**		N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:		N/A
	– Designed based on TOTAL LOAD		N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7		N/A
	– Activated before travel produced an unacceptable RISK		N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3		N/A
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests .....:		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
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**		
	–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 .....:		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**		
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES .....:		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system .....: (ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)		N/A

10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		
10.1	**X-Radiation**		
10.1.1	**The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT .....:**	No X-radiation.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE		N/A
10.1.2	**RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or .....:**		N/A
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....: **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**		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)**	No such radiation.	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.**	No laser	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)**	No such radiation.	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)**	No such radiation.	N/A
10.7	**RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE .....:** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No such radiation.	N/A

11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		
11.1	**Excessive temperatures in ME EQUIPMENT**		
11.1.1	**Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and .....:**	See appended Table 11.1.1	P

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Surfaces of test corner did not exceed 90 °C		P
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION		P
	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)	Final determination in end product.	N/A
11.1.2	**Temperature of APPLIED PARTS**		
11.1.2.1	**APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply ..... :**	No APPLIED PARTS.	N/A
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use		N/A
11.1.2.2	**APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION. :**		N/A
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:		N/A
	Maximum Temperature ..... :		—
	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)		N/A
	APPLIED PARTS surface temperature of equal to or less than 41°C		N/A
	Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted ..... :		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)		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)**	No such temperature limits.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)	No such guards.	N/A
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE..... :	No alternative method	N/A
11.1.4	**GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL**	No such guards.	N/A
11.2	**Fire prevention**		
11.2.1	**ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3**		
11.2.2	**Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS**		
11.2.2.1	**RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of..... :**	Not used in OXYGEN RICH ENVIRONMENTS ME EQUIPMENT.	N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions		N/A
	1) when temperature of material raised to its ignition temperature		N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature		N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating		N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)		N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ..... :		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)		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..... :		N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%)..... :		N/A
	3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes		N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE..... :		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 ..... :		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
11.2.2.2	**RISK of ignition did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT**		N/A
11.2.2.3	**Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks**		N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques		N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means		N/A
11.2.3	**SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered**		
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) ..... :	Not OXYGEN RICH ENVIRONMENTS ME EQUIPMENT.	N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :		N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :		N/A
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a) ..... :		N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas ..... :		N/A
11.3	**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 ..... :	Final determination in end product.	N/A
	Constructional requirements were met, or		N/A
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		N/A
	Justification, when requirement not 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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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	UL 94 approved.	P
	b) Fire ENCLOSURE met following:		
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm	Final determination to be competed in the end product for open frame model.	N/A
	2) No openings on the sides within the area included within the inclined line C in Fig 39		N/A
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials ..... :		N/A
11.4	**ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics**		
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G	Not CATEGORY AP or CATEGORY APG ME EQUIPMENT.	N/A
11.5	**ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents**		
	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)	No intended for use in conjunction with flammable agents	N/A
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT**		
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. EUT is ordinary.	N/A
11.6.2	**Overflow in ME EQUIPMENT**		
	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 ..... :	No such situation.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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**		
	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)	No such situation.	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**		
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :	EUT is ordinary.	N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION.. :		N/A
11.6.6	**Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS**		
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use ..... :	No cleaning & disinfection requirement.	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**		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests..... :	No sterilization requirement.	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)		N/A
11.6.8	**RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS..... (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	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**	No such parts.	N/A
11.8	**Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**	No such situation.	N/A

12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		
12.1	**RISKS associated with accuracy of controls and instruments stated..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No such control.	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. ..... :**	No alarm system.	N/A
12.4	**Protection against hazardous output**		
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)**	No hazardous output.	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)**		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)**		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)**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
12.4.5	**Diagnostic or therapeutic radiation**		
12.4.5.1	**Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation**	No radiation for diagnostic/therapeutic purposes.	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 ..... :**		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)**		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)**		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)**	No diagnostic or therapeutic acoustic pressure.	N/A

13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		
13.1	**Specific HAZARDOUS SITUATIONS**		
13.1.2	**Emissions, deformation of ENCLOSURE or exceeding maximum temperature**		
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		P
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24..... :	No APPLIED PARTS.	N/A
	– 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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	See appended Table 13.1.2	P
13.1.3	**– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed..... :**	See appended Table 8.7	P
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed..... :	See appended Table 8.7	P
13.2	**SINGLE FAULT CONDITIONS**		
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 leakage of liquid.	N/A
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:		N/A
13.2.13	**ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of the temperature in the test environment**		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**		
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No Heating Elements provided	N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests		N/A
	a 3) other ME EQUIPMENT with heating elements met test		N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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) ..... :		N/A
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY		N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted		N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION		N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and		N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS		N/A
	2) When more than one control provided, they were disabled in turn		N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time		N/A
13.2.13.3	**ME EQUIPMENT with motors**		
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	No motors provided in power supply.	N/A
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition		N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT		N/A
	b) Motor met running overload protection test of this clause when:		N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or		N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended		N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C)..... :		N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps		N/A
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload		N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current		N/A
	Test not conducted based on other justifications (justification)..... :		N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10		N/A
13.2.13.4	**ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION**		
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated	Continuous operation.	N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle		N/A
	Motor winding temperatures did not exceed values in 13.2.10 ..... :		N/A
	Insulation Class ..... :		—

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Maximum temperature measured (°C)..... :		—
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		
14.1	**Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or**	No Such Parts/ PESS relied upon for Basic Safety or Essential Performance	N/A
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK..... :		N/A
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)		N/A
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK		N/A
	Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304..... :		N/A
	Software development process applied according to Clause 5 of IEC 62304..... :		N/A
	Software development process for Software risk management applied according to Clause 7 of IEC 62304 ..... :		N/A
	Software development process Configuration Management applied according to Clause 8 of IEC 62304..... :		N/A
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304..... :		N/A
14.2	**Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process ..... :**		N/A
14.3	**RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan**		N/A
14.4	**A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented**		N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/A
	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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N/A
14.5	**A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained**		N/A
14.6	**RISK MANAGEMENT PROCESS**		
14.6.1	**MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS..... :**		N/A
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems.....: (ISO 14971 Cl. 4.3)		N/A
14.6.2	**Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2 :**		N/A
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure.....: (ISO 14971 Cl. 6.1)		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)**		N/A
14.8	**An architecture satisfying the requirement is specified for PEMS and each of subsystems .... : (ISO 14971 Cl. 6.3)**		N/A
14.9	**Design is broken up into sub systems and descriptive data on design environment documented ..... :**		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)**		N/A
	– milestone(s) when VERIFICATION is to be performed for each function		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION		N/A
	– selection and utilization of VERIFICATION tools		N/A
	– coverage criteria for VERIFICATION		N/A
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented		N/A
14.11	**A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE ..... :**		N/A
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented		N/A
	The person with overall responsibility for PEMS VALIDATION is independent		N/A
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)		N/A
14.12	**Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE**		N/A
	Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304 ..... :		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
14.13	**For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following ..... :**		N/A
	a) Purpose of the PEMS connection to an IT-NETWORK		N/A
	b) required characteristics of the IT-NETWORK		N/A
	c) required configuration of the IT-NETWORK		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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 characteristics required (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)		N/A
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		
	– 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**		
15.1	**RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS..... :**	No controls and indicators.	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**	No such parts.	N/A
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		N/A
15.3	**Mechanical strength**		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
15.3.1	**Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**	Final determination in end product for open frame model.	N/A
15.3.2	**Push test conducted ..... :**		N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.3	**Impact test conducted..... :**		N/A
	No damage resulting in an unacceptable RISK sustained		N/A
15.3.4	**Drop test**		
15.3.4.1	**Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested ..... :**		N/A
	No unacceptable RISK resulted		N/A
15.3.4.2	**Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test.....:**		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..... :**		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**		N/A
	Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C ..... :		N/A
	No damage resulting in an unacceptable RISK		N/A
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**	No such environmental influences.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		N/A
15.4	**ME EQUIPMENT components and general assembly**		
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)**	No following connections.	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**		
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)	RMF Reference to specific RISKS: No hazardous situation. (ISO 14971 Cl.4.2-4.4)	P
	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:		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 ..... :		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- 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	No such part.	N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating : **(ISO 14971 Cl. 4.2-4.4)**	No such part.	N/A
15.4.2.2	**Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS**		N/A
15.4.3	**Batteries**		
15.4.3.1	**Battery housings provided with ventilation.... :** **(ISO 14971 Cl. 4.2-4.4)**	No batteries.	N/A
	Battery compartments designed to prevent accidental short circuiting		N/A
15.4.3.2	**Means provided to prevent incorrect connection of polarity ..... :**		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries..... : **(ISO 14971 Cl. 4.2-4.4)**		N/A
15.4.3.3	**Overcharging of battery prevented by virtue of design ..... :**		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries..... : **(ISO 14971 Cl. 4.2-4.4)**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
15.4.3.4	**Primary lithium batteries comply with IEC 80086-4**		N/A
	Secondary lithium batteries comply with IEC 62133		N/A
15.4.3.5	**A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire ..... :**		N/A
	Protective device has adequate breaking capacity		N/A
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented		N/A
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPS provided, or		N/A
	Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION		N/A
15.4.4	**Indicator lights provided to indicate ME EQUIPMENT is ready for ..... :**	No such indicator.	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)		N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists		N/A
	Colours of indicator lights complied with 7.8.1		N/A
	Charging mode visibly indicated		N/A
15.4.5	**RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS..... :** **(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)**	No such part in power supply.	N/A
15.4.6	**Actuating parts of controls of ME EQUIPMENT**		
15.4.6.1	**a) Actuating parts cannot be pulled off or loosened during NORMAL USE**	No such part in power supply.	N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	b) Controls secured so that the indication of any scale always corresponds to the position of the control		N/A
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values per Table 30 applied knobs did not rotate ..... :		N/A
	Tests conducted with no unacceptable RISK . :		N/A
15.4.6.2	**Stops on rotating/ movable parts of controls are of adequate mechanical strength ..... :**		N/A
	Torque values in Table 30 applied ..... :		N/A
	No unexpected change of the controlled parameter when tested..... :		N/A
15.4.7	**Cord-connected HAND-HELD and foot-operated control devices**		
15.4.7.1	**a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1**	No control devices 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 ..... :		N/A
15.4.7.2	**Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :**		N/A
	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** ..... :		N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.... :		N/A
15.4.8	**Aluminium wires less than 16 mm^2 in cross-sectional area are not used**	No such wire.	N/A
15.4.9	**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		N/A
	A pressure-release device operating during NORMAL USE is provided		N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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**		
15.5.1	**Overheating**		
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..... :**	>1kHz	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 form internal windings of toroid transformers protected with double sleeving		P
	- insulation between primary and secondary windings complies with 8.8.2		P
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		P

