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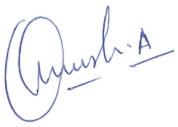
Accreditation cover page to Test Report 2204167STO-001 dated 27-Aug-2024 Issued by Intertek Semko AB

Client: Powerbox International AB

Product: OFM225 series

	Name	Signature
Tested by:	Ganesh Aripaka	
Reviewed by:	Jenny Larsson Falk	

Date of Issue: 27-Aug-2024

Ackred. nr 1003
Provning
ISO/IEC 17025

This is an Accreditation cover page to endorse that the testing and result presented in the referred report have been conducted under the SWEDAC ISO/IEC 17025 Accreditation, No. 1003

The following amendments/standards/clauses are not within the scope of SWEDAC accreditation:
Clause 11.6.7 sterilization; Annex G, AP and APG equipment excluded

Test Report issued under the responsibility of:

Total Quality. Assured.

TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1: General requirements for basic safety and essential performance

Report Number. ..... :	2204167STO-001
Date of issue ..... :	27-Aug-2024
Total number of pages ..... :	149
Name of Testing Laboratory preparing the Report ..... :	Intertek Semko AB
Applicant's name ..... :	Powerbox International AB
Address ..... :	Västberga Allé 36A SE-126 30 Hägersten Sweden
Test specification:	
Standard ..... :	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
TRF template used ..... :	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No. ..... :	IEC60601_1U
Test Report Form(s) Originator .... :	UL(US)
Master TRF ..... :	2022-05-13

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 IECEE 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 NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description ..... :	Power Supply Unit
Trade Mark(s) ..... :	P R B X POWERBOX Mastering Power
Manufacturer ..... :	Powerbox International AB
Model/Type reference ..... :	OFM225 series
Ratings ..... :	See general product information

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

☒	**CB Testing Laboratory:**	Intertek Semko AB	
Testing location/ address……:		Torshamnsgatan 43, Box 1103, SE-164 22 kista, Sweden	
Tested by (name, function, signature) .....:		Ganesh Aripaka. *Senior Project Engineer*	
Approved by (name, function, signature)...:		Jenny Larsson Falk *Technical Leader*	
☐	**Testing procedure: CTF Stage 1:**		
Testing location/ address……:			
Tested by (name, function, signature) .....:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 2:**		
Testing location/ address……:			
Tested by (name, function, signature) .....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
☐	**Testing procedure: CTF Stage 3:**		
☐	**Testing procedure: CTF Stage 4:**		
Testing location/ address……:			
Tested by (name, function, signature) .....:			
Witnessed by (name, function, signature) .:			
Approved by (name, function, signature)...:			
Supervised by (name, function, signature) :			

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

Pictures of the appliance pages 127 - 131

National deviations for Canada pages 132 - 144

National deviations for USA pages 145 - 148

Max overall uncertainty page 149

Summary of testing:

This report is based on previous evaluations and replaces the below Intertek test reports. A new report has been issued due to an update of standard from IEC 60601-1:2005+A1 to IEC60601-1:2005+A1+A2. There have been no changes made to the EUT since the last testing therefore, spot check testing has been evaluated (see page 4).

History of test reports:

Intertek Report No	Description of update
1510477STO-001	Basic Testing
1515747STO-001	Addition of 12V and 15V models
1711404STO-001	Addition of 3 models for permanent connection
1715942STO-001	- Editorial update of the report - New fuses - Changed output power for each PSU - Revised insulation diagram - Re-design of the transformers - New input test - New heating test - Additional SFC - Updated critical component list
2300272STO-001	Update of factory and applicant name and address

Tests performed (name of test and test clause):
Below tests are derived from test report No.: 1711404STO-001.

Clause	Test Name
4.11	Input power
5.9.2	Accessible parts
7.1.2	Legibility of markings
7.1.3	Durability of markings
8.4.3	Stored energy
8.5.4	Working voltage
8.7.4.7	Measurement of leakage currents
8.8.3	Dielectric strength test
8.8.4.1	Resistance to heat - Ball pressure test of thermoplastic parts
8.9	Creepage distances and air clearances
11.1	Excessive temperatures in ME Equipment.
13.2.2	Electrical single fault condition

Below test are re-evaluated in this test report

Clause	Test Name
4.11	Input power.
8.4.3	Me equipment intended to be connected to a power source by a plug.
8.7	Leakage currents and patient auxiliary currents.
8.8.3	Dielectric strength test
11.1	Excessive temperatures in Me equipment.

Testing location:
Intertek Semko AB
Torshamnsgatan 43, Box 1103,
SE-164 22 Kista, Sweden

Summary of compliance with National Differences (List of countries addressed):

- Canada
- USA

☒ **The product fulfils the requirements of**

- CSA-C22.2 No. 60601-1:14+A1+A2.
- AAMI ES60601-1:2005+A1+A2.

Statement concerning the uncertainty of the measurement systems used for the tests.

☐ **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

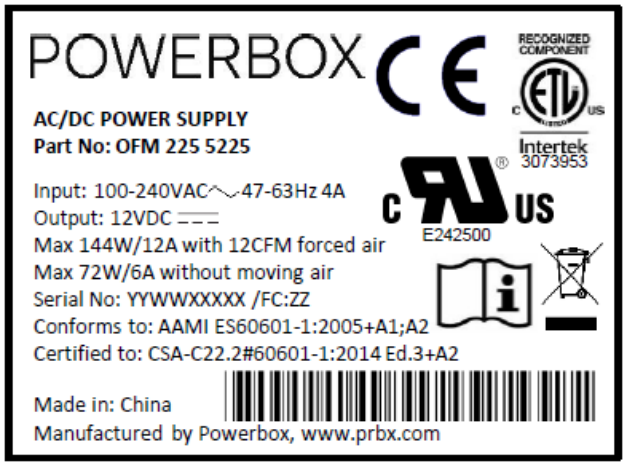
Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

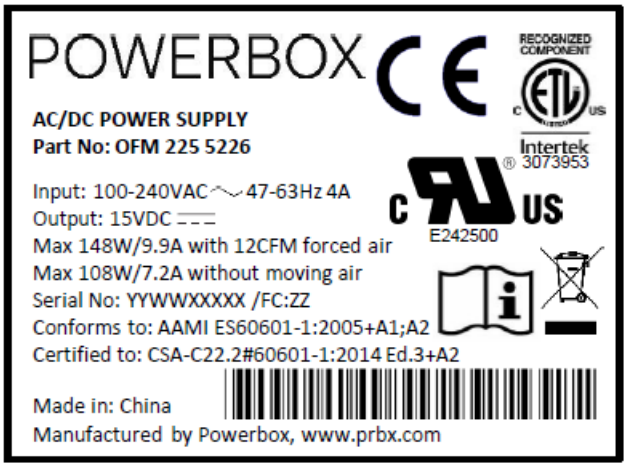
☒ **Statement not required by the standard used for type testing.**

Copy of marking plate:

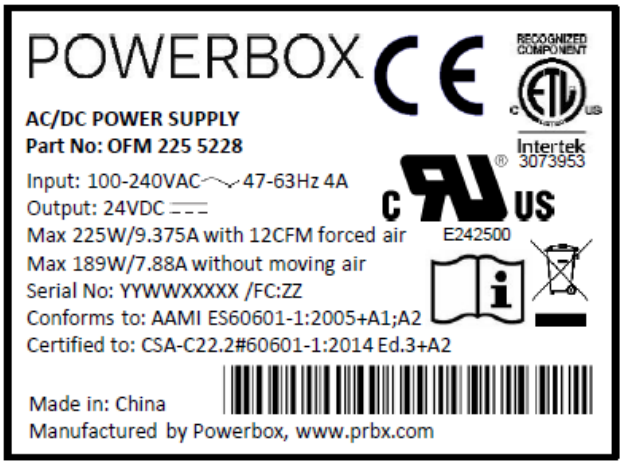
The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



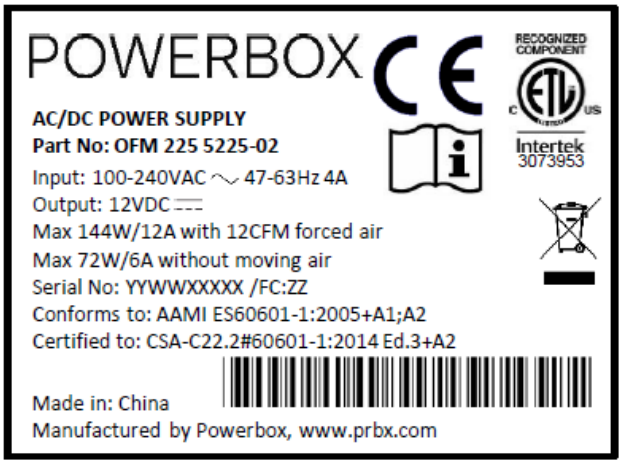
OFM225 5225 Marking label



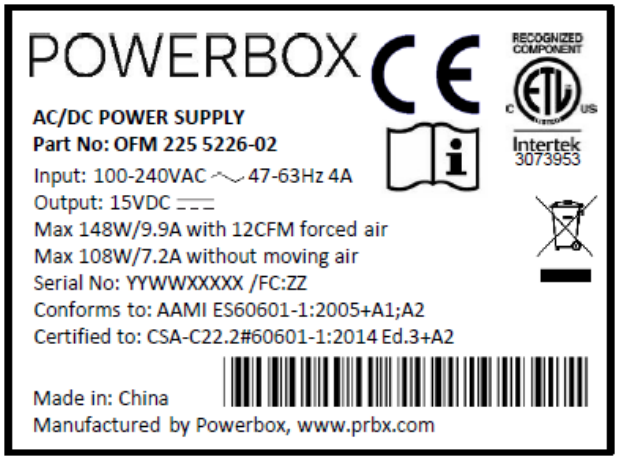
OFM225 5226 Marking label



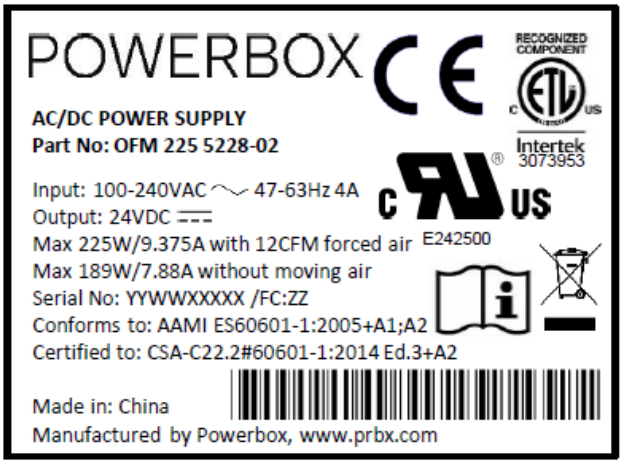
OFM225 5228 Marking label



OFM225 5225-02 Marking label

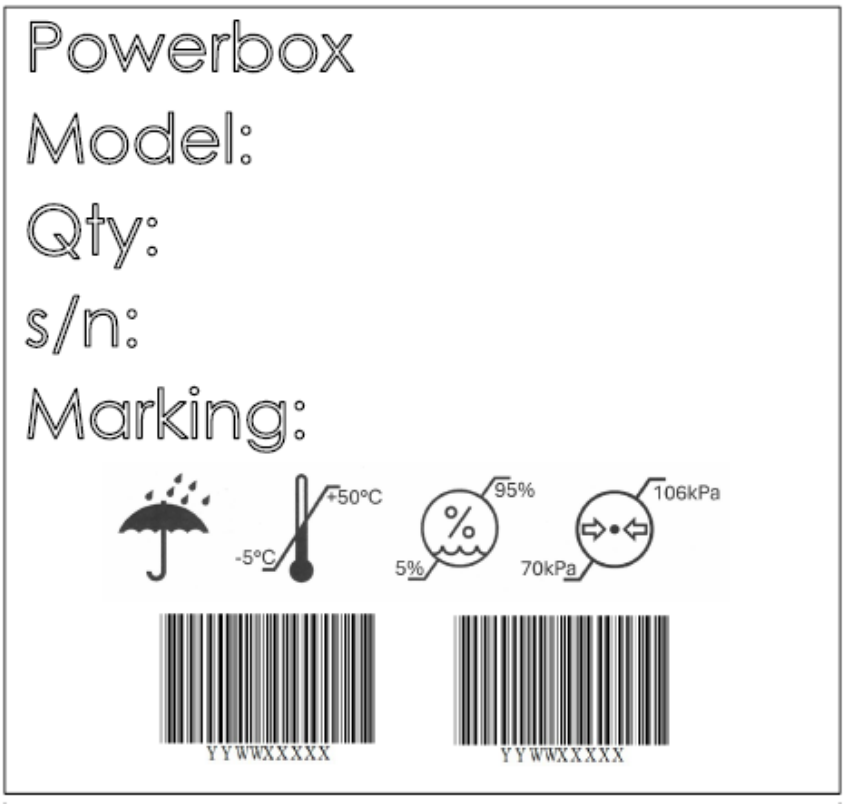


OFM225 5226-02 Marking label



OFM225 5225-02 Marking label

Packing label:



Test item particulars .....:	
Classification of installation and use .....:	Built-in purpose
Supply Connection.....:	Built-in, supply determined by end-use application
Device type (component/sub-assembly/ equipment/ system)……..:	Component
Intended use (Including type of patient, application location)……:	Power supply unit for medical applications
Mode of operation……:	Continuous
Accessories and detachable parts included……...:	N/A
Other options include…….....:	N/A
Possible test case verdicts:	
- test case does not apply to the test object.....:	N/A
- test object does meet the requirement.....:	P (Pass)
- test object was not evaluated for the requirement……...:	N/E (collateral standards only)
- test object does not meet the requirement.....:	F (Fail)
Abbreviations used in the report	
- normal condition……: N.C.	- single fault condition .....: S.F.C.
- means of Operator protection ……: MOOP	- means of Patient protection ....: MOPP
Testing.....:	
Date of receipt of test item .....:	14-Oct-2014 05-Oct-2015 29-Aug-2017 27-Sep-2017 06-Jul-2023 (2204167)
Date (s) of performance of tests.....:	30-Oct-2014 to 10-Mar-2015 28-Oct-2015 to 02-Dec-2015 29-Aug-2017 to 08-Oct-2017 17-Aug-2023 to 27-Aug-2024 (2204167STO-001)
General remarks:	
"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. **Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**	
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:	
The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	☐ **Yes** ☒ **Not applicable**
When differences exist; they shall be identified in the General product information section.	

Name and address of factory (ies) .....:	Airline Mechanical (Guangxi) Company Limited No. 1, Zhizao Third Road, Longhu Town Wanxiu District 543003 Wuzhou City, Guangxi China

General product information and other remarks:

Product description:

OFM225 is a power supply unit (PSU) intended to be built-in to MEE that can be used in hospital environments.

MEE Models and ratings:
Input:100-240VAC, 47-63Hz, 4A.
Protection classification: Built in (Class I or Class II)
Output:
OFM2255 228:24VDC:189W/7.88A or 225W/9.375A with air cooling 12CFM
OFM2255 226:15VDC:108W/7.2A or 148W/9.9A with air cooling 12CFM
OFM2255 225:12VDC:72W/6A or 144W/12A with air cooling 12CFM

Models ending with -02 are intended for built in permanently installed equipment with fuse only in the line connector.
OFM225 5228-02:24VDC, 189W/7.88A or 225W/9.375A with air cooling 12CFM
OFM225 5226-02:15VDC, 108W/7.2A or 148W/9.9A with air cooling 12CFM
OFM225 5225-02:12VDC, 72W/6A or 144W/12A with air cooling 12CFM

Environmental conditions:
The power supply is recommended to operate between 0 to +50°C. It can operate between -10°C -0°C and from +50°C to +70°C with limited output power. During transport and storage the max recommended temperature is -5 to +50°C, the transport and storage temperature shall be between -40 to +75°C.

The product is also in conformity with the following collateral standard:

- IEC 60601-1-2:2014+A1 as shown in test report no. 2204167STO-102

Considerations for end-use application/conditions of acceptability (CoA):
Intended to be built into an end-use product, thus several clauses and sub clauses are not applicable and shall be checked in the end-use application (see test report for details)
It is anticipated that the end-product manufacturer will have access to the above stated condition.