16	**ME SYSTEMS**		
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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)		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**		
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM		N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM		N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER		N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER		N/A
	c) the required information is provided:		N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– 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
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES		N/A
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard		N/A
16.3	**Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements**		N/A
	Transient currents restricted to allowable levels for the specified IPS or UPS ..... :		N/A
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified		N/A
16.4	**Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)**		N/A
16.5	**Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed**		N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION		N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :		N/A
16.6	**LEAKAGE CURRENTS**		
16.6.1	**TOUCH CURRENT in NORMAL CONDITION did not exceed 100 µA.....:**		N/A
	TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR.....:		N/A
16.6.2	**Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA....:**		N/A
16.6.3	**PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values .....:**		N/A
16.7	**ME SYSTEM complied with applicable requirements of Clause 9.....:**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
16.8	**Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE**		N/A
16.9	**ME SYSTEM connections and wiring**		
16.9.1	**Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result ..... :**		N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)		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**		N/A
16.9.2.1	**a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or**		N/A
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or		N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer		N/A
	b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and		N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or		N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to		N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT		N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:		N/A
	– CREEPAGE and CLEARANCES complied with 8.9		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– 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 ..... :		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, ...:		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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		
	RISKS associated confirmed by review..... :	Not applicable to power supply component; 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)		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		N/A
ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		
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**		N/A
G.2.2	**FLAMMABLE AESTHETIC MIXTURE WITH**		N/A
G.2.3	**A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE**		N/A
G.2.4	**ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5**		N/A
G.2.5	**ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6**		N/A
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7		N/A
G.3	**Marking, ACCOMPANYING DOCUMENTS**		
G.3.1	**CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1)..... :**		N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case		N/A
	When above marking not possible, relevant information included in instructions for use ... :		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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)..... :**		N/A
	Marking is as large as possible for the particular case		N/A
	When above marking not possible, the relevant information included in instructions for use ... :		N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3		N/A
G.3.3	**The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts**		N/A
G.3.4	**ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts**		N/A
G.3.5	**Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG**		N/A
G.4	**Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT**		
G.4.1	**a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION**		N/A
	b) Connections protected against accidental disconnection		N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,		N/A
G.4.2	**Construction details**		
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL		N/A
	b) ENCLOSURE complies with..... :		N/A
	– no openings on top covers of ENCLOSURE,		N/A
	– openings in side-covers prevented penetration of a solid cylindrical test rod		N/A
	– openings in base plates prevented penetration of a solid cylindrical test		N/A
	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION		N/A
G.4.3	**a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures**		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Use of antistatic materials with a limited electrical resistance ..... :		N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor		N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882..... :		N/A
G.4.4	**Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5**		N/A
G.5	**Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components**		
G.5.1	**ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5**		N/A
	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..... :**		N/A
G.5.3	**ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:**		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1..... :		N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 ..... :		N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1		N/A
	No extrapolation made for voltages above 42 V		N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2		N/A
	No extrapolation made for voltages above 242V		N/A
	U_{max} determined using actual resistance R		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3		N/A
	No extrapolation made for inductances larger than 900 mH		N/A
	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open		N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed		N/A
	– 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 .. :		N/A
	Alternatively, compliance was verified by examination of design data .....:		N/A
G.5.4	**External ventilation with internal overpressure**		
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:		N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,		N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)..... :		N/A
	Overpressure maintained at the site of potential ignition		N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE		N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present		N/A
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa) ..... :		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C ..... :		N/A
G.5.5	**ENCLOSURES with restricted breathing**		
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:		N/A
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing		N/A
	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 :		N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained		N/A
	Cords are fitted with adequate anchorages to limit stresses as determined by test		N/A
	Overpressure not reduced below 200 Pa		N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)		N/A
	Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C) ..... :		N/A
	Steady state operating temperature of ENCLOSURE also measured (°C) ..... :		N/A
G.6	**CATEGORY APG ME EQUIPMENT, parts and components thereof**		
G.6.1	**ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION**		N/A
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test		N/A
G.6.2	**Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :**		N/A
G.6.3	**Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..... :**		N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	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:		N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 ..... :		N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5... :		N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :		N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :		N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated		N/A
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10		N/A
	– I_{max} was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10		N/A
	– C_{max} and L_{max} are values occurring in relevant circuit		N/A
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω		N/A
	– Peak value considered when a.c. supplied		N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit ..... :		N/A
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components		N/A
	- requirement not applied to transformers complying with this standard		N/A
	- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture		N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Temperature measurements made in accordance with 11.1..... :		N/A
	- or U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6 ..... :		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..... :**		N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE		N/A
G.7	**Test apparatus for flammable mixtures according to this Clause and Fig G.7**		N/A

ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		
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**		
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component	Approved TIW is used in mains transformer.	N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		N/A
L.3	**Type Test**		
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified	Approved TIW is used in mains transformer.	N/A
	Temperature (°C)..... :		**—**
	Humidity (%)..... :		**—**
L.3.1	**Dielectric strength**		
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:	Approved TIW is used in mains transformer.	N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 6000 V for REINFORCED INSULATION (V) ..... :		N/A
L.3.2	**Flexibility and adherence**		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	Sample subjected to flexibility and adherence	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**		
	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/mm^2) ..... :		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A
L.3.4	**Retention of electric strength after bending**		
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests	Approved TIW is used in mains transformer.	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Test voltage applied between the shot and conductor		N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2) ..... :		N/A
L.4	**Tests during manufacture**		
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