1. Intended to be built into an end-use product, thus several clauses and sub-clauses are not applicable and shall be checked in the end product.
2. The OFM225 has been tested in the following temperatures: 0 to +50°C at 100% load +50 to +70 at 50% load.
3. It is anticipated that the end-product manufacturer will have access to the above stated conditions.
4. The OFM225 has been evaluated Electromagnetic disturbances according to the IEC 60601-1-2: 2014+A1:2020. EMC applicable parts of Risk Management File (RMF) and Accompanying documents according to clause 4,5,6 and 8 shall be evaluated in end-use application.
5. A suitable enclosure to protect from accessibility to electrical hazards shall be provided and subjected to applicable tests in the end-use application.
6. If a fire enclosure is provided as fire protection in the end-use application, following components have a rating of FV-2 or higher:
    - Insulated wire
    - Connectors
    - PCB:s
    - Insulating materials on which components are mounted.
7. The PSU has been tested for an altitude of max. 3000 m.
8. The PSU has been evaluated for one means of patient protection (1MOPP) for pollution degree 2,

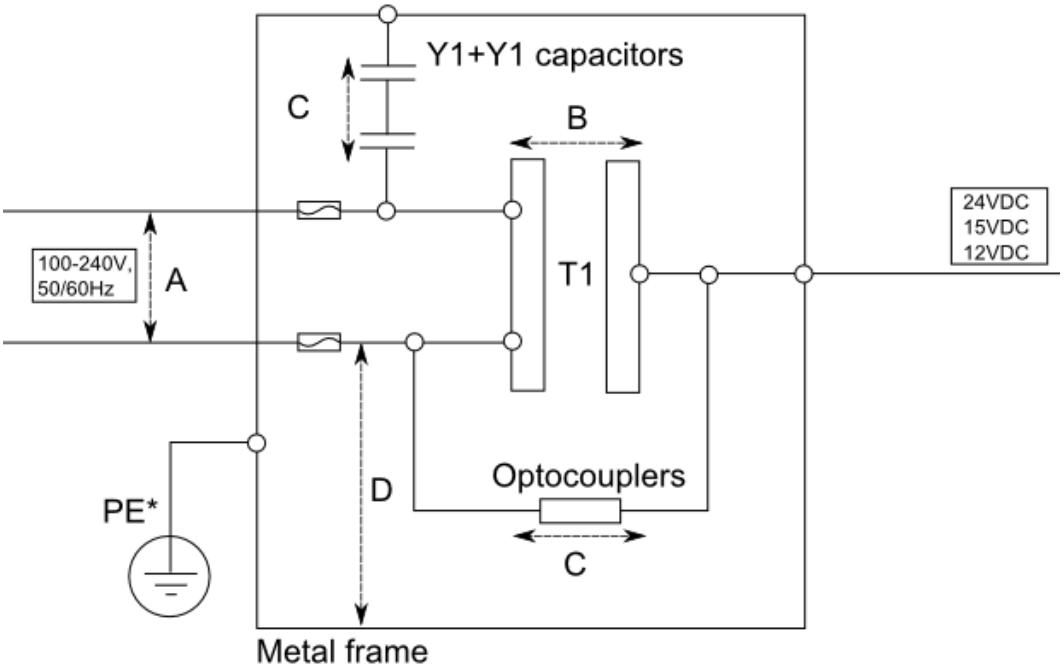
between input (primary) and PE; and two means of patient protection (2MOPP) between input (primary) and output (secondary). Under normal and single fault conditions, the outputs do not exceed 42,4Vpk ac or 60 Vdc. The suitability of protection against electrical hazards shall be subject in the evaluation of the end-use product.

9. The RMF must be evaluated for the end-use product.
10. Installation of the PSU must be done according to information in the instructions for use.
11. Can be installed in class I or Class II equipment. In Class I the PE must be connected according to instructions for use and when PSU is installed in Class II configuration, shall have the 1MOP between Line and accessible parts.
12. The PSU end-use model with ME Equipment should be evaluated with Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems), Clause 17 (EMC) and Risk Management was excluded from this investigation.
13. The PSU end-use model should be monitored using the type K-thermocouples placed on a hottest of the components with/without cooling systems and equipment should be run until all temperatures have reached steady-state (stabilization) condition.

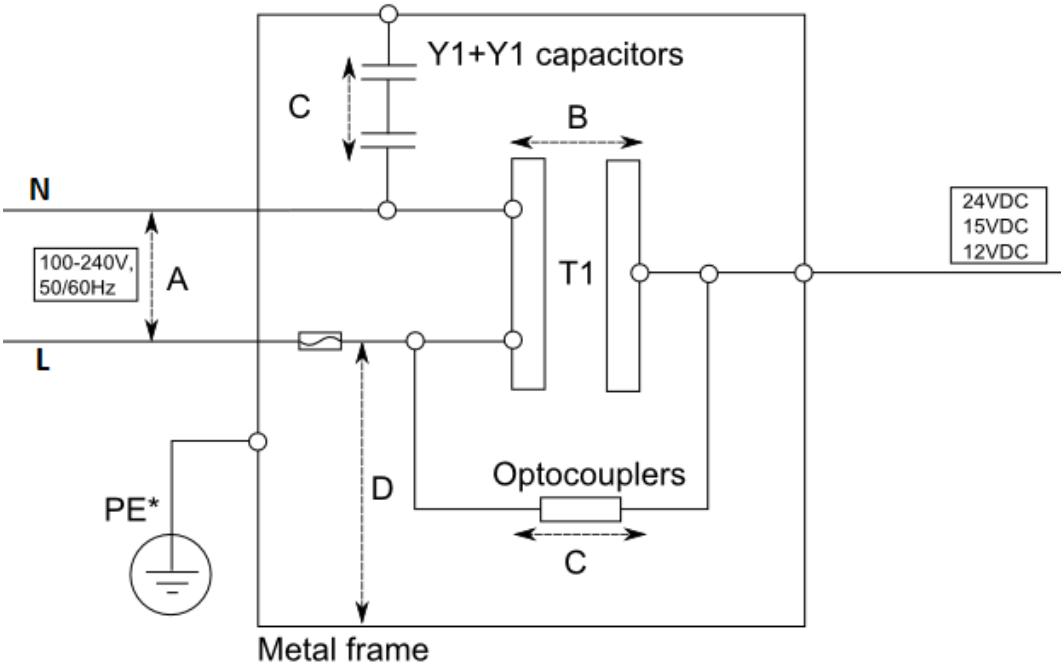
	Component location	Max allowable temperature (°C)
1.	Input connector (J4) - Ambient	105
2.	Line filter (DR4) - Ambient	105
3.	Y3 and X1 - Capacitors - Ambient	125
4.	Transformer on winding (TR1)	130-10=120
5.	Transformer on the bobbin (TR1)	150
6.	Capacitors (C45) - Ambient	105
7.	PCB/optocouplers - (OPT2) (Below transformer)	130

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

INSULATION DIAGRAM



Insulation diagram for OFM225 5225, OFM225 5226 and OFM225 5228



Insulation diagram for OFM225 5225-02, OFM225 5226-02 and OFM225 5228-02

**Only if OFM is used as Class I PSU, otherwise PE is not included*

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

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

Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
A	1MOOP	IIIb	240	339	2.5	2.3	3.0	3.0	L to N Clearance corrected for 3000m
B	2MOPP (OFM 5228)	IIIb	253	520	7.1[3)]	7.0	12 or 7.5 + 1 layer tape	12 or 7.5 + 1 layer tape	In transformer
B	2MOPP (OFM 5225) (OFM 5226)	IIIb	257	645	7.2[3)]	7.0	12 or 7.5 + 1 layer tape	12 or 7.5 + 1 layer tape	In transformer
B	2MOPP	IIIb	208	380	7.3[4)]	5	12 or 7.5 + 1 layer tape	12 or 7.5 + 1 layer tape	In transformer Cu foil - sec
C[1)]	1MOPP	IIIb	240	339	4.0	2.5	8.2	7.0	
C[2)]	2MOPP	IIIb	240	339	8.0	5.0	8.2	7.0	
D[1)]	1MOPP	IIIb	240	339	4.0	2.5	8.2	5.0	
D[2)]	2MOPP	IIIb	240	339	8.0	5.0	8.2	5.0	

[1] If Class I PSU
[2] If Class II PSU
[3] Interpolated and reduced by 1mm due to lacquered winding
[4] Interpolated
Note: The above test results are derived from test report No.: 1711404STO-001

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

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

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

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

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

4	**GENERAL REQUIREMENTS**		P
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		P
4.2	**RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS**		N/A
4.2.2	General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2019)…….:	Risk Management deemed not applicable due to MEE type (See General Product Information)	N/A
4.2.3	Evaluating RISK		N/A
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level	See General Product Information	N/A
	b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN…….. :	-	N/A
	c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.	-	N/A
	- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.	-	N/A
4.2.3.2	MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.	-	N/A
4.3	Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.	See General Product Information	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…….:	See General Product Information	N/A
4.5	Interchangeable RISK CONTROL methods utilized:	See General Product Information	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	RESIDUAL RISK resulting from the Interchangeable RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard…….: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	-	N/A
	Interchangeable 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 ……..:	See General Product Information	N/A
	MANUFACTURER assesses the risk of accessible parts coming into contact with the patient: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	-	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……:	See General Product Information See Clause 13 for Single Fault Conditions	P
	MANUFACTURER RISK ANALYSIS was used to determine failures to be tested……: (ISO 14971 Cl. 5.2-5.5)	-	N/A
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically……..:	See table 13.2	N/A
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ……..:	See Table 8.10	P
	Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS	See General Product Information	N/A
	RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings ……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	See General Product Information	N/A
	MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION ……..:	~~See Table 8.10 b.~~	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Components determined to be acceptable where used as a MEANS OF PROTECTION ……:	~~See Table 8.10 b.~~	N/A
	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……..:	-	N/A
	RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	-	N/A
	Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:	-	N/A
4.10	**Power supply**		P
4.10.1	ME EQUIPMENT is suitable for connection to indicated power source (select applicable) ……:	MEE is a PSU intended for connection to mains MEE is intended to be built into other equipment, type of connection depends on end - use product.	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:		P
	- 250 V for HAND-HELD ME EQUIPMENT (V) ……..:	-	N/A
	– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V)……:	240 VAC	P
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS	-	N/A
4.11	**Power input**		P
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%.....:	See Table 4.11	P

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

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		P
5.1	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods ……..:	Tests performed	P
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. (ISO 14971 Cl. 5.2-5.5)	See General Product Information	N/A
5.3	Tests conducted within the environmental conditions specified in technical description		P
	Temperature (ºC), Relative Humidity (%) ……..:	MEE rated for 0°C to +70° C. (0°C to +50°C at 100% load +50°C to +70°C at 50% load) 5 % - 95%rh Non-condensing.	—
	Atmospheric Pressure (kPa) ……..:	MEE rated for 70-101 kPa. MEE has a derating output below 79.5 kPa. If not forced cooling is used.	—
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)……..:	240 VAC	P
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)……:	47 - 63 Hz	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……..……..:	240 VAC	P
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered……:	-	N/A
	e)ME EQUIPMENT tested with Interchangeable ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions……:	-	N/A
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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……..:	Time: 48 h Built-in purpose	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	Temperature: 28°C Humidity = 93%RH	—
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		N/A
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS……...:	MEE has no applied parts	N/A
5.9.2	**ACCESSIBLE PARTS**		N/A
5.9.2.1	Accessibility determined using standard test finger of Fig. 6	~~See Table 5.9.2~~	N/A
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s	-	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..... :	MEE has no actuating mechanisms	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**		P
6.2	CLASS I ME EQUIPMENT, externally powered	Can be built in to Class I or Class II end-use product	N/A
	CLASS II ME EQUIPMENT, externally powered	Can be built in to Class I or Class II end-use product	N/A
	INTERNALLY POWERED ME EQUIPMENT	-	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	-	N/A
	TYPE BF APPLIED PART	-	N/A
	TYPE CF APPLIED PART	-	N/A
	DEFIBRILLATION-PROOF APPLIED PARTS	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529……...:	Built in purpose Shall be evaluated in end-product	N/A
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use……...:	MEE not intended for sterilization	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	Built-in purpose	N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION……:	Continuous operation	P
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		P
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6……:	See Table 7.1.2	P
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE		P
7.2	**Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts**		P
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ……..:	See attached copy of Marking labels	P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS ……:	-	N/A
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	-	N/A
	Single use item marked……..:	-	N/A
7.2.2	ME EQUIPMENT marked with:		P
	– the name or trademark and contact information of the MANUFACTURER	Power box	P
	– a MODEL OR TYPE REFERENCE	OFM 225 5228 OFM 225 5226 OFM 225 5225 Model differences OFM 225 5228 - 02 OFM 225 5226 - 02 OFM 225 5225 - 02	P
	– a serial number or lot or batch identifier; and	Serial number specified	P
	– the date of manufacture or use by date	Part of serial number	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	No detachable components	N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.3)	-	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……..:	-	N/A
7.2.3	Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS	-	P
	SAFETY SIGN 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted		N/A
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and ……..:	No accessories	N/A
	- with a MODEL or TYPE REFERENCE	-	N/A
	– a serial number or lot or batch identifier	-	N/A
	– the date of manufacture or use by date	-	N/A
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	-	N/A
7.2.5	ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following	-	N/A
	- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or	-	N/A
	– Table D.2, SAFETY SIGN No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or	-	N/A
	– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.	-	N/A
7.2.6	**Connection to the Supply Mains**		P
	Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	For built-in purpose. Shall be evaluated in end use product.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT	For built-in purpose. Shall be evaluated in end use product.	N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V)……:	100-240 VAC	P
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)…..:	-	N/A
	– Nature of supply and type of current……..:	AC	P
	Symbols 1-5, Table D.1 (used for same parameters……:	-	N/A
	– RATED supply frequency or RATED frequency range in hertz……..:	47- 63Hz	P
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT……..:	Shall be evaluated in the end-use product	N/A
7.2.7	RATED input in amps or volt-amps, (A, VA)……:	4 A	P
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)……..:	Input in Amps	P
	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)……..:	100-240 VAC, max 4A	P
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)……:	-	N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)……:	-	N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W)……:	-	N/A
7.2.8	**Output connectors**		P
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment	See attached copy of Marking label	P
	Rated Voltage (V), Rated Current (A)……:	See general product information	—
	Rated Power (W), Output Frequency (Hz)…….:	47-63 Hz	—

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Clause	Requirement + Test	Result - Remark	Verdict
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….:	-	N/A
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols ……..:	MEE has no applied parts	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
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum “on” and “off” time……..:	-	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 ……..:	-	N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	-	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	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.2.15	Requirements for cooling provisions marked……:	Can be used with convection. cooling only or with forced air cooling. Specified in IFU	N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage……:	Keep dry	P
	Permissible environmental conditions marked on outside of packaging……..:	Temperature: -5 to +50°C Humidity: 5-95% Non-condensing	P
	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. 5.2-5.5, 6, 7.2)	-	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 ……..:	-	N/A
	- the RATED flow rate also marked	-	N/A
7.2.19	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL……..:	-	N/A
7.2.20	Removable protective means marked to indicate the necessity for replacement when the function is no longer needed……..:	-	N/A
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms…...:	Not a mobile MEE	N/A
7.3	**Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts**		N/A
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)……:	-	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……:	-	N/A
7.3.3	Type of battery and mode of insertion marked..:	MEE has no batteries	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL……..:	-	N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK……..:	-	N/A
	RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an HAZARDOUS SITUATION if replaced incorrectly……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	-	N/A
	ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARDOUS SITUATION……:	-	N/A
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified ……..:	Non-replaceable fuses	N/A
	Voltage (V) and Current (A) rating…….	-	—
	Operating speed(s), size & breaking capacity….:	-	—
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1	Protective earth connected. directly to metal frame No terminal	P
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	-	N/A
7.3.6	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS	-	N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals……:	-	P
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	IFU Under section: Instructions for safe installation	P
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	-	N/A
	Marking for connection to a 3-phase supply, complies with IEC 60445	-	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	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.3.8	"For supply connections, use wiring materials suitable for at least X °C" or equivalent, marked at the point of supply connections	Built-in purpose	N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made	-	N/A
7.4	**Marking of controls and instruments**		N/A
7.4.1	The "on" & "off" positions of switch to control power to ME EQUIPMENT, including mains switch, marked with symbols 12 and 13 of Table D.1 or	No controls on MEE	N/A
	– indicated by an adjacent indicator light, or	-	N/A
	– indicated by other unambiguous means	-	N/A
	The "on" & "off" positions of switch to control power to parts of ME EQUIPMENT, marked with symbols 12 and 13 of Table D.1 or	-	N/A
	- marked with symbols 16 and 17 of Table D.1 or	-	N/A
	– indicated by an adjacent indicator light, or	-	N/A
	– indicated by other unambiguous means	-	N/A
	Switches that brings ME EQUIPMENT into "stand-by" may be indicated by symbol 29 of Table D.1	-	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
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	No control devices	N/A
	RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)	-	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

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Clause	Requirement + Test	Result - Remark	Verdict
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units	-	N/A
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units	-	N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3……:	-	N/A
7.5	**SAFETY SIGNS**		N/A
	SAFETY SIGN with established meaning used	Shall be evaluated in the end-use application	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. 5.2-5.5, 6, 7.2)	-	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)	No safety notices	N/A
	SAFETY SIGNS including any supplementary text or symbols described in instructions for use	-	N/A
	- and in a language acceptable to the intended OPERATOR	-	N/A
7.6	**Symbols**		P
7.6.1	Meanings of symbols used for marking described in instructions for use……:	See Instruction for use	P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable	MEE has no controls	N/A
7.7	Colours of the insulation of conductors		N/A
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	No protective earth connector, protective earth directly connected to metal frame	N/A
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations	-	N/A
7.7.3	Green and yellow insulation identify only following conductors:	-	N/A
	– PROTECTIVE EARTH CONDUCTORS	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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"	-	N/A
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	-	N/A
7.8	Indicator lights and controls		N/A
7.8.1	Red indicator lights, not flashing used only for Warning	-	N/A
	Yellow indicator lights, not flashing used only for Caution	-	N/A
	Green indicator lights used only for Ready for use	-	N/A
	Red flashing used only for HIGH PRIORITY ALARM CONDITION, interruption of current workflow needed	-	N/A
	Yellow flashing used only MEDIUM PRIORITY ALARM CONDITION, re-planning of workflow needed	-	N/A
	Yellow or Cyan, not flashing used for LOW PRIORITY ALARM CONDITION, planning of future workflow needed.	-	N/A
	Other colours: Meaning other than red, yellow, cyan or green (colour, meaning)……:	-	N/A
7.8.2	Red used only for emergency control	-	N/A
7.9	**ACCOMPANYING DOCUMENTS**		P
7.9.1	ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description	IFU: Data sheet: "Medline 225_OFM225.pdf" User guide for models OFM225 5225, OFM225 5226 and OFM225 5228 "150221_OFM225_USERGUIDE_Draft.pdf" User guide for models OFM225 5225-02, OFM225 5226-02 and OFM225 5228-02 "170523_OFM225_USERGUIDE" (2R) User guide:2024.04.10, Rev: 6, Our ref: OFM225	P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:		P

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Clause	Requirement + Test	Result - Remark	Verdict
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to……..:	IFU Under section: Contact Details	P
	– MODEL or TYPE REFERENCE……..:	IFU: Data sheet, first page User guide, first page	P
	When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT	-	N/A
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	-	N/A
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended		P
7.9.2	Instructions for use include the required information		P
7.9.2.1	– use of ME EQUIPMENT as intended by the MANUFACTURER:	IFU Under section: Intended Application of Equipment	P
	– frequently used functions,	-	N/A
	– known contraindication(s) to use of ME EQUIPMENT	-	N/A
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	Shall be evaluated in the end-use application	N/A
	– name or trademark and address of the MANUFACTURER	IFU: Data sheet, first page User guide, first page	P
	– MODEL OR TYPE REFERENCE	IFU: Data sheet, first page User guide, first page	P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:	Intended to be built into other MEE	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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	IFU Under section: Warning	P
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	-	N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	-	N/A
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	-	N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	IFU Under section: Technical Description	P
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions	-	N/A
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source	-	N/A
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries……: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	-	N/A
	Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time……..:	-	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided…….:	-	N/A
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK……:	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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	IFU: Under section: Technical Description	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/SOPs	N/A
	APPLIED PARTS specified	No applied part	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	IFU Under section: Instruction for Safe Installation	P
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device	Shall be included in end-use application IFU	N/A
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation	IFU Under section: Instruction for Safe Installation	P
7.9.2.9	Information provided to operate ME EQUIPMENT	IFU Under section: Instruction for Safe Installation	P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	IFU Under section: Explanation of Symbols	P
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message	-	N/A
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	Shall be included in end-use. application IFU	N/A
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	-	N/A
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	-	N/A
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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 such parts	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 us……..:	IFU Under section: Service and repair	P
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)	Datasheet POWERBOX Medline 225 OFM225 Series	P
7.9.2.17	Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation	-	N/A
7.9.2.18	The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization	-	N/A
	The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization	-	N/A
7.9.2.19	The instructions for use contain a unique version identifier…….:	IFU, rev: 5 Data Sheet POWERBOX Medline 225 OFM225 Series 225W Single Output AC/DC Medical Switch Mode Power Supply	P
7.9.3	**Technical description**		P
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 including	User manual Subject: User guide Rev: 5, Our ref: OFM225 Revision date: 2023.06.30	P
	-information required in 7.2		P

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Clause	Requirement + Test	Result - Remark	Verdict
	-permissible environmental conditions of use including conditions for transport and storage…….. :	IFU Under section: Environmental conditions for transport and storage.	P
	-characteristics of the ME EQUIPMENT, including range(s), accuracy, and precision of the displayed values or an indication where they can be found	See Data Sheet POWERBOX Medline 225 OFM225 Series 225W Single Output AC/DC Medical Switch Mode Power Supply No displayed valued	P
	-special installation requirements such as the maximum permissible apparent impedance of SUPPLY MAINS	See Data Sheet POWERBOX Medline 225 OFM225 Series 225W Single Output AC/DC Medical Switch Mode Power Supply	P
	-permissible range of values of inlet pressure and flow, and the chemical composition of cooling liquid	-	N/A
	-description of the means for checking the oil level in partially sealed oil filled ME EQUIPMENT or its parts	-	N/A
	-warning statement that addresses the HAZARDS that can result from unauthorized modification of the ME EQUIPMENT		P
	-information pertaining to ESSENTIAL PERFORMANCE and any necessary recurrent ESSENTIAL PERFORMANCE and BASIC SAFETY testing including details of the means, methods and recommended frequency	-	N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	-information required by 7.2		N/A
	–applicable classifications in Clause 6, warning and safety notices, and explanation of SAFETY SIGNS marked on ME EQUIPMENT	-	N/A
	– brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and	-	N/A
	a unique version identifier……..:	Included in IFU	N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		N/A
7.9.3.2	**The technical description contains the following required information**		P

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Clause	Requirement + Test	Result - Remark	Verdict
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT……:	Shall be evaluated in end-use application	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and	-	N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	-	N/A
	RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	-	N/A
	– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	-	N/A
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair	-	N/A
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description		P
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		P
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		P
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION……: (ISO 14971 Cl. 5.4)	End-use product Risk Management File identifies the hazardous situation	N/A
8.2	**Requirements related to power sources**		N/A
8.2.1	**Connection to a separate power source**		N/A
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	MEE is a power source	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

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Clause	Requirement + Test	Result - Remark	Verdict
8.2.2	**Connection to an external d.c. power source**		N/A
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	-	N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE	-	N/A
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset	-	N/A
8.3	**Classification of APPLIED PARTS**		N/A
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	MEE has no applied part	N/A
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART	-	N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	-	N/A
8.4	**Limitation of voltage, current or energy**		P
8.4.2	**ACCESSIBLE PARTS and APPLIED PARTS**		P
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT……:	No patient connections	N/A
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT……:	See Table 8.7 Shall also be evaluated in end-use application	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	Shall be evaluated in end-use application	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 Table 8.4.2 Max 24VDC, 15VDC, 12VDC	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 Table 8.4.2	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Limits in b) does not apply to SIP/SOP connectors and separate power supply connectors if the voltage measured is less than or equal to 60 V d.c. or 42,4 V peak a.c	MEE has no SIP/SOP	N/A
	d) Voltage and energy limits specified in c) above also applied to the following:	-	N/A
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	Shall be evaluated in end-use application	N/A
	– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL	-	N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	-	N/A
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N	MEE has no pre-set controls	N/A
	Test repeated with a TOOL specified in instructions for use	-	N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	-	N/A
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION	-	N/A
	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 Table 8.4.3 Voltage exceeded 60V but didn't exceed 45μC charge	N/A
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45μC….:	See 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 access covers	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL	-	N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description……:	-	N/A
8.5	**Separation of parts**		P
8.5.1	**MEANS OF PROTECTION (MOP)**		P
8.5.1.1	Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4		P
	A MEANS OF PROTECTION protecting APPLIED PARTS or parts identified by 4.6 as parts subject to the same requirements, considered as MEANS OF PATIENT PROTECTION……..:	MOPP insulation only	P
	Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION		P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		P
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		P
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test……..:	See 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	Shall be evaluated in end-use application	N/A
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION ……..:	See 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……..:	-	N/A
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	See insulation diagram	P
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (μF)……:	240VAC,1.5nF in series	—

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Clause	Requirement + Test	Result - Remark	Verdict
	Optocouplers complying with IEC 60747-5-5: 2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3	See table 8.10	
	Measurement of Air Clearance and Creepage distance on the outside	See insulation table	
	Dielectric strength test across optocoupler	See table 8.8.3	
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	Insulation between L and N See Insulation Diagram	P
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:	-	N/A
	– dielectric strength test ……..:	~~See Table 8.8.3~~	N/A
	– requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION	-	N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		P
	– limits of Tables 13 to 16 (inclusive); or		P
	– requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION	-	N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6	Shall be evaluated in the end-use product	N/A
	– or with requirements and tests of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for protective earthing……:	-	N/A
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION…….:	~~See Tables 8.8.3 and 8.10~~	N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION……..:	~~See Tables 8.8.3 and 8.10~~	N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	-	N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (μF)……..:	-	—
	Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3	See table 8.10	
	Measurement of Air Clearance and Creepage distance on the outside	See insulation table	
	Dielectric strength test across optocoupler	See table 8.8.3	

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Clause	Requirement + Test	Result - Remark	Verdict
	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
8.5.2	**Separation of PATIENT CONNECTIONS**		N/A
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE……:	No patient connections or applied parts	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
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. In this case 8.7.4.7 d) does not apply	-	N/A
	LEAKAGE CURRENT tests conducted per 8.7.4…:	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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. 5.2-5.5, 6)	-	N/A
8.5.2.3	**A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable distal from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE**		N/A
	- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT……:	-	N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter	-	N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm	-	N/A
	– conductive part pluggable into a mains socket protected from contacting 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. 5.2-5.5, 6)	-	N/A
8.5.4	**WORKING VOLTAGE**		P
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V)……..:	240 VAC	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)……:	Average value, 24 VDC, 15 VDC, 12 VDC	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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	-	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)……..:	-	N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	-	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)……..:	-	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	-	N/A
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety	-	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**		N/A
8.6.1	Requirements of 8.6.2 to 8.6.8 applied	Shall be evaluated in end-use application. The connection between PCB PE and metallic U-profile is secured by screw and washer.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Parts complying with IEC 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8	-	N/A
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR……:	-	N/A
	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	Shall be evaluated in end-use application	N/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside……..:	-	N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	No appliance inlet	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	Shall be evaluated in end-use Application.	N/A
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part,	-	N/A
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE ……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	-	N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop……:	Shall be evaluated in end-use application	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
	DETACHABLE POWER SUPPLY CORD specified by manufacturer or delivered with product	Shall be evaluated in end-use application	N/A
8.6.5	**Surface coatings**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Poorly conducting surface coatings on conductive elements removed at the point of contact	MEE has no coating	N/A
	Coating not removed when requirements for impedance and current-carrying capacity met	-	N/A
8.6.6	**Plugs and sockets**		N/A
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections	Shall be evaluated in end-use application	N/A
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	-	N/A
8.6.7	**Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR**		N/A
	– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE	-	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**		N/A
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow	Can be used in Class II MEE	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

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Clause	Requirement + Test	Result - Remark	Verdict
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		P
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3……..:	See Tables 8.7	P
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7……:	See Tables 8.7 Only leakage between primary and secondary connectors applicable, all other leakage current shall be evaluated in the end-use application Earth leakage current measured on metal frame	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)		P
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time		P
	– 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	Built-in PSU	N/A
8.7.3	**Allowable Values**		P
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b……:	See Table 8.7	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz……:	See Table 8.7	P
	c) TOUCH CURRENT did not exceed 100µA in NORMAL CONDITION and 500µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC})……..:	See Table 8.7	P
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC})……..:	See Table 8.7	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710……:	Built-In PSU purpose	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 Table 8.7	P
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION….:	No functional earth terminal	N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements……..:	See Table 8.7	P
8.8	**Insulation**		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing		P
	Insulation exempted from test (complies with clause 4.8)	-	N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	-	N/A
8.8.2	**Distance through solid insulation or use of thin sheet material**		P
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		P
	a) 0.4 mm, min, distance through insulation, or	Transformer bobbin	P
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		P
	– at least two layers of material, each passed the appropriate dielectric strength test……..:	See Table 8.8.3	P
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test……:	See Table 8.8.3	P
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		P
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		P

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Clause	Requirement + Test	Result - Remark	Verdict
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when	Complies with b)	P
	c) Wire with solid insulation, other than solvent based enamel, complying with a)	-	N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L	-	N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	UL certified TIW (primary winding A) complies with 1MOPP (SI) See Table 8.10	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	Certified TIW, only SI required	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……:	Protection provided between copper winding and TIW	P
	Finished component complied with routine dielectric strength tests of 8.8.3……:	UL certified	N/A
	Tests of Annex L not repeated since material data sheets confirm compliance……:	UL certified	N/A
8.8.3	**Dielectric Strength**		P
	Solid insulating materials with a safety function withstood dielectric strength test voltages ……..:	See Table 8.8.3	P
8.8.4	**Insulation other than wire insulation**		P
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		P
	ME EQUIPMENT and design documentation examined……:	Test preformed	P

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	-	N/A
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat……..:	-	N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat……..:	Test conducted See Table 8.8.4.1	P
	a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus…..:	No plastic enclosure	N/A
	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 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	-	N/A
8.8.4.2	**Resistance to environmental stress**		P
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9		P
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION		P
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION		P
	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	MEE has no natural latex rubber	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	-	N/A
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**		P

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive)……:	Table 12 and 16	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	-	N/A
8.9.1.16	Conductive coatings applied to non-metallic surfaces, do not result in flaking or peeling reducing any AIR CLEARANCE or CREEPAGE DISTANCE	No such 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……..:	Creepage distance and air clearance sufficient	N/A
8.9.3	**Spaces filled by insulating compound**		N/A
8.9.3.1	Only solid insulation requirements applied where distances between conductive parts filled with insulating compound	-	N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests	-	N/A
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

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.4	Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree ……:	No such grooves	P
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES	Bulit-in PSU	N/A
8.10	**Components and wiring**		P
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely……:	Shall be evaluated in end-use application.	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	-	N/A
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment……:	No detachable connectors in MEE, all conductors are secured	P
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS	No such connectors	N/A
8.10.3	Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken ……:	~~See Table 5.9.2~~	N/A
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		N/A
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION	-	N/A
8.10.4.2	Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3	-	N/A
	Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3	-	N/A
8.10.5	**Mechanical protection of wiring**		N/A
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges……:	No moving parts	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS	-	N/A
8.10.6	Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead	-	N/A
8.10.7	a) Insulating sleeve adequately secured…….:	No insulating sleeves	N/A
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics		N/A
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C…….:	~~See Table 8.10~~	N/A
8.11	**MAINS PARTS, components and layout**		P
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles…….:	Shall be evaluated in the end-use application	N/A
	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)	Shall be evaluated in the end-use application	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	Shall be evaluated in the end-use application.	N/A
	- the isolation device specified in the ACCOMPANYING DOCUMENTS		N/A
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ……:	Shall be evaluated in the end-use application	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……:	No mains switch	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……:	Shall be evaluated in the end-use application	N/A
	g) A fuse or a semiconductor device not used as an isolating means		P

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Clause	Requirement + Test	Result - Remark	Verdict
	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	-	N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage	-	N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause	-	N/A
	Standard test finger applied	-	N/A
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	-	N/A
8.11.3	**POWER SUPPLY CORDS**		N/A
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	Shall be evaluated in end-use application	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):	-	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……:	Shall be evaluated in end-use application	N/A
	For ME EQUIPMENT utilizing POWER SUPPLY CORDS and operating at currents greater than 63 A, apply the electrical regulations appropriate for the jurisdiction in which the ME EQUIPMENT is to be used.	-	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 ……:	-	N/A
8.11.3.5	**Cord anchorage**		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	-	N/A
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or	-	N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or	-	N/A
	– metal provided with an insulating lining affixed to cord anchorage	-	N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	-	N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components	-	N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals	-	N/A
	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	-	N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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**		N/A
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection	Shall be evaluated in end-use application	N/A
	Terminals alone are not used to keep conductors in position	Shall be evaluated in end-use application	N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors	-	N/A
	Screws and nuts clamping external conductors do not serve to secure any other component	-	N/A
8.11.4.2	**Arrangement of MAINS TERMINAL DEVICES**		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	Only 2 pins (L and N), protective earth connected directly to metal frame	N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL	Shall be evaluated in end-use application	N/A
	e) 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	Shall be evaluated in end-use application	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