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

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

4.2.2	**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 / Cl. 1-9	—	Risk Management Process (excluding production and post-production)	P
3.2	GTQPR05000 / Cl. 1-6	—	Adequate Resources	P
3.2	GTQPR05000 / Cl. 4	—	Assignment of qualified personnel	P
3.2	GTQPR05000 / Cl. 5	—	Policy for determining criteria for risk acceptability	P
3.3	—	GT-RMPLAN2014-002	Cl. 1.2 Responsibilities and qualification	P
3.4a	—	GT-RMPLAN2014-002	Cl. 1.1 Scope	P
3.4b	—	GT-RMPLAN2014-002	Cl. 1.2 Responsibilities and qualification	P
3.4c	—	GT-RMPLAN2014-002	Cl. 1.4 Risk management process	P
3.4d	—	GT-RMPLAN2014-002	Cl. 1.3 Criteria for risk acceptability	P
3.4e	—	GT-RMPLAN2014-002	Cl. 1.5 Verification plan	P
3.5	—	GT-RM2014-002		P
4.1	—	GT-RM2014-002	Cl. 3 Refer to GTQPR05000	P
4.2	—	GT-RM2014-002	Cl. 5 Device description	P
4.3	—	GT-RM2014-002	Cl. 6.2 Possible hazards analysis	P
4.4	—	GT-RM2014-002	Cl. 6.3 Estimation of the risk(s) for each hazardous situation	P
5	—	GT-RM2014-002	Cl. 7 Risk evaluation	P
6.2	—	GT-RM2014-002	Cl. 8.1 Risk reduction analysis / Risk Reduction plan	P
6.3	—	GT-RM2014-002	Cl. 8.1 Risk reduction analysis / Verification	P
6.4	—	GT-RM2014-002	Cl. 8.2 Residual risk evaluation	P
6.5	—	GT-RM2014-002	Cl. 8.3 Risk/benefit analysis	P
6.6a	—		No such situation.	N/A
6.6b	—		No such situation.	N/A
6.7	—	GT-RM2014-002	Cl. 10.1 Completeness of risk control	P
7	—	GT-RM2014-002	Cl. 10.2. Evaluation of overall residual risk acceptability	P
8	—	GT-RM2014-002	Cl. 10 Risk Management Conclusion	P

IEC 60601-1			
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**		
Supplementary Information: **Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.**				

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)**	**Power factor (cos φ)**
Tested on model GTM43007-A3005-F, 5Vdc output, 6A					
Normal condition	264	50/60	0.30	36.6	<0.9
Normal condition	240	50/60	0.32	36.4	<0.9
Normal condition	100	50/60	0.68	36.5	<0.9
Normal condition	90	50/60	0.77	36.8	<0.9
Tested on model GTM43007-A4509-F, 9Vdc output, 5A					
Normal condition	264	50/60	0.41	52.5	<0.9
Normal condition	240	50/60	0.46	52.5	<0.9
Normal condition	100	50/60	0.95	53.1	<0.9
Normal condition	90	50/60	1.07	53.6	<0.9
Tested on model GTM43007-A6024-F, 24Vdc output, 2.5A					
Normal condition	264	50/60	0.51	66.9	<0.9
Normal condition	240	50/60	0.57	66.6	<0.9
Normal condition	100	50/60	1.22	68.0	<0.9
Normal condition	90	50/60	1.41	68.9	<0.9
Tested on model GTM43007-A6036-F, 36Vdc output, 1.66A					

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

Normal condition	264	50/60	0.52	66.8	<0.9
Normal condition	240	50/60	0.56	66.6	<0.9
Normal condition	100	50/60	1.22	68.3	<0.9
Normal condition	90	50/60	1.42	69.3	<0.9
Tested on model GTM43007-A6048-F, 48Vdc output, 1.25A					
Normal condition	264	50/60	0.53	68.4	<0.9
Normal condition	240	50/60	0.57	68.3	<0.9
Normal condition	100	50/60	1.21	68.4	<0.9
Normal condition	90	50/60	1.40	69.1	<0.9
Supplementary Information:					

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

7.1.2	**TABLE: Legibility of Marking**	P
Markings tested	**Ambient Illuminance (lx)**	**Remarks**
Outside Markings (Clause 7.2) ..... :	100-1500	Readable
Inside Markings (Clause 7.3) ..... :		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	-
Ink/other printing material or process..... :	See Table 8.10	-

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

7.1.3	**TABLE: Durability of marking test**		P
Material (composition) of Warning Label ..... :			-
Ink/other printing material or process..... :			-
Other..... :			-
Marking Label Tested:			**Remarks**
See Table 8.10			P

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.

8.4.2	**TABLE: TABLE: Working Voltage / Power Measurement**					P
Test supply voltage/frequency (V/Hz)[1] ..... :						
Location From/To	**Measured values**					**Remarks**
	Vrms	**Vpk or Vdc**	**Peak-to-peak ripple[2]**	**Power W/VA**	**Energy (J)**	
Transformer, primary to secondary	<324Vrms					For all models
Secondary output connector		<48Vdc				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**
Connector pins 1 and 2	13	12	13	13	11	12	13	12	13	13

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

Calculated stored charge (μc)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Connector pin 1 and earth pin	<45μC									
Connector pin 2 and earth pin	<45μC									

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

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:					

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			

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

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 (mΩ)**	**Maximum allowable impedance (mΩ)**	
Final judgement in end product for open frame model					
Supplementary information: **PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩME 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
Final judgement shall be made on this component when installed in the end product.				
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC
No PE connection, output terminal to ground				
NC, 0, B	264	60	67.4	100 µA
NC, 1, B	264	60	77.2	100 µA
SFC, phase failure, 1, B	264	60	167.3	500 µA
SFC, phase failure, 1, B	264	60	187.3	500 µA
NC, 0, B	264	60	69.7	100 µA
NC, 1, B	264	60	78.1	100 µA
SFC, phase failure, 1, B	264	60	170.3	500 µA
SFC, phase failure, 1, B	264	60	191.1	500 µA

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

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)
--	--	--	--	--
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
--	--	--	--	--
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)
--	--	--	--	--
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
--	--	--	--	--
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)
--	--	--	--	--
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
--	--	--	--	--
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
--	--	--	--	--
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
--	--	--	--	--

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

Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed	—	—	—	Maximum allowed values: Type B & BF: 1000 µA Type CF: N/A
--	--	--	--	--
Function Earth Conductor Leakage Current (FECLC)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
--	--	--	--	--

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	MOPP	240 x 1.414		1500	No breakdown
C	2MOPP	240 x 1.414		4000	No breakdown
D	2MOPP	240 x 1.414		4000	No breakdown
E	2MOPP	240 x 1.414		4000	No breakdown
F	2MOPP	240 x 1.414		4000	No breakdown
G	2MOPP	240 x 1.414		4000	No breakdown
H	2MOPP	240 x 1.414		4000	No breakdown

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

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)**
Bobbin of T1		
T375HF	125	1.2
T375J	125	1.3
PM-9820	125	1.3
CP-J-8800	125	1.4
Supplementary information:		

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**		P
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**
See the table 13.1			
Supplementary information: Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE			

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

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

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

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.					

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	PACIFIC WIN INDUSTRIAL LTD	PW-02 PW-03	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E228070

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

Alt.	YILIHUA	YLH-1 YLH-2	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E251781
Alt.	AREX	02V0 04V0	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E186016
Alt.	BRITE PLUS ELECTRONICS (SUZHOU) CO LTD	DKV0-3A DGV0-3A	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E177671
Alt.	SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD	TCX	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL E250336
Alt.	Interchangeable	Interchangeable	Min. V-0, min 1.6 mm thickness, 130°C	IEC/EN 60601-1 UL 796	Tested with appliance UL Approved.
Fuse (F1, F2) (F2 is optional.)	Conquer Electronics Co., Ltd.	MST	T2A, 250 V, Rated breaking capacity 100A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40017118 UL E82636
Alt.	Ever Island Electric Co., Ltd. and Walter Electric	2010	T2A, 250 V, Rated breaking capacity 130A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40018781 UL E220181
Alt.	Bel Fuse Ltd.	RST	T2A, 250V, Rated breaking capacity 100A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40011144 UL E20624
Alt.	Das & Sons International Ltd.	385T series	T2A, 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	T2A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40012592 UL E221465
Alt.	Walter Electronic Co. Ltd.	ICP series	T2A, 250V, Rated breaking capacity 50A.	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40012824 UL E56092
Alt.	Zhongshan Lanbao Electrical Appliances Co., Ltd.	RTI-10 series	T2A, 250V, Rated breaking capacity 50A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40017009 UL E213695
Alt.	Sun Electric Co.	5T	T2A, 250V, Rated breaking capacity 100A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40027241 UL E166522
Alt.	Bel Fuse Ltd.	5ST	T2A, 250V, Rated breaking capacity 35A	IEC/EN 60127-2 UL 248-1 UL 248-14	VDE 40000507 UL E20624

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

Earthing wire for class I model	KUNSHAN NEW ZHICHENG ELECTRONICS TECHNOLOGIES CO LTD	1007, 1015	Min. 18AWG, min. 300Vac, min. 80°C	IEC/EN 60601-1 UL 758	Tested with appliance UL E237831
Alt.	SUZHOU YEMAO ELECTRONIC CO LTD	1007, 1015	Min. 18AWG, min. 300Vac, min. 80°C	IEC/EN 60601-1 UL 758	Tested with appliance UL E353532
Alt.	ZHUANG SHAN CHUAN ELECTRICAL PRODUCTS (KUNSHAN) CO LTD	1007, 1015	Min. 18AWG, min. 300Vac, min. 80°C	IEC/EN 60601-1 UL 758	Tested with appliance UL E333601
Alt.	GLOBTEK INC	1007, 1015	Min. 18AWG, min. 300Vac, min. 80°C	IEC/EN 60601-1 UL 758	Tested with appliance UL E464257
Alt.	Interchangeable	Interchangeable	Min. 18AWG, min. 300Vac, min. 80°C	IEC/EN 60601-1 UL 758	Tested with appliance UL approved.
Heatsink (HS1)	Interchangeable	Interchangeable	Aluminum. Approximate overall dimension 60mm by 15mm, min.1.5mm thick, secured to PWB by soldering	IEC/EN 60601-1	Tested with appliance
Heatsink (HS2) (for 5-9V)	Interchangeable	Interchangeable	Aluminum. Approximate overall dimension 50mm by 22mm by 38mm, min.1.0mm thick, secured to PWB by soldering	IEC/EN 60601-1	Tested with appliance
Heatsink (HS2) (for 9.1-48V)	Interchangeable	Interchangeable	Aluminum. Approximate overall dimension 50mm by 6mm by 18mm, min.1.4mm thick, secured to PWB by soldering	--	Tested with appliance
Insulation tape provided on heatsink[2]	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	Min.130°C	IEC/EN 60601-1 UL 510	Tested with appliance UL E246820
Alt.	3M COMPANY	1350F-1 1350T-1	Min.130°C	IEC/EN 60601-1 UL 510	Tested with appliance UL E17385

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

Alt.	BONDTEC PACIFIC CO.,LTD	370S	Min.130°C	IEC/EN 60601-1 UL 510	Tested with appliance UL E175868
Alt.	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ series CT series WF series	Min.130°C	IEC/EN 60601-1 UL 510	Tested with appliance UL E165111
Alt.	JINGJIANG JINGYI	JY25-A	Min.130°C	IEC/EN 60601-1 UL 510	Tested with appliance UL E246950
Insulation tubing provided on heatsink or fuse or class I earth wire[2]	SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD	RSFR RSFR-H RSFR-HPF	600V, 125°C	IEC/EN 60601-1 UL 224	Tested within appliance UL E203950
Alt.	QIFURUI ELECTRONICS CO	QFR-h	600V, 125°C	IEC/EN 60601-1 UL 224	Tested within appliance UL E225897
Alt.	DONGGUAN SALIPT CO LTD	SALIPT S-901-300 SALIPT S-901-600	Min. 300V, 125°C	IEC/EN 60601-1 UL 224	Tested within appliance UL E209436
Alt.	GUANGZHOU KAIHENG ENTERPRISE GROUP	K-2 (+) K-2 (CB)	Min. 300V, 125°C	IEC/EN 60601-1 UL 224	Tested within appliance UL E214175
Alt.	CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-HFT	Min. 300V, 125°C	IEC/EN 60601-1 UL 224	Tested within appliance UL E180908
Alt.	SHENZHEN WOLIDA TRADING CO LTD	RSFR-H	600V, 125°C	IEC/EN 60950-1 UL 224	Tested within appliance E329530
Y-Capacitor (CY1, CY2) (optional)	SUCCESS ELECTRONICS CO LTD	SE SB	Type Y1, max. 2200pF, min. 250V, 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40037221 VDE 40037211 UL E114280
Alt.	MURATA MFG CO LTD	KX	Type Y1, max. 2200pF, min. 250V, 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40002831 UL E37921
Alt.	WALSIN TECHNOLOGY CORP	AH	Type Y1, max. 2200pF, min. 250V, 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, 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40001831 UL E201384

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

Alt.	HAOHUA ELECTRONIC CO	CT7	Type Y1, max. 2200pF, min. 250V, 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40003902 UL E233106
Alt.	JERRO ELECTRONICS CORP	JX-series	Type Y1, max. 2200pF, min. 250V, 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40032158 UL E333001
Alt.	TDK CORP	CD	Type Y1, max. 2200pF, min. 250V, 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 124321 UL E37861
Alt.	Hongzhi	Y	Type Y1, max. 2200pF, min. 250V, 125°C	IEC/EN 60384-14	VDE 40004354
Alt.	WELSON INDUSTRIAL CO LTD	WD	Type Y1, max. 2200pF, min. 250V, 125°C	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 115455 UL E104572
X Capacitor (CX1) (optional)	Cheng Tung	CTX	Max. 0.33uF, 310V, 110°C, type X1 or X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40022642 UL E193049
Alt.	Ultra Tech Xiphi Enterprise Co. Ltd.	HQX	Max.0.33uF, 275V, 100°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40015608 UL E183780
Alt.	Dain Electronics Co., Ltd.	MPX, MEX and NPX	Max.0.33uF, 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.0.33uF, 300V, 110°C, type X2	IEC/EN 60384-14 UL 60384-14 UL 1414	VDE 40014686 UL E237560
Alt.	Hongzhi Enterprises Ltd.	MPX	Max.0.33uF, 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.0.33uF, 250V, 100°C, type X2	IEC/EN 60384-14	VDE 40022417 UL E311166
Line filter (LF1) (optional)	GlobTek/HAOPUWEI/HEJIA/BOAM	LF019	Class B	IEC/EN 60601-1	Tested with appliance
Line filter (LF2) (optional)	GlobTek/HAOPUWEI/HEJIA/BOAM	LF018	Class B	IEC/EN 60601-1	Tested with appliance
Optocoupler (U2)	LITE-ON Technology Corporation	LTV-817C	2MOPP at working voltage 250Vrms, 100°C	IEC/EN 60601-1	SIQ CB Report No.T223-0437/12
Alt.	Everlight Electronics Co., Ltd.	EL817	2MOPP at working voltage 250Vrms, 100°C	IEC/EN 60601-1	SIQ CB Report No.T223-0106/13