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Clause	Requirement + Test	Result - Remark	Verdict
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test	-	N/A
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		P
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection….:	Fuse provided for each supply lead for standard models: OFM225 5225 OFM225 5226 OFM225 5228 Models ending with -02 are intended for permanent installation and fuse only in Line: OFM225 5225-02 OFM225 5226-02 OFM225 5228-02 See Table 8.10	P
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT…….:		P
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	-	N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART		P
	Protective devices have adequate breaking capacity based on MANUFACTURER'S expectation of the highest branch circuit current and/or prospective short circuit current:	See Table 8.10	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
8.11.6	**Internal wiring of the MAINS PART**		N/A
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable.:	Shall be evaluated in end-use application	N/A
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient……:	-	N/A
9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		N/A
9.2	**HAZARDS associated with moving parts**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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……:	MEE is a PSU will be used in built-in purpose Shall be evaluated in end-use application	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. 5.2-5.5, 6, 7.1-7.4)	-	N/A
	All RISKS associated with moving parts have been reduced to an acceptable level	-	N/A
9.2.2	**TRAPPING ZONE**		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	-	N/A
	– Gaps in Clause 9.2.2.2, or	-	N/A
	– Safe distances in Clause 9.2.2.3, or	-	N/A
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or	-	N/A
	– Continuous activation in Clause 9.2.2.5	-	N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM	-	N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20….:	-	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**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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**		N/A
	Continuous activation used as a RISK CONTROL, complies with the following	-	N/A
	a) movement was in OPERATOR'S field of view	-	N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR	-	N/A
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or	-	N/A
	- the continuous activation system is SINGLE FAULT SAFE	-	N/A
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement	-	N/A
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK	-	N/A
9.2.3	**Other MECHANICAL HAZARDS associated with moving parts**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.2.3.1	Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated	MEE has no moving parts	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**		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power……:	MEE has no emergency stopping devices	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. 5.2-5.5, 6, 7.1-7.5)	-	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
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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. 5.2-5.5, 6, 7.1-7.4)	-	N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered……..:	-	N/A
9.4	**Instability HAZARDS**		N/A
9.4.1	ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE	MEE is a PSU and used for built-in purpose	N/A
9.4.2	**Instability – overbalance**		N/A
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested ……..:	MEE is a PSU and used for built-in purpose	N/A
9.4.2.2	**Instability excluding transport**		N/A
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE…….:	MEE is a PSU and used for built-in purpose	N/A
	A warning provided when overbalance occurred during 10° inclined plane test		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
9.4.2.3	**Instability from horizontal and vertical forces**		N/A
	a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it	MEE is a PSU and used for built-in purpose	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**		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE	MEE is a PSU and used for built-in purpose	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)**		N/A
9.4.3.1	a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control	MEE is a PSU and used for built-in purpose	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
9.4.3.2			N/A
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test……..……..:	MEE is a PSU and used for built-in purpose	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**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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	MEE has no grips and other handling devices	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**		N/A
9.5.1	Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	MEE has 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**		N/A
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and	MEE is a PSU and used for built-in purpose. MEE has No acoustic energy	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. 5.2-5.5, 6, 7.1-7.4)	-	N/A
	All identified RISKS mitigated to an acceptable level	-	N/A
9.6.2	**Acoustic energy**		N/A
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE	MEE has No acoustic energy	N/A
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA)……..……..:	-	—

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Clause	Requirement + Test	Result - Remark	Verdict
	- 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. 5.2-5.5, 6, 7.1-7.4)	-	N/A
9.6.3	**Hand-transmitted vibration**		N/A
	Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values	MEE has no such design	N/A
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2)……..:	-	N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s^2)…….:	-	N/A
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	MEE has no pressure vessels and parts subject to pneumatic and hydraulic pressure	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
	– 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

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Clause	Requirement + Test	Result - Remark	Verdict
9.7.4	MAXIMUM EQUIPMENT PRESSURE did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for the part, except allowed for pressure relief devices in 9.7.7confirmed 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 MAXIMUM EQUIPMENT PRESSURE was more than 50 kPa, and product of MAXIMUM EQUIPMENT PRESSURE and volume was more than 200 kPa……...…….:	-	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
	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 EQUIPMENT 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. 5.3-5.5, 6, 7.1-7.4)	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

9.8	**HAZARDS associated with support systems**		N/A
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK…….:	MEE has no support systems in design	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. 5.2-5.5, 6, 7.1-7.4)	-	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
	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 Interchangeable 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. 5.3-5.5, 6, 7.1-7.4)	-	N/A
	All identified RISKS are mitigated to an acceptable level	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	When test was 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. 5.3-5.5, 6, 7.1-7.4)	-	N/A
9.8.3	**Strength of PATIENT or OPERATOR support or suspension systems**		N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints……:	MEE has no support or suspension systems	N/A
	RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings……...: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	-	N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts	-	N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER	-	N/A
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications	-	N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS	-	N/A
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS	-	N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance ……..:	-	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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**		N/A
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided for the support system	MEE has no mechanical protective devices used	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
	– Considers 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
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE	-	N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced	-	N/A
9.8.4.3	**MECHANICAL PROTECTIVE DEVICE intended to function once**		N/A
	–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE..:	MEE has no mechanical protective devices used	N/A
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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**		N/A
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES……:	MEE has no support systems	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system……..……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	-	N/A
10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		N/A
10.1	**X-Radiation**		N/A
10.1.1	The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT……:	MEE has no x-ray radiation in design	N/A
	Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE	-	N/A
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or……..……:	-	N/A
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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. 5.3-5.5, 6, 7.1-7.4)	-	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 60825-1:2014 applied to lasers including laser diodes, laser light barriers or similar with a wavelength range of 180nm to 1 mm.	-	N/A
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	-	N/A
10.6	RISK associated with infrared radiation other than emitted by lasers addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	-	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. 5.3-5.5, 6, 7.1-7.4)	-	N/A
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		P
11.1	**Excessive temperatures in ME EQUIPMENT**		P
11.1.1	Temperatures on ACCESSIBLE PARTS did not exceed values in Tables 22 and……..:	See table 11.1.1	P
	Surfaces of test corner did not exceed 90 °C	-	N/A
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	-	N/A
	RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS……..……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	MEE is a PSU used in built-in purpose. MEE has no applied parts and accessible parts	N/A
11.1.2	**Temperature of APPLIED PARTS**		N/A
11.1.2.1	APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply……:	MEE has no applied parts	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	-	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. 5.3-5.5, 6, 7.1-7.4)	-	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. 5.3-5.5, 6, 7.1-7.4)	-	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. 5.3-5.5, 6, 7.1-7.4)	Built-in purpose	N/A
	Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	Built-in purpose	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. 5.3-5.5, 6, 7.1-7.4)	MEE is a PSU used in built-in purpose. MEE has no applied parts	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	e) Where thermal regulatory devices make this method inappropriate, Interchangeable methods for measurement are justified in the RISK MANAGEMENT FILE……:	-	N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	-	N/A
11.2	Fire prevention		N/A
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3	-	N/A
11.2.2	**Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS**		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of……:	Not intended for Oxygen rich environments	N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions	-	N/A
	1) when temperature of material raised to its ignition temperature	-	N/A
	2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature	-	N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating	-	N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton	-	N/A
	5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton	-	N/A
	Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	-	N/A
	Interchangeable 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

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Clause	Requirement + Test	Result - Remark	Verdict
	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. 5.3-5.5, 6, 7.1-7.4)	-	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
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

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Clause	Requirement + Test	Result - Remark	Verdict
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means	-	N/A
11.2.3	**SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered**		N/A
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2)……:	-	N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3)……:	-	N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a)……..:	-	N/A
	– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a)……:	-	N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas……..:	-	N/A
11.3	**Constructional requirements for fire ENCLOSURES of ME EQUIPMENT**		P
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2……:	Shall be evaluated in the end-use application	N/A
	Constructional requirements were met, or		N/A
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE …….. : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	-	N/A
	Justification, when requirement not met……:	-	N/A
	a) Flammability classification of insulated wire and connectors within fire ENCLOSURE is minimum V-2, , when test in accordance with IEC 60695-11-10 or……:	See Table 8.10	P
	insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide as determined by examination of data on materials……..:	PTFE	P
	Flammability classification of printed circuit boards, and insulating material on which components are mounted is V-2, or better, based on IEC 60695-11-10 as decided by examination of materials data……:	See Table 8.10	P
	If no Certification, V 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	-	N/A
	b) Fire ENCLOSURE met following:	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm	-	N/A
	2) No openings on the sides within the area included within the inclined line C in Fig 39 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	-	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**		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G	MEE is not intended for use with flammable anaesthetics	N/A
11.5	**ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents**		N/A
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE ……..……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	MEE is not 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**		P
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.....:	Shall be evaluated in end-use application	N/A
11.6.2	**Overflow in ME EQUIPMENT**		N/A
	ME EQUIPMENT incorporates a reservoir or liquid storage that did not wet any MEANS OF PROTECTION, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE……:	MEE is a PSU, will be evaluated in end-use product	N/A
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.	-	N/A
11.6.3	**Spillage on ME EQUIPMENT and ME SYSTEM**		N/A
	ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test……..: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	MEE is a PSU, will be evaluated in end-use product	N/A
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill…….:	-	N/A
11.6.5	**Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		N/A
	ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)…….:	MEE is a PSU, will be evaluated in end-use product	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**		N/A
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use…….:	MEE is a PSU, will be evaluated in end-use product	N/A
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER……:	-	N/A
11.6.7	**Sterilization of ME EQUIPMENT and ME SYSTEMS**		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests……..:	MEE is a PSU, will be evaluated in end-use product	N/A
	RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	-	N/A
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented	-	N/A
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	-	P
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		N/A
12.1	RISKS associated with accuracy of controls and instruments stated……: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No controls, PSU for built-in purpose	N/A
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING……:	-	N/A
12.3	MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020……:	-	N/A
12.4	**Protection against hazardous output**		N/A
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	SELV output voltage	N/A
12.4.2	- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4))	-	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. 5.2-5.5, 6, 7.1-7.4)	-	N/A
12.4.4	RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS……: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	-	N/A
12.4.5	**Diagnostic or therapeutic radiation**		N/A
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation	-	N/A
	Radiation safety ensured by compliance with requirements of appropriate standards	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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. 5.2-5.5, 6, 7.1-7.4)	-	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. 5.2-5.5, 6, 7.1-7.4)	-	N/A
12.4.6	RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT…….: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	-	N/A
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		P
13.1	**Specific HAZARDOUS SITUATIONS**		P
13.1.2	**Emissions, deformation of ENCLOSURE or exceeding maximum temperature**		P
	– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur		P
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur	-	N/A
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24……...:	No applied parts	N/A
	– Temperatures of Accessible PARTS THAT ARE LIKELY TO BE TOUCHED, but not intended to be touched did not exceed limits in Table 34…….:	No applied parts	N/A
	- Temperatures of ACCESSIBLE PARTS intended to be touched did not exceed limits in Table 23	Built-in purpose	N/A
	–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
	Temperatures measured according to 11.1.3		P
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where……...:	-	N/A
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION ..... :	~~See Table 13.1.2~~	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- or secondary circuits mounted on materials with a minimum flame rating of -V1, and	-	N/A
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and	-	N/A
	- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and	-	N/A
	- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide	-	N/A
	- or components in the circuit have HIGH INTEGRITY CHARACTERISTICS..... :	-	N/A
	– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation	-	N/A
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	-	N/A
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed……..:	See Table 8.7	P
	– voltage limits for ACCESSIBLE PARTS and APPLIED PARTS did not exceed……..:	See Table 8.7	P
13. 2	**SINGLE FAULT CONDITIONS**		P
13.2.1	During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination	See Table 8.7	P
	ME EQUIPMENT complied with 13.2.2 -13.2.12…..:		P
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF is not evaluated for PSU	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 test environment temperature	-	N/A
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted	-	N/A
13.2.13.2	**ME EQUIPMENT with heating elements**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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	-	N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests	-	N/A
	a 3) other ME EQUIPMENT with heating elements met test	-	N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively	-	N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration	-	N/A
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time	-	N/A
13.2.13.3	**ME EQUIPMENT with motors**		N/A
	a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable	-	N/A
	To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test	-	N/A
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition	-	N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT	-	N/A
	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

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Clause	Requirement + Test	Result - Remark	Verdict
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10	-	N/A
13.2.13.4	**ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION**		N/A
	ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated	-	N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle	-	N/A
	Motor winding temperatures did not exceed values in 13.2.10……:	-	N/A
	Insulation Class……:	-	—
	Maximum temperature measured (°C)……:	-	—
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		N/A
14.1	Requirements in 14.2 to 14,12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or	MEE has no software in intended use	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. 5.2-5.5, 6)	-	N/A
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK	-	N/A
	When the requirements of 14.2 to 14.13 apply, the requirements of IEC 62304:2006 and IEC 62304:2006/AMD1:2015 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS		N/A
	Software development process for Software Classification applied in accordance with Clause 4.3 and 4.4 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……..:	-	N/A
	Software development process applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……..……...:	-	N/A
	Software development process for Software risk management applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015…….:	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Software development process Configuration Management applied according to Clause 8 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……:	-	N/A
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015……..:	-	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	-	N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	-	N/A
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained	-	N/A
14.6	**RISK MANAGEMENT PROCESS**		N/A
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS……..:	-	N/A
	RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems……..: (ISO 14971 Cl. 5.3)	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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. 7.1)	-	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. 7.2)	-	N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems …..: (ISO 14971 Cl. 7.2)	-	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. 7.2)	-	N/A
	– milestone(s) when VERIFICATION is to be performed for each function	-	N/A
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION	-	N/A
	– selection and utilization of VERIFICATION tools	-	N/A
	– coverage criteria for VERIFICATION	-	N/A
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented	-	N/A
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE……..:	-	N/A
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented	-	N/A
	The person with overall responsibility for PEMS VALIDATION is independent	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 7.2)	-	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 and 4.4 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015……:	-	N/A
	Software Process for Software changes applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015……..:	-	N/A
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015……..:	-	N/A
	Configuration management of software changes applied per Clause 8 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015……:	-	N/A
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015…:	-	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
	d) technical specifications of the network connection, including security specifications	-	N/A
	e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK	-	N/A
	f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.2)	-	N/A
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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 identify, analyse, evaluate and control these RISKS	-	N/A
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis	-	N/A
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment	-	N/A
15	**CONSTRUCTION OF ME EQUIPMENT**		P
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING ROCESS……..:	MEE has no controls	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	-	N/A
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring	-	N/A
15.3	**Mechanical strength**		P
15.3.1	Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	Shock and vibration according to subclause 10.1.2 of IEC 60601-1-11 performed (see General Product Information) The other mechanical tests shall be evaluated in end-use application	P
15.3.2	Push test conducted ……..:	PSU built in purpose	N/A
	No damage resulting in an unacceptable RISK sustained	-	N/A
15.3.3	Impact test conducted……:	PSU built in purpose	N/A
	No damage resulting in an unacceptable RISK sustained	-	N/A
15.3.4	**Drop test**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested …….:	~~See Table 15.3~~	N/A
	No unacceptable RISK resulted	-	N/A
15.3.4.2	Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test……:	~~See Table 15.3~~	N/A
	No damage resulting in an unacceptable RISK sustained	-	N/A
15.3.5	MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests…….:	~~See Table 15.3~~	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	-	N/A
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK	RMF shall be evaluated in end-use application	N/A
15.4	**ME EQUIPMENT components and general assembly**		P
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists,……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	RMF shall be evaluated in end-use application	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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**		P
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. 5.2-5.5, 6)		N/A
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT	No thermal cut-outs	N/A
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided……..: (ISO 14971 Cl. 5.2-5.5)		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. 5.2-5.5)	Operation of fuse causes MEE to shut down. No hazards	P
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS		N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests		N/A
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17	-	N/A
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13……:	See Table 13.2	P
	- 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	Fuses separately certified	P

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Clause	Requirement + Test	Result - Remark	Verdict
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times	-	N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted	-	N/A
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating	-	N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating…..: (ISO 14971 Cl. 5.2-5.5)	-	N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS	-	N/A
15.4.3	**Batteries**		N/A
15.4.3.1	Battery housings provided with ventilation…….: (ISO 14971 Cl. 5.2-5.5)	MEE has 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. 5.2-5.5)	-	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. 5.2-5.5)	-	N/A
15.4.3.4	Primary lithium batteries comply with IEC 60086-4	-	N/A
	Secondary lithium batteries comply with IEC 62133 or IEC 62133-2	-	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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……:	Shall be evaluated in the end-use product	N/A
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	-	N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational	-	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters……..: (ISO 14971 Cl. 5.2-5.5)	-	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. 5.2-5.5, 6, 7.1-7.4)	MEE has no pre-set controls	N/A
15.4.6	**Actuating parts of controls of ME EQUIPMENT**		N/A
15.4.6.1	a) Actuating parts cannot be pulled off or loosened during NORMAL USE	MEE has no actuating parts	N/A
	b) Controls secured so that the indication of any scale always corresponds to the position of the control	-	N/A
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL	-	N/A
	When torque values per Table 30 applied knobs did not rotate ……..:.	-	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

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Clause	Requirement + Test	Result - Remark	Verdict
	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**		N/A
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	MEE has no control devices	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	-	N/A
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed	-	N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	-	N/A
	A pressure-release device operating during NORMAL USE is provided	-	N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage	-	N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements	-	N/A
15.5	**MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5**		P
15.5.1	**Overheating**		P
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating……..:	See Table 13.2	P
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		P

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Clause	Requirement + Test	Result - Remark	Verdict
	Dielectric strength test conducted after short circuit and overload tests ……:		P
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ……..:	See Table 13.2	P
	Short circuit applied directly across output windings	Switched Mode Power Supply	N/A
15.5.1.3	Multiple overload tests conducted on windings:		N/A
15.5.2	Transformers operating at a frequency above 1kHz tested according to clause 8.8.3……:	See table 8.8.3	P
	Transformer windings provided with adequate insulation		N/A
	Dielectric strength tests were conducted ……:	See table 8.8.3	P
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with……..:	-	P
	- Means provided to prevent displacement of end turns		P
	- protective earth screens with a single turn have insulated overlap		N/A
	- Exit of wires form internal windings of toroid transformers protected with double sleeving		N/A
	- insulation between primary and secondary windings complies with 8.8.2		P
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4		P
16	**ME SYSTEMS**		N/A
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	MEE is a PSU intended to be used built-in purpose Shall be used in end-product application	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM……..: (ISO 14971 Cl. 5.2-5.5, 6)	-	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