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

Transformer (T1)	GlobTek/BOAM/ HAOPUWEI	TF024 for 5-6.5V TF025 for 6.6-8.9V TF026 for 9-13V TF027 for 13.1-17V TF028 for 17.1-24.9V TF029 for 25-34.9V TF032 for 35-48V	Class B, with critical component listed below	IEC/EN 60601-1	Tested with appliance
-Insulation system	GLOBTEK INC	GTX-130-TM	Class B	IEC/EN 60601-1 UL 1446	Tested with appliance UL E243347
-Alt.	SHAN DONG BOAM ELECTRIC CO LTD	BOAM-01	Class B	IEC/EN 60601-1 UL 1446	Tested with appliance UL E252329
-Alt.	WUXI HAOPUWEI ELECTRONICS CO LTD	ZT-130	Class B	IEC/EN 60601-1 UL 1446	Tested with appliance UL E315275
-Magnet wire (Primary)	PACIFIC ELECTRIC WIRE & CABLE (SHENZHEN) CO LTD	UEWN/U	130°C	IEC/EN 60601-1 UL 1446	Tested with appliance UL E201757
-Alt.	JUNG SHING WIRE CO LTD	UEW-4 UEY-2	130°C	IEC/EN 60601-1 UL 1446	Tested with appliance UL E174837
-Alt.	JIANGSU HONGLIU MAGNET WIRE TECHNOLOGY CO LTD	2UEW/130	130°C	IEC/EN 60601-1 UL 1446	Tested with appliance UL E335065
-Alt.	CHANGZHOU DAYANG WIRE & CABLE CO LTD	2UEW/130	130°C	IEC/EN 60601-1 UL 1446	Tested with appliance UL E158909
-Alt.	WUXI JUFENG COMPOUND LINE CO LTD	2UEWB	130°C	IEC/EN 60601-1 UL 1446	Tested with appliance UL E206882
-Alt.	JIANGSU DARTONG M & E CO LTD	UEW	130°C	IEC/EN 60601-1 UL 1446	Tested with appliance UL E237377
-Alt.	SHANDONG SAINT ELECTRIC CO LTD	UEW/130	130°C	IEC/EN 60601-1 UL 1446	Tested with appliance UL E194410

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

-Alt.	ZHEJIANG LANGLI ELECTRIC EQUIPMENTS CO LTD	UEW	130°C	IEC/EN 60601-1 UL 1446	Tested with appliance UL E222214
-Secondary wire of T1 (TIW)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW (B)	Min.130°C	IEC/EN 60601-1 UL 2353	Tested with appliance UL E211989
-Alt.	COSMOLINK CO LTD	TIW-M	Min.130°C	IEC/EN 60601-1 UL 2353	Tested with appliance UL E213764
-Alt.	FURUKAWA ELECTRIC CO LTD	TEX-E	Min.130°C	IEC/EN 60601-1 UL 2353	Tested with appliance UL E206440
-Alt.	TOTOKU ELECTRIC CO LTD	TIW-2	Min.130°C	IEC/EN 60601-1 UL 2353	Tested with appliance UL E166483
-Alt.	E&B TECHNOLOGY CO LTD	E&B-XXXB E&B-XXXB-1	Min.130°C	IEC/EN 60601-1 UL 2353	Tested with appliance UL E315265
-Bobbin	CHANG CHUN PLASTICS CO LTD	T375J T375HF	V-0, 150°C, min thickness: 0.6mm	IEC/EN 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E59481
-Alt.	SUMITOMO BAKELITE CO LTD	PM-9820	V-0, 150°C, min thickness: 0.6mm	IEC/EN 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E41429
-Alt.	HITACHI CHEMICAL CO LTD	CP-J-8800	V-0, 150°C, min thickness: 0.6mm	IEC/EN 60601-1 UL 94 UL 746 A/B/C/D	Tested with appliance UL E42956
-Insulating tape	3M COMPANY ELECTRICAL MARKETS DIV (EMD)	1350F-1 1350T-1	130°C	IEC/EN 60601-1 UL 510	Tested with appliance UL E17385
-Alt.	BONDTEC PACIFIC CO LTD	370S	130°C	IEC/EN 60601-1 UL 510	Tested with appliance UL E175868
-Alt.	JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD	PZ CT WF	130°C	IEC/EN 60601-1 UL 510	Tested with appliance UL E165111
-Alt.	JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD	JY25-A	130°C	IEC/EN 60601-1 UL 510	Tested with appliance UL E246950
-Alt.	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	130°C	IEC/EN 60601-1 UL 510	Tested with appliance UL E246820

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

Connector (CON1)	JOINT TECH ELECTRONIC INDUSTRIAL CO LTD	A7920WV-2P	Min 250V	IEC/EN 60601-1 UL 1977	Tested with appliance UL E179987
Alt.	MOLEX INCORPORATED	41791 series	Min 250V	IEC/EN 60601-1 UL 1977	Tested with appliance UL E29179

Supplementary information:

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

2) 2 layers of insulating tape or 1 layer of min. 0.4 mm thickness insulating tube can be used alternatively for wrapping around heatsink.

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) An asterisk 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**	

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

Toes	**> 50**		**> 50**	
Arm	**> 120**		**> 120**	
Hand, wrist, fist	**> 100**		**> 100**	
Finger	**> 25 or < 8**		**> 25 or < 4**	
Supplementary information: [1] In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.				

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

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

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

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

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

9.4.2.4.3	**TABLE: Castors and wheels – Movement over a threshold**	N/A

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

ME EQUIPMENT preparation	Test Condition (speed of movement)	Remarks
--	--	--
Supplementary information:		

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

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

9.4.4	TABLE: Grips and other handling devices	N/A
CLAUSE AND NAME OF TEST	**Test Condition**	**Remarks**
--	--	--
Supplementary information:		

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

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

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

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			

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**					P
Model No. ..... :		1	2	3	4	5
Test ambient (°C) ..... :		40	40	40	40	40
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**
90V, 60Hz						
1	1	LF1 winding	130	66.3		
	2	CX1 body	100	59		
	3	C8 body	105	78.7		
	4	T1 winding	130-10=120	89.5		COR method not used

IEC 60601-1					
Clause	**Requirement + Test**		**Result - Remark**		**Verdict**
	5	T1 core	130	86.7	
	6	PCB near Q1 (HS1)	130	76.7	
	7	PCB near Q2 (HS2)	130	81.6	
	8	PCB near U2	130	75	
	9	C9 body	105	74.5	
264V, 60Hz					
1	1	LF1 winding	130	57.9	
	2	CX1 body	100	55.5	
	3	C8 body	105	71.5	
	4	T1 winding	130-10=120	92.7	COR method not used
	5	T1 core	130	90	
	6	PCB near Q1 (HS1)	130	74.8	
	7	PCB near Q2 (HS2)	130	79.1	
	8	PCB near U2	130	74.1	
	9	C9 body	105	75.6	
90V, 60Hz					
2	1	LF1 winding	130	77.4	
	2	CX1 body	100	65.1	
	3	C8 body	105	87.3	
	4	T1 winding	130-10=120	94.6	COR method not used
	5	T1 core	130	97.8	
	6	PCB near Q1 (HS1)	130	94.8	
	7	PCB near Q2 (HS2)	130	99.6	
	8	PCB near U2	130	85.8	
	9	C9 body	105	85	
264V, 60Hz					
2	1	LF1 winding	130	61.7	
	2	CX1 body	100	60.9	
	3	C8 body	105	77.7	
	4	T1 winding	130-10=120	99.0	COR method not used
	5	T1 core	130	102.6	
	6	PCB near Q1 (HS1)	130	81.3	

IEC 60601-1					
Clause	**Requirement + Test**		**Result - Remark**		**Verdict**
	7	PCB near Q2 (HS2)	130	101.2	
	8	PCB near U2	130	87.0	
	9	C9 body	105	84.2	
90V, 60Hz					
3	1	LF1 winding	130	87.6	
	2	CX1 body	100	64.0	
	3	C8 body	105	91.1	
	4	T1 winding	130-10=120	98.0	COR method not used
	5	T1 core	130	96.8	
	6	PCB near Q1 (HS1)	130	106.4	
	7	PCB near Q2 (HS2)	130	76.6	
	8	PCB near U2	130	81.0	
	9	C9 body	105	74.1	
264, 60Hz					
3	1	LF1 winding	130	60.8	
	2	CX1 body	100	58.4	
	3	C8 body	105	75.4	
	4	T1 winding	130-10=120	111.7	COR method not used
	5	T1 core	130	109.2	
	6	PCB near Q1 (HS1)	130	83.1	
	7	PCB near Q2 (HS2)	130	83	
	8	PCB near U2	130	87.3	
	9	C9 body	105	75.4	
90V, 60Hz					
4	1	LF1 winding	130	72.6	
	2	CX1 body	100	68.9	
	3	C8 body	105	91.9	
	4	T1 winding	130-10=120	105.2	COR method not used
	5	T1 core	130	102.1	
	6	PCB near Q1 (HS1)	130	106.8	
	7	PCB near Q2 (HS2)	130	89.3	
	8	PCB near U2	130	88.9	

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

	9	C9 body	105	70.1	
264, 60Hz					
4	1	LF1 winding	130	59.3	
	2	CX1 body	100	56.4	
	3	C8 body	105	74.3	
	4	T1 winding	130-10=120	113.3	COR method not used
	5	T1 core	130	116.6	
	6	PCB near Q1 (HS1)	130	83.6	
	7	PCB near Q2 (HS2)	130	96.7	
	8	PCB near U2	130	97.1	
	9	C9 body	105	76.1	

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 - S**ee RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

[6] Model No.1 is GTM43007-A3005-F. Model No.2 is GTM43007-A4509-F. Model No.3 is GTM43007-A6024-F. Model No.4 is GTM43007-A6048-F.

Information from Risk Management, as applicable: N/A

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.		

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

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

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:

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

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

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

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

Supplementary information:

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.2	**Electrical SINGLE FAULT CONDITIONS per Clause 8.1:**	**—**	**—**
	BD1 short circuit	Fuse open	No
	C8 short circuit	Fuse open	No
	Q1 short circuit	Circuit protected.	No
	U2 Sec. short circuit	Circuit protected.	No
	U2 Pri. short circuit	Circuit protected.	No
	U2 Sec. open circuit	Circuit protected.	No
	U2 Pri. open circuit	Circuit protected.	No
	D2 short circuit	Circuit protected.	No
13.2.3	**Overheating of transformers per Clause 15.5:**	**—**	**—**
		See 15.5	No
13.2.4	**Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:**	**—**	**—**
		No 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)**	**—**	**—**

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.7	**Impairment of cooling that could result in a HAZARD using test method of 11.1:**	—	—
	Single ventilation fans locked consecutively	No fan used	N/A
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	No ventilation opening	N/A
	Simulated blocking of filters	No filter	N/A
	Flow of a cooling agent interrupted	No cooling agent used	N/A
13.2.8	**Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:**	—	—
		No moving part	N/A
13.2.9	**Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10**	—	—
		No 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 stared 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:**	—	—
13.2.12	**Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):**	—	—

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)]**		N/A
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**
15.3.2	**Push Test**	**Force = 250 N ± 10 N for 5 s**	N/A

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

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) =**	N/A
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) =**	N/A
Supplementary information:			

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]:						264V	—
RATED input frequency (Hz):						60Hz	—
Winding tested	**Class of insulation (A, B, E, F, or H)**	**Type of protective device (fuse, circuit breaker) /Ratings**	**Protective device operated Yes/No**	**Time to THERMAL STABILITY (when protective device did not operate)(Min)**	**Maximum allowed temp from Table 31 (ºC)**	**Maximum winding temp measured (ºC)**	**Ambient (ºC)**
TF024	B	N/A [2]	No	5 Min	165[3]	<30	25
TF025	B	N/A [2]	No	5 Min	165[3]	<30	25
TF026	B	N/A [2]	No	5 Min	165[3]	<30	25
TF027	B	N/A [2]	No	5 Min	165[3]	<30	25
TF028	B	N/A [2]	No	5 Min	165[3]	<30	25
TF029	B	N/A [2]	No	5 Min	165[3]	<30	25
TF032	B	N/A [2]	No	5 Min	165[3]	<30	25

Supplementary information:

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

[2] SMPS current limiting circuits operated immediately.

[3] Thermocouples are used, so the limit is to be reduced by10 ºC.

15.5.1.3	**TABLE: transformer overload test – conducted only when protective device**	P

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

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

WINDING TESTED	Class of insulation (A, B, E, F, H)	Type of protective device used (fuse, circuit breaker)/Ratings	Maximum allowed temp from Table 31 (ºC)	Maximum winding temp measured (ºC)	Ambient (ºC)
TF024	B	Fuse 2A (OL current 0.40A)	165[2]	123	25
TF025	B	Fuse 2A (OL current 0.54A)	165[2]	125	25
TF026	B	Fuse 2A (OL current 0.54A)	165[2]	126	25
TF027	B	Fuse 2A (OL current 0.74A)	165[2]	126	25
TF028	B	Fuse 2A (OL current 0.73A)	165[2]	127	25
TF029	B	Fuse 2A (OL current 0.74A)	165[2]	126	25
TF032	B	Fuse 2A (OL current 0.79A)	165[2]	125	25

Supplementary information:

[1] Loads on other windings between no load and their NORMAL USE load.

Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32.

Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved.

- Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.

[2] Thermocouples are used, so the limit is to be reduced by 10 ° C.

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				P
Transformer Model/Type/ Part No	**Test voltage applied between**	**Test voltage, (V)**	**Test frequency (Hz)**	**Breakdown Yes/No**	**Deterioration Yes/No**
All models	Primary & secondary windings	4000	60	No	No
All models	Core & secondary windings	4000	60	No	No

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

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

1. Each transformer model is identical in insulation construction including clearance and creepage except number of turns per coil.

2. The core of transformer (T1) is considered as primary winding, the TIW is used in secondary winding of transformer (T1).

3. All types of transformer from all manufacturers listed in table 1.5.1 are tested.

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)**	
--	--	--	--	--	
Supplementary information:					

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

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

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

Differences according to.....: US National standard ANSI/AAMI ES60601-1: 2005 / A2:2010

Attachment Form No.....: US_ND_IEC60601_1G
Attachment Originator .....: Underwriters Laboratories Inc.
Master Attachment.....: 2011-04

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

	US NATIONAL DIFFERENCES		
4.8 b	Replacement: where there was no relevant IEC/ISO standard, the relevant US ANSI standard applied		P
	- when no relevant US ANSI standard existed, the requirements of this standard applied		P
4.10.2	Replacement: Rated voltage not exceeding 250V dc or single phase ac. or 600V poly-phase ac for me equipment and me systems up to 4kVA	Higher than 4kVA	N/A
	Rated voltage not exceeding 600 V for all other me equipment and me systems		P
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		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		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.7.3 d	Earth leakage current values are not higher than the stated values		P
	5 mA in normal condition		P
	10 mA in single fault condition		P
8.11	Addition prior to the first paragraph: a) To comply with the NEC, add the following requirements to this clause:		
	Addition: permanently connected me equipment provided with field wiring provision in accordance with NEC	Final determination in end product.	N/A
	Installation of connecting cords between equipment parts comply with NEC		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,		N/A
	2) Not exposed to abuse: The cable was as in item 1) above, or		N/A
	i) Type SPT-2, SP-2, or SPE-2, or equivalent		N/A
	ii) Type SVR, SVRO, SVE, or equivalent or similar multiple-conductor appliance wiring material,		N/A
	iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more,		N/A
	- enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more	.	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		N/A
	- or employ a Listed tamper resistant cover in accordance with NEC		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		N/A
8.11.3.2	Addition: The flexible cord is a type acceptable for the particular application,		N/A
	- and it is acceptable for use at a voltage not less than the rated voltage of the appliance		N/A
	- and has an ampacity as in NEC, not less than the current rating of the appliance		N/A

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.11.3.3	Addition: To comply with NFPA 99, for X-Ray me equipment with an attachment plug, the current rating on a hospital grade plug is 2X the maximum input current of the equipment	Not X-ray equipment.	N/A

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

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

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

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

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

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

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

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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	National standard reference: SN EN 60601-1:2006		
	Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7, Mercury - Annex 1.7 of SR 814.81 applies for mercury. Switches containing mercury such as thermostats, relays and level controllers are not allowed. Ordinance on chemical hazardous risk reduction SR 814.81, Annex 2.15 Batteries Annex 2.15 of SR 814.81 applies for batteries containing cadmium and mercury. Note: Ordinance relating to environmentally hazardous substances, SR 814.013 of 1986-06-09 is not longer in force and superseded by SR 814.81 of 2009-02-01 (ChemRRV).		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: - SEV 6533-2:2009 Plug type 11, L + N, 250V 10A - SEV 6534-2:2009 Plug type 12, L + N + PE, 250V 10A - SEV 6532-2:2009 Plug type 15, 3L + N + PE, 250/400V 10A Supply cords of portable electrical appliances having a rated current not exceeding 16 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: - SEV 5933-2:2009 Plug type 21 L + N, 250 V, 16A - SEV 5934-2:2009 Plug type 23 L + N + PE, 250 V, 16A - SEV 5932-2:2009 Plug type 25 3L + N + PE, 250/400V 16A Note: 16 A plugs are not often used in Swiss domestic installation system. See TRF template regulatory requirements Switzerland on IECEE Website R.R. TRF templates.		N/A