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Clause	Requirement + Test	Result - Remark	Verdict
	– tests performed in NORMAL CONDITION, except as specified	-	N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM	-	N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated	-	N/A
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR	-	N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards	-	N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	-	N/A
16.2	**ACCOMPANYING DOCUMENTS of an ME SYSTEM**		N/A
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM	-	N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM	-	N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER	-	N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER	-	N/A
	c) the required information is provided:	-	N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM	-	N/A
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard	-	N/A
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM	-	N/A
	– additional safety measures to be applied during installation of ME SYSTEM	-	N/A
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT	-	N/A
	– additional measures to be applied during preventive maintenance	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES	-	N/A
	– assembly of ME SYSTEMS and modifications during actual service life 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

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Clause	Requirement + Test	Result - Remark	Verdict
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**		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION did not exceed 100µA……..:	-	N/A
	TOUCH CURRENT did not exceed 500µA 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
16.8	Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	-	N/A
16.9	**ME SYSTEM connections and wiring**		N/A
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result……:	-	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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
	– 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

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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 and protected by only the SUPPLY MAINS circuit over-current release, did not exceed 200 mΩ	-	N/A
	The impedance of an earth pathway protected by an additional intermediate circuit breaker or fuse rated 13A or lower, did not exceed 400 mΩ	-	N/A
	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part	-	N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL	-	N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage	-	N/A
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		N/A
	RISKS associated confirmed by review……:	See test report: 2204167STO-102 Shall be evaluated in end-use application.	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. 5.2-5.5, 6, 7.1-7.4)	-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**	N/A

ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			N/A
Clause of ISO 14971	**Document Ref. in RMF (Document No. paragraph/clause, version)**		**Result - Remarks**	**Verdict**
	General process	**Particular Medical Device**		
—	—	—	—	—
Supplementary Information:				

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 (VAC)**	**Frequency (Hz)**	**Current (A)**	**Power (W)**	**Power factor (cos φ)**
OFM225 5225 12VDC Normal load 6A without forced cooling	100	47	0.85	80.41	0.93
	120	47	0.70	79.53	0.93
	240	47	0.38	80.46	0.85
	100	63	0.84	80.08	0.93
	120	63	0.71	79.54	0.92
	240	63	0.40	79.80	0.80
OFM225 5225 12VDC Normal load 12A with forced cooling	100	47	1.76	167.54	0.94
	120	47	1.45	165.02	0.94
	240	47	0.74	164.32	0.91
	100	63	1.75	167.59	0.94
	120	63	1.45	165.21	0.94
	240	63	0.74	161.90	0.90

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Clause	Requirement + Test	Result - Remark	Verdict

4.11	TABLE: Power Input					P
Operating Conditions / Ratings		**Voltage (VAC)**	**Frequency (Hz)**	**Current (A)**	**Power (W)**	**Power factor (cos φ)**
OFM225 5228 24VDC Normal load 7.88A without forced cooling		100	47	2.19	208.09	0.94
		120	47	1.80	205.24	0.94
		240	47	0.90	201.72	0.92
		100	63	2.17	207.87	0.94
		120	63	1.79	205.37	0.94
		240	63	0.91	201.68	0.91
OFM225 5228 24VDC Normal load 9.37A with forced cooling		100	47	2.63	249.27	0.94
		120	47	2.15	244.85	0.94
		240	47	1.06	238.84	0.93
		100	63	2.60	248.75	0.95
		120	63	2.13	244.56	0.95
		240	63	1.08	238.77	0.92
OFM225 5226 15VDC Normal load 7.88A without forced cooling		100	47	1.33	125	-
		100	63	1.10	125	-
		120	63	2.38	124	-
		240	47	0.57	122	-
		240	63	0.58	122	-
OFM225 5226 15VDC Normal load 9.9A with forced cooling		100	47	1.82	172	-
		100	63	1.81	172	-
		120	63	1.50	170	-
		240	47	0.76	167	-
		240	63	0.77	167	-

Supplementary Information:

OFM225 5228: 100-240VAC, 47-63Hz, 4A.
OFM225 5226: 100-240VAC, 47-63Hz, 4A.
OFM225 5225: 100-240VAC, 47-63Hz, 4A.

Output simulated with resistive load according to maximum output current.

Note: OFM225 5226 15VDC test results are derived from test report No: 1715942STO-001.

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Clause	Requirement + Test	Result - Remark	Verdict

5.9.2	TABLE: Determination of ACCESSIBLE parts		P
Location	**Determination method (NOTE1)**	**Comments**	
---	---	Evaluated in end-use product	
Supplementary information: MEE is an open-frame PSU will be used built-in applications. Hence will be evaluated in end-use product. 1) NOTE: 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).....:	100-1500lx	Clearly legible, 1m 30° angle	
Inside Markings (Clause 7.3).....:	-	No marking found inside the MEE	
Controls & Instruments (Clause 7.4).....:	-	No such parts in MEE	
SAFETY SIGNS (Clause 7.5).....:	-	No Safety signs on the MEE	
Symbols (Clause 7.6).....:	-	No Symbols found on the MEE	
Supplementary information: Test results are derived from test report No: 1715942STO-001. 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 .....:	Printed adhesive label	Not affected	
Ink/other printing material or process .....:	Ink printing	Not affected	
Material (composition) of Warning Label .....:	-	No warning Label	
Ink/other printing material or process .....:	-	No warning Label	
Other.....:	-	-	
Marking Label Tested:		**Remarks**	
Product rating label		Pass	
Supplementary information: Test results are derived from test report No: 1715942STO-001. Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.			

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					P
Test supply voltage/frequency (V/Hz)[1]: 240 VAC, 63 Hz						
Location From/To	**Measured values**					**Remarks**
	Vrms	**Vpk or Vdc**	**Peak-to-peak ripple[2]**	**Power W/VA**	**Energy (J)**	
Primary (AC) to Earth	240	339	-	-	-	-
Primary (AC) Pole - Pole	240	339	-	-	-	-
OFM225 5228 Primary-secondary	253	520	-	-	-	Max measured between T1 and transformer secondary pins 24VDC out
OFM225 5226 Primary-secondary	258	645	-	-	-	Max measured between T1 and transformer secondary pins 15VDC out
OFM225 5225 Primary-secondary	258	645	-	-	-	Max measured between T1 and transformer secondary pins 12VDC out
OFM 225 5225,5226,5228	208	380	-	-	-	Measured between Cu foil (prim) and secondary pins
OFM 225 5225	-	12 Vdc	-	-	-	Secondary to earth
OFM 225 5226	-	15 Vdc	-	-	-	Secondary to earth
OFM 225 5228	-	24 Vdc	-	-	-	Secondary to earth

Supplementary Information: The above test results are derived from test report No: 1715942STO-001.

[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

[3] Voltage measurement of all conductive ACCESSIBLE PARTS of the SIP/SOP connection or separate power supply output connections to earth used a resistor of 10 kΩ + 500 Ω. See clause 8.4.2

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Clause	Requirement + Test	Result - Remark	Verdict

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

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

Voltage measured (V)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	**106**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**

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

Calculated stored charge (μc)										
Voltage Measured Between:	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Plug pins 1 and 2	**34.98**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**

Supplementary information: Testing has been evaluated for model: OFM 225 5228 (24Vdc)

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

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

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

Supplementary information:

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

Test Condition: Figs. 9 & 10	**Measurement made on accessible part**	**Applied part with test voltage**	**Test voltage polarity**	**Measured voltage between Y1 and Y2 (mV)**	**Remarks**
---	---	---	---	---	---

Supplementary information:

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Clause	Requirement + Test	Result - Remark	Verdict

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

8.5.5.2	TABLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load		N/A
Test Voltage applied to	**Measured Energy E1 (mJ)**	**Measured Energy E2 (mJ)**	**Energy E1 as % of E2 (%)**
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth	---	---	---
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth	---	---	---
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth	---	---	---
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth	---	---	---
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 Ω with ME Equipment connected; E2= Measured energy delivered to 100 Ω without ME equipment connected.			

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS				N/A
Type of ME EQUIPMENT & impedance measured between parts	**Test current (A) /Duration (s)**	**Voltage drop measured between parts (V)**	**Maximum calculated impedance (mΩ)**	**Maximum allowable impedance (mΩ)**	
---	**---**	**---**	**---**	**---**	
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**					

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Clause	Requirement + Test	Result - Remark	Verdict

8.7	TABLE: leakage current	P

Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (µA)	Remarks
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC; 10mA NFW
OFM225 5228, 24VDC				
Measured with frequency weighted device				
ER; NC; S1=1; S5=1	264	63	115.19	OFM225 5228, 24VDC Under No load condition Class I Configuration
ER; NC; S1=1; S5=0	264	63	120.89	
ER; SFC; S1=0; S5=1	264	63	161.26	
ER; SFC; S1-0; S5=0	264	63	165.06	
Measured with non-frequency weighted device				
ER; NC; S1=1; S5=1	264	63	113.44	OFM225 5228, 24VDC Under No load condition Class I Configuration
ER; NC; S1=1; S5=0	264	63	118.34	
ER; SFC; S1=0; S5=1	264	63	245.82	
ER; SFC; S1-0; S5=0	264	63	246.40	
Measured with frequency weighted device				
ER; NC; S1=1; S5=1	264	63	101.79	OFM225 5228, 24VDC With loading condition 7.88A (without cooling system) Class I Configuration
ER; NC; S1=1; S5=0	264	63	105.77	
ER; SFC; S1=0; S5=1	264	63	161.65	
ER; SFC; S1-0; S5=0	264	63	162.12	
Measured with non-frequency weighted device				
ER; NC; S1=1; S5=1	264	63	112.70	OFM225 5228, 24VDC With loading condition 7.88A (without cooling system) Class I Configuration
ER; NC; S1=1; S5=0	264	63	115.92	
ER; SFC; S1=0; S5=1	264	63	218.42	
ER; SFC; S1-0; S5=0	264	63	229.65	
Measured with frequency weighted device				
ER; NC; S1=1; S5=1	264	63	97.39	OFM225 5228, 24VDC With loading condition 9.37A (with cooling system)
ER; NC; S1=1; S5=0	264	63	101.63	
ER; SFC; S1=0; S5=1	264	63	154.21	
ER; SFC; S1-0; S5=0	264	63	154.13	
Measured with non-frequency weighted device				
ER; NC; S1=1; S5=1	264	63	108.96	
ER; NC; S1=1; S5=0	264	63	112.86	

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Clause	Requirement + Test			Result - Remark	Verdict
ER; SFC; S1=0; S5=1	264	63	201.47	OFM225 5228, 24VDC With loading condition 9.37A (with cooling system) Class I Configuration	
ER; SFC; S1-0; S5=0	264	63	201.30		
OFM225 5225, 12VDC					
Measured with frequency weighted device					
ER; NC; S1=1; S5=1	264	63	112.51	OFM225 5225, 12VDC Under No load condition Class I Configuration	
ER; NC; S1=1; S5=0	264	63	116.96		
ER; SFC; S1=0; S5=1	264	63	152.48		
ER; SFC; S1-0; S5=0	264	63	153.36		
Measured with non-frequency weighted device					
ER; NC; S1=1; S5=1	264	63	110.17	OFM225 5225, 12VDC Under No load condition Class I Configuration	
ER; NC; S1=1; S5=0	264	63	114.77		
ER; SFC; S1=0; S5=1	264	63	236.58		
ER; SFC; S1-0; S5=0	264	63	236.98		
Measured with frequency weighted device					
ER; NC; S1=1; S5=1	264	60	98.78	OFM225 5225, 12VDC With loading condition 6A (without cooling system) Class I Configuration	
ER; NC; S1=1; S5=0	264	60	95.15		
ER; SFC; S1=0; S5=1	264	60	146.97		
ER; SFC; S1-0; S5=0	264	60	147.22		
Measured with non-frequency weighted device					
ER; NC; S1=1; S5=1	264	63	107.16	OFM225 5225, 12VDC With loading condition 6A (without cooling system) Class I Configuration	
ER; NC; S1=1; S5=0	264	63	103.52		
ER; SFC; S1=0; S5=1	264	63	184.34		
ER; SFC; S1-0; S5=0	264	63	185.40		
Measured with frequency weighted device					
ER; NC; S1=1; S5=1	264	63	99.01	OFM225 5225, 12VDC With loading condition 12A (with cooling system) Class I Configuration	
ER; NC; S1=1; S5=0	264	63	95.33		
ER; SFC; S1=0; S5=1	264	63	147.62		
ER; SFC; S1-0; S5=0	264	63	147.61		
Measured with non-frequency weighted device					
ER; NC; S1=1; S5=1	264	63	112.01	OFM225 5225, 12VDC With loading condition 12A (with cooling system) Class I Configuration	
ER; NC; S1=1; S5=0	264	63	107.86		
ER; SFC; S1=0; S5=1	264	63	185.50		
ER; SFC; S1-0; S5=0	264	63	185.09		

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Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC; 10mA NFW
OFM225 5228, 24VDC				
Measured with frequency weighted device				
TC; NC; S1=1; S5=1; S7=1	264	63	13.75	Class I Configuration
TC; NC; S1=1; S5=0; S7=1	264	63	13.58	
TC; SFC; S1=1; S5=1; S7=0	264	63	16.30	Class II Configuration (Earth disconnected)
TC; SFC; S1=1; S5=0; S7=0	264	63	17.49	
TC; SFC; S1=0; S5=1; S7=1	264	63	114.03	Class I Configuration (Line disconnected)
TC; SFC; S1=0; S5=0; S7=1	264	63	118.72	
Remarks: OFM225 5228, 24VDC Touch current at secondary output pins				
Measured with non-frequency weighted device				
TC; NC; S1=1; S5=1; S7=1	264	63	14.40	Class I Configuration
TC; NC; S1=1; S5=0; S7=1	264	63	14.67	
TC; SFC; S1=1; S5=1; S7=0	264	63	19.19	Class II Configuration (Earth disconnected)
TC; SFC; S1=1; S5=0; S7=0	264	63	21.50	
TC; SFC; S1=0; S5=1; S7=1	264	63	112.44	Class I Configuration (Line disconnected)
TC; SFC; S1=0; S5=0; S7=1	264	63	116.75	
Remarks: OFM225 5228, 24VDC Touch current at secondary output pins				
OFM225 5225, 12VDC				
Measured with frequency weighted device				
TC; NC; S1=1; S5=1; S7=1	264	63	6.44	Class I Configuration
TC; NC; S1=1; S5=0; S7=1	264	63	6.43	
TC; SFC; S1=1; S5=1; S7=0	264	63	6.55	Class II Configuration (Earth disconnected)
TC; SFC; S1=1; S5=0; S7=0	264	63	6.53	
TC; SFC; S1=0; S5=1; S7=1	264	63	111.62	Class I Configuration (Line disconnected)
TC; SFC; S1=0; S5=0; S7=1	264	63	116.15	
Remarks: OFM225 5225, 12VDC Touch current at secondary output pins				
Measured with non-frequency weighted device				
TC; NC; S1=1; S5=1; S7=1	264	63	5.78	Class I Configuration
TC; NC; S1=1; S5=0; S7=1	264	63	5.76	
TC; SFC; S1=1; S5=1; S7=0	264	63	6.01	Class II Configuration (Earth disconnected)
TC; SFC; S1=1; S5=0; S7=0	264	63	6.03	
TC; SFC; S1=0; S5=1; S7=1	264	63	110.32	Class I Configuration (Line disconnected)
TC; SFC; S1=0; S5=0; S7=1	264	63	114.23	

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Remarks: OFM225 5225, 12VDC Touch current at secondary output pins				
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)
See Touch Currents, leakage complies with type B/BF requirements	-	-	-	-
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	—	—	—	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA
N/A				
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
N/A				
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
N/A				
Fig. 19 – Patient Auxiliary Current	—	—	—	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
N/A				
Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
N/A				
Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	—	—	—	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
N/A				
Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	—	—	—	Maximum allowed values: Type B: NA Type BF: 5000 µA Type CF: 100 µA
N/A				

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

Supplementary information: PSU has been evaluated for means of patient protection and consider as a BF applied part requirements.