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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	National standard reference: JIS T0601-1:2012		
1.1	At the end, add the following: JIS T0601-1:1999 is applicable until 2017.05.31.		—
1.3	In NOTE 3, add the following: In Japan, to check the concerned JIS standard is required.		—
1.4	At the end of NOTE, add the following: In Japan, application of the concerned JIS standard(s) is required.		—
2	Except the part of the first paragraph, Attention and NOTE, replace the existing part listing standards with the following, and apply these properly in the following clauses if any: JIS B7761-3, Hand-transmitted vibration-Part 3: General requirements for measurement and evaluation NOTE: ISO 5349-1, Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration - Part 1: General requirements (IDT) JIS B9707, Safety of machinery-Safety distances to prevent danger zones being reached by the upper limbs NOTE: ISO 13852, Safety of machinery - Safety distances to prevent danger zones being reached by the upper limbs (IDT) JIS B9711, Safety of machinery-Minimum gaps to avoid crushing of parts of the human body NOTE: ISO 13854, Safety of machinery - Minimum gaps to avoid crushing of parts of the human body (IDT) JIS C0445, Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system NOTE: IEC 60445, Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system (IDT) JIS C0447, Man-machine interface (MMI) - Actuating principles NOTE: IEC 60447, Basic and safety principles for man-machine interface, marking and identification		—

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	- Actuating principles (IDT) JIS C0920:2003, Degrees of protection provided by enclosures (IP Code) NOTE: IEC 60529:2001, Degrees of protection provided by enclosures (IP Code) (IDT) JIS C1509-1, Electroacoustitcs - Sound level meters- Part 1: Specifications NOTE: IEC 61672-1, Electroacoustics - Sound level meters - Part 1: Specifications (IDT) JIS C1509-2, Electroacoustics -Sound level meters - Part 2: Pattern evaluation tests NOTE: IEC 61672-2, Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests (IDT) JIS C2134, Method for the determination of the proof and the comparative tracking indices of solid insulating materials NOTE: IEC 60112, Method for the determination of the proof and the comparative tracking indices of solid insulating materials (IDT) JIS C3301:2000, Rubber insulated flexible cords NOTE: IEC 60245-4:1994, Rubber insulated cables of rated voltages up to and including 450/750 V - Part 4: Cords and flexible cables, Amendment 1:1997 (NEQ) JIS C3306:2000, Polyvinyl chloride insulated flexible cords NOTE: IEC 60227-5:1997, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V - Part 5: Flexible cables (cords) (NEQ) JIS C4003, Electrical insulation-Thermal evaluation and designation NITE: IEC 60085, Electrical insulation - Thermal evaluation and designation (MOD) JIS C5101-14:2009, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains NOTE: IEC 60384-14:2005, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains (IDT) JIS C6065:2007, Audio, video and similar electronic apparatus-Safety requirements		

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

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	JIS C60364-4-41, Low-voltage electrical installations-Part 4-41: Protection for safety - Protection against electric shock NOTE: IEC 60364-4-41, Electrical installations of buildings - Part 4-41: Protection for safety - Protection against electric shock (IDT) JIS C60664-1:2009, Insulation coordination for equipment within low-voltage systems - Part 1:Principles, requirements and tests NOTE: IEC 60664-1:2007, Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests (IDT) JIS C60695-11-10, Fire hazard testing-Part11-10:Test flames-50W horizontal and vertical flame test methods NOTE: IEC 60695-11-10, Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods (IDT) JIS T0307, Medical devices-Symbols to be used with medical device labels, labelling and information to be supplied NOTE: ISO 15223，Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied (IDT) JIS T0601-1-3, Medical electrical equipment-Part 1-3: General requirements for basic safety and essential performance-Collateral Standard: Radiation protection in diagnostic X-ray equipment NOTE: IEC60601-1-3, Medical electrical equipment - Part 1: General requirements for safety - 3. Collateral standard: General requirements for radiation protection in diagnostic X-ray equipment (IDT) JIS T14971:2003, Medical devices-Application of risk management to medical devices NOTE: ISO 14971:2000, Medical devices - Application of risk management to medical devices (IDT) JIS Z8202 (all parts), Quantities and units NOTE: ISO 31 (all parts), Quantities and units (IDT) JIS Z8203, SI units and recommendations for the use of their multiples and of certain other units NOTE: ISO 1000, SI units and recommendations for the use of their multiples and of certain other units (IDT)		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	JIS Z8736-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1 : Measurement at discrete points NOTE: ISO 9614-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points (IDT) JIS Z9101:2005, Safety colours and safety signs-Design principles for safety signs in workplaces and public areas NOTE: ISO 3864-1:2002, Graphical symbols - Safety colours and safety signs - Part 1: Design principles for safety signs in workplaces and public areas (IDT) ISO 780, Packaging - Pictorial marking for handling of goods NOTE: The corresponding JIS standard is JIS Z0150 Packaging-Pictorial marking for handling of goods (MOD) ISO 1853, Conducting and dissipative rubbers, vulcanized or thermoplastic—Measurement of resistivity NOTE: The corresponding JIS standard is JIS K6271 Rubber, vulcanized or thermoplastic-Determination of volume and surface resistivity (MOD) ISO 2878, Rubber - Antistatic and conductive products - Determination of electrical resistance ISO 2882, Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits ISO 3746, Acoustics - Determination of sound power levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane ISO 7000-DB:2004, Graphical symbols for use on equipment - Index and synopsis ISO 7010:2003, Graphical symbols - Safety colours and safety signs - Safety signs used in workplaces and public areas ISO 10993 (all parts), Biological evaluation of medical devices NOTE: The corresponding JIS standard is JIS T0993-1 Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process (MOD). However, other Parts than Part 1 and Part 7 have still not been		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	published as JIS. ISO 11134, Sterilization of health care products - Requirements for validation and routine control - Industrial moist heat sterilization NOTE: At present, as the corresponding JIS or international standards, the following exist: JIS T0816-1:2010 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (IDT) ISO 11135, Medical devices - Validation and routine control of ethylene oxide sterilization NOTE: At present, as the corresponding JIS or international standards, the following exist: JIS T0801-1:2010 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT) ISO 11137, Sterilization of health care products - Requirements for validation and routine control – Radiation Sterilization NOTE: At present, as the corresponding JIS or international standards, the following exist: JIS T0806-1:2010 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT) ISO 23529, Rubber - General procedures for preparing and conditioning test pieces for physical test methods NOTE: The corresponding JIS standard is JIS K6250 Rubber-General procedures for preparing and conditioning test pieces for physical test methods (MOD) IEC 60079-5，Explosive gas atmospheres－Part		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	5: Equipment protection by powder filling “q” IEC/TR 60083, Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries NOTE: The corresponding JIS standard is JIS C8513 Safety of primary lithium batteries (MOD) IEC 60127-1, Miniature fuses - Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links NOTE: The corresponding JIS standard is JIS C6575-1 Miniature fuses-Part 1: Definitions of miniature fuses and general requirements for miniature fuse-links (MOD) IEC 60227-1:1993, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements，Amendment 1:1995 and Amendment 2:1998 NOTE: The corresponding JIS standard is JIS C3662-1:2009 Polyvinyl chloride insulated cables of rated voltages up to and including 450/750V - Part 1: General requirements (MOD) IEC 60245-1:2003, Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 1: General requirements NOTE: The corresponding JIS standard is JIS C3663-1:2007 Rubber insulated cables-Rated voltages up to and including 450/750 V-Part 1: General requirements (MOD) IEC 60252-1, AC motor capacitors - Part 1: General - Performance, testing and rating - Safety requirements -Guide for installation and operation IEC 60320-1, Appliance couplers for household and similar general purposes - Part 1: General requirements NOTE: The corresponding JIS standard is JIS C8283-1 Appliance couplers for household and similar general purposes-Part 1: General requirements (MOD) IEC 60335-1:2001, Household and similar electrical appliances - Safety - Part 1: General requirements NOTE: The corresponding JIS standard is JIS C9335-1:2003 Household and similar electrical appliances - Safety - Part 1 : General requirements (MOD)		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	IEC 60417-DB:2002, Graphical symbols for use on equipment IEC 60601-1-2, Medical electrical equipment - Part 1 - 2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests NOTE: The current “JIS T0601-1-2:2012 Medical electrical equipment - Part 1-2: General requirements for safety - Electromagnetic compatibility - Requirements and tests” corresponds to IEC 60601-1-2:2001 and Amendment 1:2004. IEC 60601-1-6, Medical electrical equipment - Part 1 - 6: General requirements for basic safety and essential performance - Collateral standard: Usability NOTE: As the corresponding international standard, IEC 62336 is applicable. IEC 60601-1-8, Medical electrical equipment - Part 1 - 8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems NOTE: The corresponding JIS standard is now under drafting. IEC 60730-1:1999, Automatic electrical controls for household and similar use - Part 1: General requirements, Amendment 1:2003 and Amendment 2:2007 NOTE: The corresponding JIS standard is JIS C9730-1:2010 Automatic electrical controls for household and similar use-Part 1:General requirements (MOD) IEC 60851-3:1996, Winding wires - Test methods - Part 3: Mechanical properties, Amendment 1:1997 and Amendment 2:2003 IEC 60851-5:1996, Winding wires - Test methods - Part 5: Electrical properties, Amendment 1:1997 and Amendment 2:2004 IEC 60851-6:1996, Winding wires - Test methods - Part 6: Thermal properties and Amendment 1:1997 IEC 60878:2003, Graphical symbols for electrical equipment in medical practice IEC 60884-1, Plugs and socket-outlets for household and similar purposes - Part 1: General		