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

8.7	**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	
OFM225 5228, 24VDC ****					
ER, NC, S5=1/0, B, A	264	63	89	Class I version only	
ER, SFC, S5=1/0, S1=0, B, A	264	63	131	Class I version only	
OFM225 5226, 15VDC *					
ER, NC, S5=1/0, B, A	264	63	89	Class I version only	
ER, SFC, S5=1/0, S1=0, B, A	264	63	131	Class I version only	

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Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC
OFM225 5228, 24VDC **				
Secondary connector, NC, S5=1/0, B (sec. circuits)	264	63	27	Class I
Secondary connector, SFC, S7=0, S5=1/0, B, A (sec. circuits)	264	63	89	Class I
Secondary connector, SFC, S1=0, S5=1/0, B, A (sec. circuits)	264	63	35	Class I
Secondary connector, NC, S5=1/0, B (sec. circuits)	264	63	89	Class II
Secondary connector, SFC, S1=0, S5=1/0, B, A (sec. circuits)	264	63	131	Class II
OFM225 5226, 15VDC *				
Secondary connector, NC, S5=1/0, B (sec. circuits)	264	63	22.7	Class I
Secondary connector, SFC, S7=0, S5=1/0, B, A (sec. circuits)	264	63	81.6	Class I
Secondary connector, SFC, S1=0, S5=1/0, B, A (sec. circuits)	264	63	33.7	Class I
Secondary connector, NC, S5=1/0, B (sec. circuits)	264	63	85.2	Class II
Secondary connector, SFC, S1=0, S5=1/0, B, A (sec. circuits)	264	63	125.7	Class II
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)
See Touch Currents, leakage complies with type B/BF requirements	---	---	---	---
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)

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Clause	Requirement + Test	Result - Remark	Verdict

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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
---	---	---	---	---
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: Test results are derived from test report No: 1715942STO-001

*Representative for OFM225 5226-02, OFM225 5225 and OFM225 5225-02 since both versions overall have same components, including the same transformer.

**Representative for OFM225 5228-02 since both versions overall have same components, including the same transformer.

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

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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.**		
OFM225 5228, D OFM225 5225, D	1MOPP	340 VAC	-	1500	No
OFM225 5228, C OFM225 5225, C	2MOPP	340 VAC	-	5656[1)]	No
Mylar sheet	2MOPP	340 VAC	-	5656[1)]	No
The below test results are derived from test report No.: 1711404STO-001					
OFM225 5228, B *	2MOPP	520 VAC	-	4471	No
OFM225 5226, B *	2MOPP	645 VAC	-	4824	No
OFM225 5225, B ***	2MOPP	645 VAC	-	4824	No
2 layer of tape CT-280	2MOPP	380 VAC	-	4074	No
1 layer of tape KA 180	1MOPP	380 VAC	-	2500	No

Supplementary information:

[1] Interchangeablely, 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)**
Mains terminal	125°C	0.8

Supplementary information:

resistance to heat for insulation of thermoplastic materials that used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION established by performing the ball-pressure test in at a temperature 25 °C higher than the temperature of the insulation measured during the tests of 13.2.2 to 13.2.13 (inclusive).

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8.9.2	**TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4**		**N/A**
Specific areas of circuits short-circuited and test conditions	**Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1)]**	**HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No**	**Remarks**
---	**---**	**---**	**---**
Supplementary information: [1)] Note: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE			

8.9.3.2	**Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts**			**N/A**
Part Test	**8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7**	**Dielectric test voltage**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**	**Crack or voids in the insulating compound: Yes/No**
---	**---**	**---**	**---**	**---**
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**
---	**---**	**---**	**---**	**---**
Supplementary information: [1)] T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.				

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8.10	TABLE: Critical components information				P
Object / part No.	**Manufacturer/ trademark**	**Type / model**	**Technical data**	**Standard**	**Mark(s) of conformity[1)]**
Fuse (F1,F2)	Littelfuse Inc.	215 215-Serie(s)	T4A, 250V	IEC/EN 60127-1: 2006+A1+A2 IEC/EN 60127-2:2014 UL 248-1 UL 248-14 CSA-C22.2 No. 248.1:2011	VDE 40013521 UL E10480
	Hollyland Company Limited	50CT			VDE 40014896 UL E156471
	Interchangeable	Interchangeable			UL
Line Filter (DR1)	Chief sound electronics (Shenzhen) co., ltd	SMP-L-0198	6.5mH	IEC 60601-1: 2005+A1+A2	Tested in appliance
Triple insulated wire (DR1)	Dah jin technology co ltd	TLW-BB	130°C (B)	UL 2353, UL 60601-1 IEC 60950-1	UR E236542
Magnet Wire (DR1)	Heng ya electric (dongguan) ltd	TYA1-130	130°C	UL 1446	UR E197768
Varnishes (DR1)	Hang cheung coatings (huiyang) ltd	8562*	Helical Coil Temp 155 °C	UL 1446	UR E200154
Plastic (DR1)	Chang chun plastics co ltd	T375J / T355J	V-0 Max. temp:150°C	UL 94	cURus E59481
PCB	Countcash limited	C-29	V-0, Max. temp: 130°C	UL 796	UL E123150
	Milord Technology (HK) Ltd	D			UL E176756
	Interchangeable	Interchangeable			UL
Optocoupler (OPT1, OPT2)	Lite-On Technology Corporation	LTV-817C	Viso = 5kV	UL 1577 IEC/EN 60747-5 - 5:2011+A1	UL E113898 VDE 40015248
	Everlight electronics co ltd	EL817			UL E214129 VDE 132249
X-Capacitor (X1)	Okaya electric industries co ltd	LE-MX-MR	0.33uF, Class X2 250V Operating temp: -50°C - +100°C	IEC/EN 60384-14: 2005 (Ed.2) UL1414	UL E47474
	Tenta Electric Industrial Co	MEX			VDE 119119 UL E222911
	Winday Electronic (Dong Guan) Co Ltd	MPX, MPX Serie(s)			VDE 40030283 UL E302125
	Europtronic (suzhou) co ltd	MPX, MPX2			VDE 40025981 UL E211347

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	Dongguan Easy-gather Electronic Co., Ltd.	MKP-X2			VDE 40022258 UL E252221
	Xiamen Faratronic Co. Ltd.	MKP62			VDE 40000358 UL E186600
	Interchangeable	Interchangeable			UL
Y - Capacitor (y1, y2, y3, y4)	Dongguan Easy-gather Electronic Co., Ltd	DCF	1.5nF Class Y1 400V Operating temp: -25°C - +85°C	IEC/EN 60384-14:2005 UL 60384-14 (Ed.2)	VDE 40022942 UL E252221
	Murata Mfg. Co., Ltd.	KX152M			VDE 40002831 UL E37921
	Success Electronics Co Ltd (SEC)	SB			VDE 40020001 UL E114280
	Vishay electronic gmbh	WKP			VDE136493 UL E183844
	Interchangeable	Interchangeable			UL
Heat Shrink Tube	Shenzhen woer heat-shrinkable material co ltd	RSFR-H	600V, 125°C, VW-1	UL 224	UL E203950
	Changyuan electronics group co ltd	CB-HFT, CB-HFT(XY), CYG-MT			UL E180908
	Interchangeable	Interchangeable			UL
Transformer (TR1) OFM225 5225, OFM225 5225-02, 12VDC; OFM225 5226, OFM225 5226-02, 15VDC	Chief Sound Industries Ltd	SMP-TR-0347	Max. temp 130°C Class B	IEC 60601-1: 2005+A1+A2	Tested with appliance
Transformer (TR1) OFM225 5228, OFM225 5228-02, 24 VDC	Chief Sound Industries Ltd	SMP-TR-0340	Max. temp 130°C Class B	IEC 60601-1: 2005+A1+A2	Tested with appliance
Bobbin (TR1)	Chang chun plastics co., ltd.	T375J(G5)(G6),T375HF,T200HF,T355J	Phenolic, V-0, 150°C, min.	ANSI/UL 94 UL 1694	UL E59481

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	Sumitomo bakelite co ltd	PM-9820,PM-9830,PM-9850	thickness 0.69mm.	UL 723	UL E41429
	E i dupont de nemours & co inc	FR530, FR530L			UL E41938
Magnet wire (TR1)	Pacific electric wire & cable (shenzhen) co ltd	Uew/u	130°C Polyurethane enameled Copper wire	ANSI/UL 1446	UL E201757
	Heng ya electric (dongguan) ltd	tya1-130(uew/qa-b), tya1-u155(uew/qa-f)			UL E197768
	Siam pacific electric wire & cable co ltd	Uew-f, uew-u&			UL E142108
	Interchangeable	Interchangeable			UL
Insulation tape (TR1)	Jingjiang Yahua Pressure Sensitive Glue Co Ltd	CT* (b)(g), PZ*(b),CT* (c)(g)， WF* (c)(h), CT-280B	Polyester Yelllow Tape 130°C, used on winding D, H	CAN/UL 510A	UL E165111
	P leo & co (b c) ltd	1P801,1P802			UL E126174
	Symbio inc	KA180			UL E50292
	Interchangeable	Interchangeable			UL
Triple insulation wire (TR1)	Dah Jin Technology Co Ltd	TLW-B	Max. 130°C Class B	IEC/EN 60950-1	VDE 40008834 UL E236542
	Great leoflon industrial co ltd	TRW(B) Serie(s)			VDE 136581 UL E211989
	Furukawa	TEX-E			VDE 006735
	Huizhou Dongju Fluo Tech Plastic Co., Ltd	TLW-FXXX			VDE 40047395
	Shenzhen kaizhong hedong new materials co ltd	TIW-B, TIW-F			VDE 40038861
	Huizhou Golden Ocean Wire Co., Ltd.	XYW (B), XYW (F)			VDE 40017563
	Shanghai Xiangxiang Electron Co., Ltd.	TKW-B			VDE 40026588

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	Interchangeable	Interchangeable			UL
Insulation tube (TR1)	Changyuan electronics group co ltd	CB-TT-L,CB-TT-S,CB-TT-T	200°C, VW-1 Teflon Tube, used on ending of primary windings	UL 224	UL E180908
	Shenzhen woer heat-shrinkable material co ltd	RSFR-H			UL E203950
Resistor (NTC1)	Thinking electronic industrial co., ltd.	SCK-102	240VAC, Max operating temp: 170 °C	EN 60539-1 & UL 60730-1 UL 1434	UL E138827
	Interchangeable	Interchangeable			UL
Mylar Sheet	Dupont hongji films foshan co ltd	M031	VTM-2, 105 °C, 0.4mm thick	UL 746 IEC 60601-1: 2005+A1+A2	UL E93687
	Jiangsu Yuxing	6023D			UL E212271
	Shenzhen Xing Fu Cheng	XFCPP-WT35F, XFCPP-WT35T, XFCPP-WT10F			UL E360093
Mains terminal (J4)	Tyco Electronics Corp	640383-3	V-0, 7 A (Max) Temp: -55 to 105 °C	UL1077 IEC/EN 60601-1	UL E28476
Marking label	Guangdong Zhongguan New Material Technology Co Ltd	ZG-W/50	Bright white PET Adhesive Name: SZZGJZYJ-01 Service Temperature: -10～70 ℃	UL 969, IEC 60601-1: 2005+A1	UR, MH61958 Tested in appliance

Supplementary information:

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

8.10 b	TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS				N/A
Object / part No.	**Manufacturer/ trademark**	**Type / model**	**Technical data**	**Standard**	**Mark(s) of conformity[1)]**
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Supplementary information:

1) Provided evidence ensures the agreed level of compliance. See OD-CB2039.

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8.11.3.5	TABLE: CORD ANCHORAGES			N/A
Cord under test	**Mass of equipment (kg)**	**Pull (N)**	**Torque Nm)**	**Remarks**
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Supplementary information:				

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

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

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

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

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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**
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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
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**
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Supplementary information:		

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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
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Supplementary information:

9.4.4	TABLE: Grips and other handling devices	N/A

Clause and Name of Test	Test Condition	Remarks
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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	
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Supplementary Information:

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

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

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Surface area under test Surface no./ Description[1)]	Measured Radiation, pA/kg (µSv/h) (mR/h)	Remarks
1/ /		

Supplementary information:
[1)] Measurements made at 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. .....:	OFM225 5228: 24VDC			
Test ambient (°C) .....:	See below (Ch 101)			
Test supply voltage/frequency (V/Hz)[4)] ..:	Case A: 85VAC at 47Hz	Case B: 264VAC at 63Hz		

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
				Case A	Case B	
OFM225 5228: 24VDC	101	Ambient	-	70.1	70.9	-
	102	Input connector (J4) - Ambient	105	82.3	76.7	-
	103	Line filter (DR4) - Ambient	105	91.1	86.6	-
	104	Y3 and X1 - Capacitors - Ambient	125	90.6	88.0	-
	105	Transformer on winding (TR1)	130-10=120[3)]	105.9	109.6	-
	106	Transformer on the bobbin (TR1)	150	97.8	98.8	-
	107	Capacitors (C45) - Ambient	105	99.5	99.3	-
	108	PCB/optocouplers - (OPT2) (Below transformer)	130	101.1	105.4	-

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.

Information from Risk Management, as applicable**:**

Notes:
ME Equipment configuration:
- Test has been conducted at 70 °C under maximum normal loading condition without cooling at 7.88 A resistive load.

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11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT					P
Model No. .....:		OFM225 5228	OFM225 5226	OFM225 5225		
Test ambient (°C) .....:		50 -70	50-70	50-70		
Test supply voltage/frequency (V/Hz)[4]...:		85/47	85/47	85/47		

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
OFM225 5228 24V Forced cooling 12CFM amb.50°C Rated output	1	Transformer winding	120(Cl.B 130-10)	100	P
	2	PCB/optocouplers (below transformer)	105	88.5	P
	4	Choke (mains filter)	105	69.7	P
	5	PCB/ heatsink	105	80.5	P
	6	Y- and X-capacitors	85	53.3	P
	7	Ambient (Secondary side)	-	56.5	P
	8	Ambient at fan	-	50.5	P
OFM225 5228 24V No cooling amb.50°C Rated output	1	Transformer winding	120(Cl.B 130-10)	101.0	P
	2	PCB/optocouplers (below transformer)	105	99.0	P
	4	Choke (mains filter)	105	87.5	P
	5	PCB/ heatsink	105	98.3	P
	6	Y- and X-capacitors	105	77.0	P
	7	Ambient (Secondary side)	-	50.0	P
	8	Ambient at fan	-	-	P
OFM225 5226 15V Forced cooling 12CFM amb.50°C Rated output	1	Transformer winding	120(Cl.B 130-10)	91.0	P
	2	PCB/optocouplers (below transformer)	105	79.4	P
	4	Choke (mains filter)	105	63.5	P
	5	PCB/ heatsink	105	70.8	P
	6	Y- and X-capacitors	85	52.0	P
	7	Ambient (Secondary side)	-	55.0	P
	8	Ambient at fan	-	50.5	P
OFM225 5226	1	Transformer winding	120(Cl.B 130-10)	99.4	P

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Clause	Requirement + Test			Result - Remark	Verdict
15V No cooling amb.50°C Rated out put	2	PCB/optocouplers (below transformer)	105	98.0	P
	4	Choke (mains filter)	105	91.0	P
	5	PCB/ heatsink	105	85.6	P
	6	Y- and X-capacitors	105	63.2	P
	7	Ambient (Secondary side)	-	49.9	P
	8	Ambient at fan	-	-	P
OFM225 5225 12V Forced cooling 12CFM amb.50°C Rated out put	1	Transformer winding	120(Cl.B 130-10)	88.3	P
	2	PCB/optocouplers (below transformer)	105	80.8	P
	4	Choke (mains filter)	105	62.7	P
	5	PCB/ heatsink	105	73.6	P
	6	Y- and X-capacitors	85	52.1	P
	7	Ambient (Secondary side)	-	56.6	P
	8	Ambient at fan	-	50.8	P
OFM225 5225 12V No cooling amb.50°C Rated output	1	Transformer winding	120(Cl.B 130-10)	83.8	P
	2	PCB/optocouplers (below transformer)	105	80.6	P
	4	Choke (mains filter)	105	77.3	P
	5	PCB/ heatsink	105	76.6	P
	6	Y- and X-capacitors	105	60.3	P
	7	Ambient (Secondary side)	-	49.5	P
	8	Ambient at fan	-	-	P
		Operation at amb. 70C			
OFM225 5228 24V Forced cooling 12CFM amb.70°C Output decreased to 20V	1	Transformer winding	120(Cl.B 130-10)	107	P
	2	PCB/optocouplers (below transformer)	105	99.0	P
	4	Choke (mains filter)	105	84.0	P
	5	PCB/ heatsink	105	89.7	P
	6	Y- and X-capacitors	85	72.4	P
	7	Ambient (Secondary side)	-	75.6	P
	8	Ambient at fan	-	70.3	P
OFM225 5226	1	Transformer winding	120(Cl.B 130-10)	111.7	P

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Clause	Requirement + Test		Result - Remark		Verdict
15V Forced cooling 12CFM amb.70°C Output decreased to 14.5V	2	PCB/optocouplers (below transformer)	105	102.6	P
	4	Choke (mains filter)	105	84.9	P
	5	PCB/ heatsink	105	93.8	P
	6	Y- and X-capacitors	85	73.1	P
	7	Ambient (Secondary side)	-	75.6	P
	8	Ambient at fan	-	70.0	P
OFM225 5225 12V No cooling 12CFM amb.70°C Normal output 12V	1	Transformer winding	120(Cl.B 130-10)	101.0	P
	2	PCB/optocouplers (below transformer)	105	98.0	P
	4	Choke (mains filter)	105	94.0	P
	5	PCB/ heatsink	105	95.0	P
	6	Y- and X-capacitors	85	79.0	P
	7	Ambient (Secondary side)	-	67	P
	8	Ambient at fan	-	68	P
		Disconnected fan			
OFM225 5228 24V amb.50°C Output decreased to 18.2V 7.33A	1	Transformer winding	120(Cl.B 130-10)	104.2	P
	2	PCB/optocouplers (below transformer)	105	98.9	P
	4	Choke (mains filter)	105	97.2	P
	5	PCB/ heatsink	105	91.2	P
	6	Y- and X-capacitors	85	73.2	P
	7	Ambient (Secondary side)	-	53.9	P
	8	Ambient at fan	-	50.7	P
OFM225 5225 12V amb.50°C Output decreased to 11.2V 11.27A	1	Transformer winding	120(Cl.B 130-10)	110.3	P
	2	PCB/optocouplers (below transformer)	105	105.0	P
	4	Choke (mains filter)	105	99.7	P
	5	PCB/ heatsink	105	101.3	P
	6	Y- and X-capacitors	85	65.8	P
	7	Ambient (Secondary side)	-	51.4	P
	8	Ambient at fan	-	50.8	P

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Clause	Requirement + Test	Result - Remark	Verdict

Supplementary information: The test results are derived from the test report No.: 1711404STO-001

Tested in different positions (vertically, horisontally, sides and bottom downwards), worst case presented in the above table

[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.

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: Interchangeable 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.		**---**
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):		**Remarks**
1.		**---**
2.		**---**
3.		**---**
Test parameters selected representing worst case conditions for ME EQUIPMENT:		**Remarks**
Oxygen concentration (%)..... :		**---**
Fuel ..... :		**---**
Current (A) ..... :		**---**
Voltage (V)..... :		**---**

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

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:

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 Cl. 8.1:**	**—**	**—**
	Short circuit t4 C-E	Primary fuse opened instantly. No hazard.	No
	Short circuit C2	Primary fuse opened instantly. No hazard	No
	Short circuit C9	Spark, R1 broken after test. Primary fuse opened instantly.	No
	Short circuit T1, D-S pin 2-3	Primary fuse opened instant, inrush current 10A. When replaced fuse, unit works.	No

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Short circuit T1, D-G pin 1-2	Primary fuse opened instant, inrush current 7.5A.	No
	Short circuit output	Output 25A 0.16V = 4VA, continuously. No significant increase in temperature or hazard. Test duration 30 min.	No
	Short circuit D5	Short circuit D5 without load, nothing happens. With load, current decrease from 6.2A to 4.2 & voltage decrease from 24V to 16V. Short circuit D5 no. 2 added. With load, current decrease to 3.6A & 14V.	No
	Short circuit C1	Fuse opened instantly within 1s, inrush measured 5.2A. No increase in temperature or hazard.	No
	Short circuit opt1 3-4 (OFM225 5228)	After 5 seconds PSU powered down, could be started after short circuit was removed	No
	Short circuit opt1 1-2 (OFM225 5228)	Current 6.25A increased to 7.8A, voltage increased 4V, input current increased from 0.68A to 1.06A	No
	Short circuit opt2 3-4 (OFM225 5228)	After 5 seconds PSU powered down, could be started after short circuit was removed	No
	Short circuit opt2 1-2 (OFM225 5228)	Current 6.25A increased to 7.8A, voltage increased 4V, input current increased from 0.68A to 1.06A	No
	Short circuit opt2 1-2 (OFM225 5228)	Current 6.25A increased to 7.8A, voltage increased 4V, input current increased from 0.68A to 1.06A	No
	Short circuit opt2 3-4 (1R) (OFM 225 5225)	After 5 seconds PSU powered down, could be started after short circuit was removed	No
	Short circuit opt1 1-2 with MUL (OFM 225 5225 with forced cooling)	Current increased to 22.2A, voltage increased to 12.5V Transformer temperature rose to 63.4°C	No

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	Short circuit opt1 1-2 with MUL (OFM 225 5225 without forced cooling)	Current increased to 22.2A, voltage increased to 12.5V After 20 minutes current reached 19.6A and voltage was 10.8V. Transformer temperature rose to 84.2°C	NO
	Short circuit opt2 1-2 with MUL (OFM 225 5225 with forced cooling)	Current increased by 0.1A, voltage increased by 0.1V	NO
13.2.3	**Overheating of transformers per Clause 15.5:**	**—**	**—**
	Output overload OFM225 5228 Input 90/264V T50C	MEE cuts current & voltage within 30 min. Transformer highest temp 107C measured, highest output 14.6A 23.5V decreased to 12A 20V after 30min.	NO
	Output overload OFM225 5228 Input 90/264V T25C	MEE cuts current & voltage within 30min. Transformer highest temp 96C measured highest output 13A 23V decreased to 11.5A 21V	No
	Short circuit of transformer output STR1-GND	Input power decreased from 246W to 219W, output voltage decreased from 14.5V to 13.12V. No hazard or high temp in transformer	NO
	Short circuit of transformer output STR2-GND	Input power decreased from 248W to 226W, output voltage decreased from 14.5V to 13.3V. No hazard or high temp in transformer	NO
	Short circuit of transformer output STR2-GND	Power unchanged. Normal function, no hazard	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:**	**—**	**—**
	---	**---**	**---**
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:**	**—**	**—**
	---	**---**	**---**

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
	---	---	---
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	—	—
	Single ventilation fans locked consecutively	---	---
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls	---	---
	Simulated blocking of filters	---	---
	Flow of a cooling agent interrupted	---	---
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
	---	---	---
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1)] – Also see 13.10	—	—
	---	V measured =	
	---	V measured =	
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:	---	---
	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	---	---
	Temperatures measured as specified in 11.1.3 d)		
	Temperatures did not exceed limits of Table 26		
	---	---	---
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):	—	—

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Clause	Requirement + Test	Result - Remark	Verdict

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	---	---	---

Supplementary information: Test results are derived from the test report No: 1715942STO-001

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**
---	---	---	---

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

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

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

15.5.1.2	TABLE: transformer short circuit test short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION						N/A
Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)1):							—
RATED input frequency (Hz)……:							—
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)**
---	---	---	---	---	---	---	---

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.

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

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

Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1)] .....:	
RATED input frequency (Hz) .....:	
Test current just below minimum current that would activate protective device and achieve THERMAL STABILITY under method a) (A) .....:	
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A).....:	

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)
---	---	---	---	---	---

Supplementary information: *) see Table 13 overload of transformer
[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.

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7	N/A

Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
---	---	---	---	---	---

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

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS	N/A

Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (µA)	Measured TOUCH CURRENT in NORMAL CONDITION (µA)	Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)	Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)
	100		500	
	100		500	
	100		500	

Supplementary information:

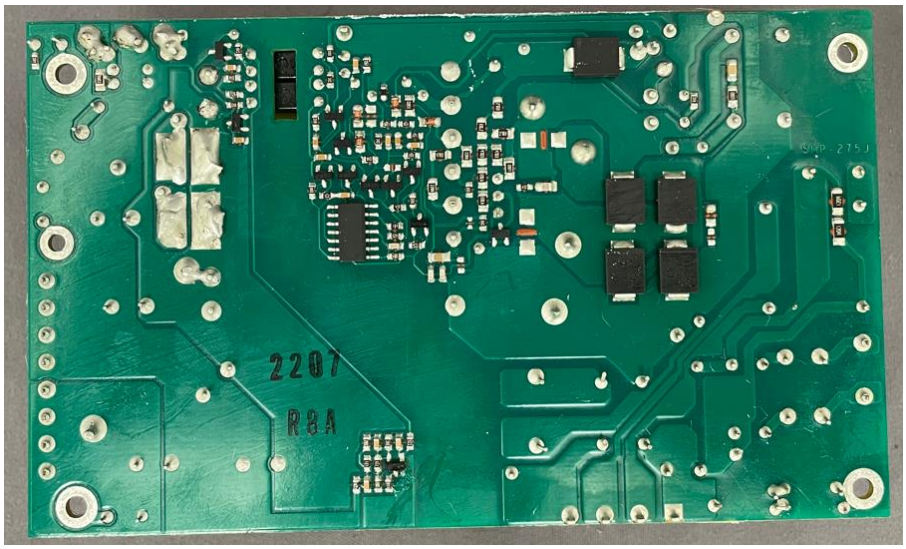
IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

SP	**TABLE: Additional or special tests conducted**	N/A

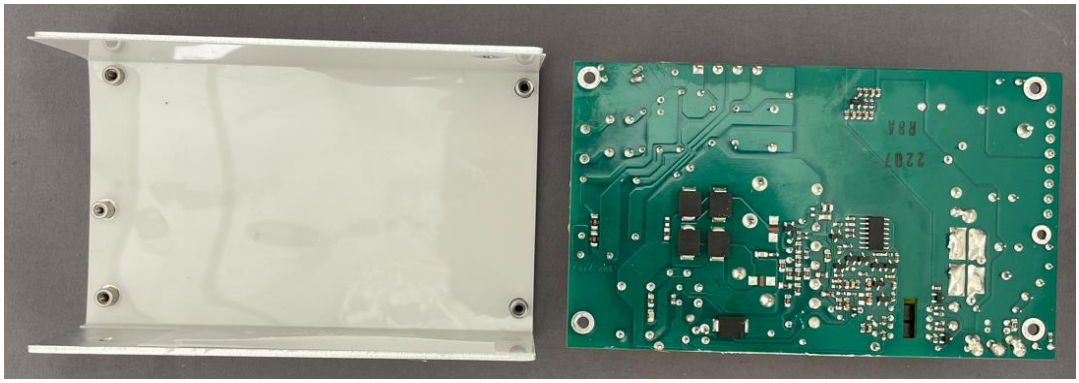
Clause and Name of Test	**Test type and condition**	**Observed results**
Supplementary information:		

ATTACHMENT TO IEC 60601-1 TEST REPORT – PICTURES OF THE APPLIANCE

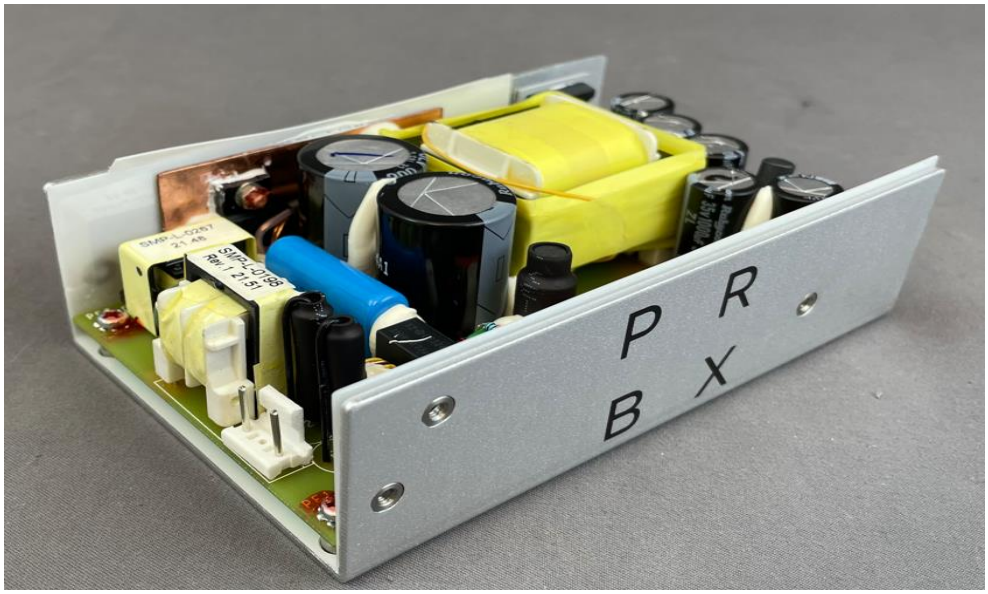
OFM225 5228: 24VDC: Top View



OFM225 5228: 24VDC: PCB - Bottom View



OFM225 5228: 24VDC: Internal View



OFM225 5228: 24VDC: Overview

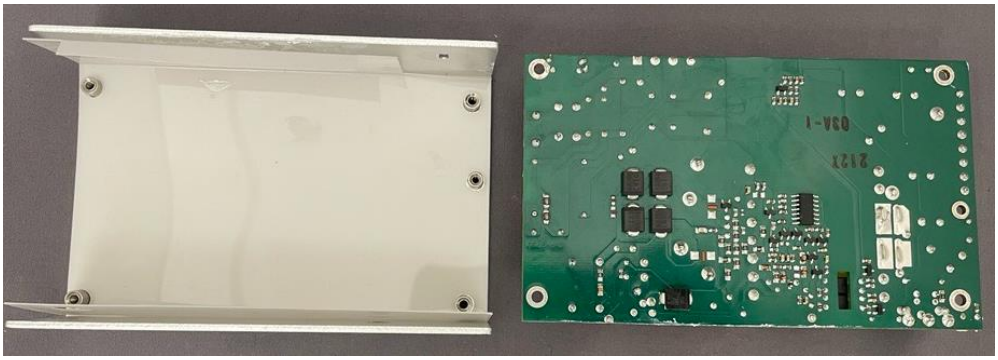
OFM225 5228: 24VDC: Overview

ATTACHMENT TO IEC 60601-1 TEST REPORT – PICTURES OF THE APPLIANCE

OFM225 5228: 24VDC: Dimensional View

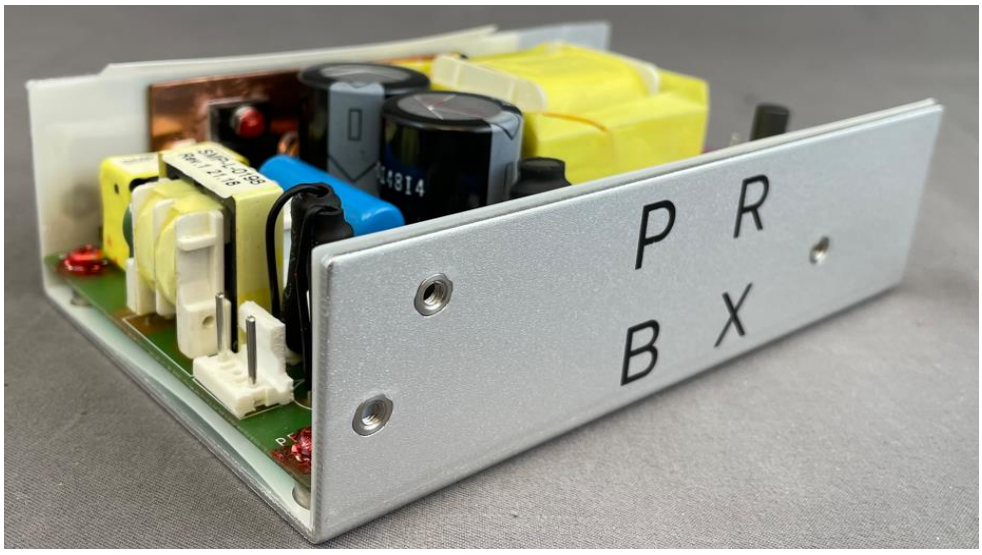
OFM225 5228: 24VDC: Dimensional View

OFM225 5225: 12VDC: Top View



OFM225 5228: 24VDC: Internal View

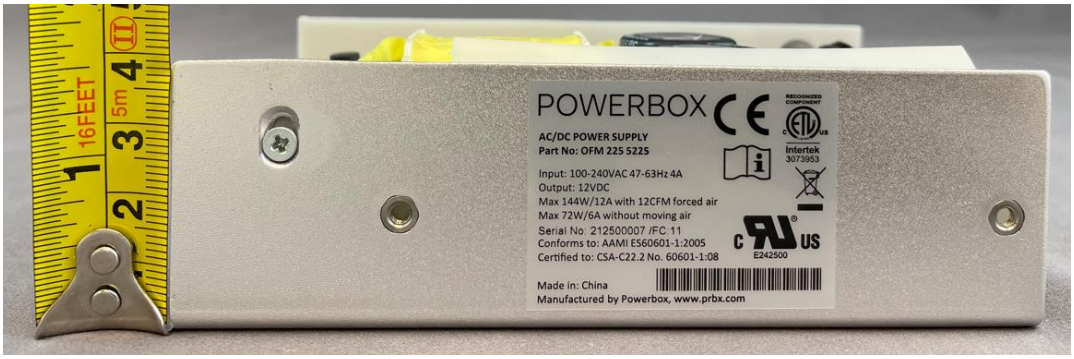
OFM225 5225: 12VDC: Overview



OFM225 5225: 12VDC: Overview

ATTACHMENT TO IEC 60601-1 TEST REPORT – PICTURES OF THE APPLIANCE

OFM225 5225: 12VDC: Dimensional View



OFM225 5225: 12VDC: Dimensional View

OFM225 5225: 12VDC: Dimensional View

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT

IEC 60601 1:2005, IEC 60601-1:2005/AMD1:2012

AND IEC 60601-1:2005/AMD2:2020

CANADA NATIONAL DIFFERENCES

MEDICAL ELECTRICAL EQUIPMENT — PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE

Differences according to.....:	Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
TRF template used: ..... :	IECEE OD-2020-F3, Ed. 1.1
Attachment Form No. .....:	CA_ND_IEC60601_1U
Attachment Originator .....:	CSA Group (CA)
Master Attachment .....:	Dated 2022-08-08

Note *: IEC CANADIAN NATIONAL DIFFERENCES in Canada are called CANADIAN DEVIATIONS.