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	requirements IEC 60950-1:2001, Information technology equipment – Safety - Part 1: General requirements NOTE: The corresponding JIS standard is JIS C 6950-1:2009 Information technology equipment - Safety - Part 1: General requirements (MOD) IEC 61058-1:2000, Switches for appliances - Part 1: General requirements and Amendment 1:2001 NOTE: The corresponding JIS standard is JIS C4526-1:2005 Switches for appliances - Part 1: General requirements (MOD) IEC 61558-1:1997, Safety of power transformers, power supply units and similar products - Part 1: General requirements and tests and Amendment 1:1998 NOTE: No corresponding JIS exists. However, as the standard corresponding to IEC 61558-1:2005, the following exists: JIS C 61558-1:2008 Safety of power transformers, power supplies, reactors and similar products - Part 1: General requirements and tests (MOD) IEC 61558-2-1, Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications NOTE: The corresponding JIS standard is JIS C61558-2-1 Safety of power transformers, power supplies, reactors and similar products-Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications (MOD)		
3.61	Add NOTE as follows: NOTE In this standard, MECHANICAL HAZARD is understandable suitably by replacing with mechanical HAZARD, mechanical HADARDOUS SITUATION, HARM or unacceptable RISK.		—
3.70	Replace the existing text with: condition in which all means provided for protection against HAZARDOUS SITUATION or HAZARDS are intact		—

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
4.2	Replace the existing NOTE 2 with the following: NOTE 2 Conditions or faults that can give rise to HAZARDOUS SITUATIONS are identified in the clauses of this standard. In these cases, it will often be necessary to carry out a RISK MANAGEMENT PROCESS to determine what the actual HAZARDOUS SITUATIONS are and the tests that need to be done to show that the identified HAZARDOUS SITUATIONS do not arise in the specified circumstances.		—
4.10.1	In the existing text, replace “a separate power supply” with “a separate power supply (e.g., a power supply of other equipment)”.		—
7.3.3	In the third paragraph, replace “could result in a HAZARD” with “could result in a HAZARDOUS SITUATION”.		—
7.4.3	Replace the existing first paragraph with the following: Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to JIS Z8202 (ISO 31 (IDT)) except the base quantities listed in Table 1 may be expressed in the indicated units, which are used in conjunction with the SI units system or as the approved combination. Replace the title of Table 1 with the following: Units which are used in conjunction with the SI units system or as the approved combination		N/A
7.7.4	Under the existing text, add the following: If polyvinyl chloride insulated flexible cord of JIS C3306 or rubber insulated flexible cord of JIS C3301 is used, the conductor may be coloured "white".		N/A
7.7.5	Under the existing text, add the following: If polyvinyl chloride insulated flexible cord of JIS C3306 or rubber insulated flexible cord of JIS C3301 is used, conductors may be of the colour specified in the said standards.		N/A
7.9.3.2	In the fourth dash, replace “the nature of the HAZARD” with “the HAZARDOUS SITUATION”.		—
8.4.2	For Item c), at the end of the paragraph of “For such parts, the voltage to earth or --,” replace “at a potential up to 2 V” with “at a potential of 2 V or more”. For Item c), replace the existing NOTE with NOTE 1, and add the following new NOTE 2: NOTE 2 – The corresponding international standard specifies as “not exceed 20 J at a potential up to 2 V”. However, 1.2.8.9 of IEC		—

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
	60950-1, which was quoted by the said international standard, specifies as “2 V or more”. Therefore, this JIS standard was harmonized to IEC 60950-1.		
8.8.2	For a), add the following NOTE: NOTE – Generally, “distance through insulation” means the thickness of insulation. However, for example, if a transformer installed into a metal case is insulated by filler, the thickness is always not uniformly. Therefore, such expression was used.		P
8.8.3	Between the third dash and the paragraph of “Initially, not more than --”, add the following new paragraph. During the above-mentioned tests, the state of the power switch shall be kept with closed circuit.		P
8.9.1.2	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.3	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.4	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.5	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.6	At the end of the title of this sub-clause, add “(Apply to MOOP and MOPP)”.		—
8.9.1.7	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.8	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.9	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.10	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.11	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.12	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.13	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—
8.9.1.14	At the end of the title of this sub-clause, add “(Apply to MOOP)”.		—

IEC 60601-1			
Clause	**Requirement + Test**	**Result - Remark**	**Verdict**
8.11.3.2	Add the following between the first paragraph and the second paragraph: And, rubber insulated flexible cords of JIS C3301, polyvinyl chloride insulated flexible cords of JIS C3306 or cords of which the robustness is equal to or more than those are usable. Add the following between the second paragraph and the last paragraph: And, in the case of cords of JIS C3306, shall not use; - for polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 60 °C, and; - for grade heat-resistant polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 75 °C.		N/A
9.2.2.2	In the bottom column of Table 20, replace the existing text with the following: [a] The values in this table are taken from JIS B9711 (ISO 13854 (IDT)).		—
9.2.2.4.4	In the second dash, replace “no HAZARD or damage shall result” with “any HAZARDOUS SITUATION or unacceptable RISK shall result”.		—
9.2.4	In e), replace “no HAZARD or damage shall result” with “no HAZARDOUS SITUATION or unacceptable RISK shall result”.		—
9.4.4	In the first paragraph of a), replace “and no HAZARDS can develop” with “and no HAZARDOUS SITUATION can develop”.		—
9.7.5	In the last paragraph, delete “unmarked”.		—
9.8.4.1	Replace the existing NOTE with the following: NOTE The upper carriage of the human body test mass apparatus is formed of wood or a similar material. The bottom portion is foam. The resiliency or spring factor of the foam (ILD or IFD ratings) has not been specified. The foam is cylindrical, rather than spherical.		N/A
10.1.1	In the paragraph, replace “0,5 mR/h” with “0,5 mR/h ≈ 5 µGy/h”; and in NOTE 2, “0,1 mR/h” with “0,5 mR/h ≈ 1 µGy/h”.		N/A
11.1.1	To the existing text of a in the Table 22, add the following: (For example, the maximum temperature limit of a transformer with three insulating materials of Class A, Class B and Class E shall be 105 °C of Class A of the lowest limit.)		P
13.2.7	In the title of this sub-clause, replace “in a HAZARD” with “in a HAZARDOUS SITUATION”.		—

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

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