	Canadian National Differences		P
1	**Scope, object and related standards**		P
1.1	**Scope**		P
	[Replace the first paragraph with the following] This Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be used in accordance with CSA C22.1 (Canadian Electrical Code, Part I) and CSA Z32.		P
	[Add the following note] Note 1A: In the IEC 60601 Standards series adopted for use in Canada, the Canadian standards may modify, replace, or delete requirements contained in the IEC standard as appropriate to the ME EQUIPMENT and ME SYSTEMS under evaluation, and they may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements		---
1.3	**Collateral standards**		P
	[Replace this clause with the following] Applicable Canadian 60601 collateral standards become normative at the date of their publication and apply together with this Standard.		P

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict

1.4	**Particular standards**		P
	[Replace this clause with the following] Applicable Canadian 60601/80601 particular standards may modify, replace, or delete requirements contained in this Standard. The requirement of a Canadian 60601/80601 particular safety standard takes priority over this Standard.		P
2	**Normative references**		P
	In this CSA Group adoption, any reference to International Standards shall be replaced by the relevant National Standard of Canada. **Note 1DV:** *For additional information about normative Standards in Canada, refer to the* Canadian Electrical Code, Part I, *Appendix A.* Where reference is made to CSA Group Standards, such reference are considered to refer to the latest edition and all amendments published to that edition. This Standard refers to the following Standards, and the years shown indicate the latest editions available at the time of printing: **CSA Group** B51-09 Boiler, pressure vessel, and pressure piping code C22.1-21 Canadian Electrical Code, Part I C22.2 No. 0:20 General requirements — Canadian Electrical Code, Part II C22.2 No. 0.4-17 *Bonding of electrical equipment* C22.2 No. 21-95 (R2009) Cord sets and power supply cords C22.2 No. 42-10 General use receptacles, attachment plugs, and similar wiring devices C22.2 No. 49-10 Flexible cords and cables C22.2 No. 100:14 (R2019) *Motors and generators* C22.2 No. 248 series of Standards Low-voltage fuses C22.2 No. 308-18 Cord reels and multi-outlet assemblies		P

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
	CAN/CSA-E61558-2-1-03 (R2012) Safety of power transformers, power supply units and similar — Part 2: Particular requirements for separating transformers for general use CSA C22.2 No. 62368-1:19 Audio/video, information and communication technology equipment — Part 1: Safety requirements Z32-09 Electrical safety and essential electrical systems in health care facilities CAN/CSA-Z305.8-03 (R2013) Medical supply units Z305.12-06 (R2012) Safe storage, handling, and use of portable oxygen systems in residential buildings and health care facilities Z305.13-09 Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings CAN/CSA-Z5359-10 Low-pressure hose assemblies for use with medical gases CAN/CSA-Z9170-1-11 Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases, vacuum, and anaesthetic gas scavenging systems CAN/CSA-Z10524-1:12 Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices CAN/CSA-Z15002:12 Flow-metering devices for connection to terminal units of medical gas pipeline systems **ASME (American Society of Mechanical Engineers)** PTC 25-2008 Pressure Relief Devices **CGA (Compressed Gas Association)** V-1-2013 Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections V-5-2008 (reaffirmed 2013) Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications) **ISO (International Organization for Standardization)** 32:1977 Gas cylinders for medical use — Marking for identification of content 407:2004 Small medical gas cylinders — Pin-index yoke-type valve connections		

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
	9170-2:2008 Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems		
3	**Terminology and definitions**		P
3.41	**HIGH VOLTAGE**		P
	[Replace this Clause in the Canadian deviations in the adopted Standard with the following] voltage above 1000 V ac for ac circuits or voltage above 1060 V dc for dc circuits, as defined in the *Canadian Electrical Code, Part I*	Noted	P
4.	**General requirements**		P
4.1A	*[Add the following clause]* General requirements applicable to ME EQUIPMENT and ME SYSTEMS are provided in CAN/CSA-C22.2 No. 0.		P
4.8	**Components of ME EQUIPMENT**		P
	[Replace Items a) and b) and Note 2 with the following]		P
	a) The applicable safety requirements of a relevant CSA Group, IEC, or ISO Standard; or		P
	b) where there is no relevant CSA Group, IEC, or ISO Standard, the requirements of this Standard shall be applied		P
	Note 2: If there are neither requirements in this Standard nor in a CSA Group, 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**		P
	[Replace the first sentence with the following] ME EQUIPMENT intended to be connected to SUPPLY MAINS shall be in accordance with the Canadian Electrical Code, Part I, and the following RATED voltages shall not be exceeded:		P
7.	**ME EQUIPMENT identification, marking and documents**		N/A
7.5	**Safety signs**		N/A
	[Replace the paragraph starting with "When supplementary text" in IEC Amendment 1 with the following] When supplementary text is placed together with safety signs, the supplementary text shall be in English and French for the intended OPERATOR.		N/A
7.7	**Colours of the insulation of conductors**		N/A

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict

7.7.1	**PROTECTIVE EARTH CONDUCTOR**		P
	[Replace Clause 7.7.1 in the adopted Standard with the following] A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green or green and yellow coloured insulation.	Shall be evaluated in end-use application	N/A
7.7.2	**PROTECTIVE EARTH CONNECTIONS**		N/A
	[Replace Clause 7.7.2 in the adopted Standard with the following] A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION of any insulation on conductors shall be identified by either green or green and yellow colours at least at the termination of the conductors.	Shall be evaluated in end-use application	N/A
7.7.3	**Green or green and yellow insulation**		N/A
	[Replace Clause 7.7.3 in the adopted Standard, as modified by IEC Amendment 1, with the following]		N/A
	Identification by green or green and yellow insulation shall only be used for:		N/A
	- PROTECTIVE EARTH CONDUCTORS (see Clause 8.6.2);		N/A
	- conductors as specified in Clause 7.7.2; **Note:** In other safety Standards such as CSA C22.2 No. 62368-1, internal connections between conductive parts and the main protective earth are called "protective bonding conductors".	Shall be evaluated in end-use application	N/A
	- POTENTIAL EQUALIZATION CONDUCTORS (see Clause 8.6.7);		N/A
	- FUNCTIONAL EARTH CONDUCTORS (see Clause 8.6.9).		N/A
7.7.4	**Neutral conductor**		N/A
	[Replace Clause 7.7.4 in the adopted Standard with the following] Colours of neutral conductors and POWER SUPPLY CORD conductors shall be in accordance with the *Canadian Electrical Code, Part I*, CSA C22.2 No. 21, and CSA C22.2 No. 49.	Shall be evaluated in end-use application	N/A
7.7.5	**POWER SUPPLY CORD conductors**		N/A
	[Replace Clause 7.7.5 in the adopted Standard with the following] Colours of conductors in POWER SUPPLY	Shall be evaluated in end-use application	N/A

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
	CORDS shall be in accordance with the Canadian Electrical Code, Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49.		
	Compliance with the requirements of Clause 7.7 is checked by inspection.		N/A
7.9	**ACCOMPANYING DOCUMENTS**		P
7.9.2.1	**General**		P
	[Replace the last paragraph in the adopted Standard with the following] The instructions for use shall be in English and French for the intended OPERATOR.	As per the intended application PSU will be used and installed by service personals. Therefore, English version is sufficient.	N/A
8	**Protection against electrical HAZARDS from ME EQUIPMENT**		P
8.6	**Protective earthing, functional earthing and potential equalization of ME EQUIPMENT**		P
8.6.4	**Impedance and current-carrying capability**		N/A
	[Replace Clause 8.6.4 in the adopted Standard, as modified by IEC Amendments 1 and 2, with the following]		N/A
	PROTECTIVE EARTH CONNECTIONS shall be able to carry fault currents reliably and without excessive voltage drop.	Shall be evaluated in end-use application	N/A
	Impedance and current-carrying capability shall comply with CSA C22.2 No. 0.4.		N/A
	For PERMANENTLY INSTALLED ME EQUIPMENT and ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, the impedance between the PROTECTIVE EARTH TERMINAL (inside the ME EQUIPMENT) and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ. For ME EQUIPMENT with an APPLIANCE INLET, the impedance between the earth pin of the APPLIANCE INLET and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ……..:		N/A
	In addition to the test above, for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD or any DETACHABLE POWER SUPPLY CORD (supplied or specified by the MANUFACTURER), the impedance between the protective earth pin of the MAINS PLUG and the PROTECTIVE EARTH TERMINAL (inside the ME EQUIPMENT) shall not exceed 100 mΩ…….:		N/A
	Where an APPLIANCE INLET forms the supply connection to ME EQUIPMENT, the earth pin of the APPLIANCE INLET is regarded as the PROTECTIVE EARTH TERMINAL. The combined testing requirements above are equivalent to 200 mΩ impedance testing requirements as described in IEC 60601-1.		N/A

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
	Separate testing is required to comply with CSA C22.2 No. 0.4.		
	Testing shall be carried out using a DETACHABLE POWER SUPPLY CORD as provided or specified (length and cross-sectional area as per the Canadian Electrical Code, Part I) by the MANUFACTURER.		N/A
	The test current shall have the following characteristics: — for cord-connected equipment, twice the rating of the attachment plug cap, but not less than 40 A; — for equipment for permanent connection to the supply, twice the rating of the fuse that is required by the *Canadian Electrical Code*, *Part I* for the branch circuit to which the equipment is connected, up to 250 A; and — 500 A for equipment for permanent connection to the supply when a branch circuit fused at over 250 A is required.		N/A
	Compliance is checked by the following test: — for test currents up to 500 A, the measured potential drop shall not exceed 4 V; — for equipment that requires branch circuit fusing over 250 A, the measured potential drop multiplied by the required fusing and divided by 250 shall not exceed 4 V; — there shall be no melting of any metal in the bond and no heating or burning that is likely to create a fire hazard; and — the time duration— the time duration for testing is indicated in Table 8.6.4A:		N/A
	Table 8.6.4A **Time duration of impedance test current** **Fusing of branch circuit required for equipment (A)** / **Time (min)** 0–30 / 2 31–60 / 4 61–100 / 6 101–200 / 8 201 and over / 10 **Note:** *Additional information can be found in CSA C22.2 No. 0.4.*		N/A
	Interchangeablely, dc may be used for this test, if the ME EQUIPMENT is rated dc.		N/A
	Note: When protective earth is relied on as a MEANS OF PROTECTION, the test current is determined based on the location where a fault could occur. If the prospective fault is in the mains supply circuit prior to the overcurrent protection included in the ME EQUIPMENT, the test current for that part of the protective earth circuit is based on the rating of the external overcurrent protection included in the building infrastructure or specified in the ACCOMPANYING DOCUMENTS (two times the interrupt rating of the external overcurrent protection). If the prospective fault is in the mains		N/A

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
	supply circuit after the overcurrent protection included in the ME EQUIPMENT, the test current is based on the rating of the overcurrent protection included in the ME EQUIPMENT (two times the interrupt rating of the ME EQUIPMENT overcurrent protection). In either case, the minimum test current is 40 A. The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop. If the measured impedance is within the permitted limit, either the impedance measurement is then repeated using a current source with a no-load voltage sufficient to deliver the specified current into the total impedance, or the current-carrying ability of the relevant protective earth conductor and protective earth connection is confirmed by checking that their cross-sectional area is at least equal to that of the relevant current-carrying conductors.		
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		P
8.7.3	**Allowable values**		P
	[Add the following paragraph] Allowable values shall be in accordance with the Canadian Electrical Code, Part I.		P
8.11	**MAINS PARTS, components and layout**		N/A
8.11.3.2	**Types**		N/A
	[Replace this clause with the following]		N/A
	The following requirements for POWER SUPPLY CORDS shall apply:		N/A
	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENt shall be:		N/A
	i) if moulded-on type, a hospital-grade mains plug complying with CSA C22.2 No. 21;		N/A
	ii) a hospital-grade disassembly attachment plug type complying with CSA C22.2 No. 42; or		N/A
	iii) Class II equipment having fuses on the line side(s), and the neutral may use a non-polarized attachment plug or a polarized attachment plug. CSA configuration type 1-15P shall be required and meets 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 is 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

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
	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) A detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type:		N/A
	i) that 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;		N/A
	ii) for which it 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) that 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) The detachable POWER SUPPLY CORD shall:		N/A
	i) comply with the applicable requirements of CSA C22.2 No. 21; and		N/A
	ii) not be smaller than No. 18 AWG, and the mechanical serviceability is not less than:		N/A
	1) Type SJ or equivalent for ME EQUIPMENT that is mobile or exposed to abuse; and		N/A
	2) Type SV or equivalent for ME EQUIPMENT that is not exposed to abuse (or Type HPN if required because of temperature). **Note:** See CSA C22.2 No. 49 for requirements for the cord types mentioned in Sub-item 2).		N/A
	d) Installation of POWER SUPPLY CORDS shall meet the requirements of the Canadian Electrical Code, Part I, as applicable.		N/A
	[Add the following to this Canadian deviation in the adopted Standard] The POWER SUPPLY CORD used with the ME EQUIPMENT shall be in accordance with the temperature rating to which it has been RATED. **Note 1DV:** Refer to the Canadian Electrical Code, Part I, Tables 11 and 12 for additional information.		N/A
	Compliance is checked by inspection and measurement……..:		N/A
8.11.3.3	**Cross-sectional area of POWER SUPPLY CORD conductors**		N/A
	[Replace Clause 8.11.3.3 in the adopted Standard, as modified by Amendment 2, with the following] The NOMINAL cross-sectional area of conductors of any POWER SUPPLY CORD of ME EQUIPMENT shall be not less than the requirements of the Canadian Electrical Code,		N/A

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
	Part I, and CSA C22.2 No. 21. **Note:** Table 17 can be used for European countries or other countries where the nominal cross-sectional area is measured in mm2 (HAR); American Wire Gauge (AWG) is the nominal cross-sectional area used in Canada as per the Canadian Electrical Code, Part I.		
	Compliance is checked by inspection……..:		N/A
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		P
	[Replace Clause 8.11.5 in the Canadian deviations in the adopted Standard with the following] Installation of overcurrent protective devices shall be in accordance with the Canadian Electrical Code, Part I		P
9	**Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS**		P
9.7	**Pressure vessels and parts subject to pneumatic and hydraulic pressure**		N/A
9.7.5	**Pressure vessels**		N/A
9.7.5	*[Replace this clause with the following]* Pressure vessels shall comply with the requirements of CSA B51, as applicable		N/A
9.7.7	**Pressure-relief device**		N/A
	[Add the following as the first paragraph of this Clause] A pressure-relief device shall comply, as applicable, with the requirements of ASME PTC 25 or equivalent Canadian requirements.		N/A
13	**HAZARDOUS SITUATIONS and fault conditions**		P
13.2	**SINGLE FAULT CONDITIONS**		P
13.2.9	**Interruption and short circuiting of motor capacitors**		N/A
	[Replace the second paragraph of the compliance statement in the adopted Standard with the following] The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor that complies with IEC 60252-1 or is included as part of the evaluation of the motor in accordance with CSA C22.2 No. 100, and the ME EQUIPMENT is not intended for unattended use (including automatic or remote control).		N/A
	For additional test criteria, see Clause 13.2.10.		N/A
15	**Construction of ME EQUIPMENT**		P

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict

15.4	**ME EQUIPMENT components and general assembly**		P
15.4.1	**Construction of connectors**		P
	[Add the following item]		
	bA) The point of connection of gas cylinders to ME EQUIPMENT is gas-specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on ME EQUIPMENT shall be:		N/A
	i) gas-specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1380 kPa (200 psi); or		N/A
	ii) DISS type complying with CGA V-5 for pressures 1380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359		N/A
	Note: Users of this Standard should consult the CSA Z305 series of Standards, CAN/CSA-Z9170-1, ISO 9170-2, 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**		P
	[Replace this Clause with the following]		
	Internal wiring of ME EQUIPMENT shall be in accordance with the Canadian Electrical Code, Part I.		P
	Except for flexible cord, equipment wire, control circuit insulated conductors, and cable, insulated conductors shall be not smaller than No. 14 AWG when made of copper and not smaller than No. 12 AWG when made of aluminum. **Note 1:** See the Canadian Electrical Code, Part I, Rule 4-002.	Evaluated in end-use application	N/A
	The maximum current that an equipment wire of a given size may carry shall be as specified in Table 12 of the Canadian Electrical Code, Part I. **Note 2:** For additional information refer to the Canadian Electrical Code, Part I, Rule 4-014.		N/A
15.5	**MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5**		P
15.5.1.3	**Overload test**		P
	[Replace the second and third dashed items of Item b) of Clause 15.5.1.3 in the adopted Standard with the following]		P
	- Fuses not in accordance with IEC 60127-1 but in accordance with the CSA C22.2 No. 248 series of Standards: 30 min at the current according to the characteristics supplied by the fuse manufacturer, specifically the 30 min clearing-time current. If no	Fuses certified according to CSA C22.2 No. 248.1	P

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Clause	Requirement + Test	Result - Remark	Verdict
	30 min clearing-time current data is available, the test current from Table 32 is used until THERMAL STABILITY is achieved.		
	- Other protective device as per the Canadian Electrical Code, Part I: until THERMAL STABILITY at a current just below that which caused the device to operate in Item a).		N/A
	This portion of the overload test is concluded at the specified time or when a second protective device opens.		N/A
16	**ME SYSTEMS**		N/A
16.1	**General requirements for the ME SYSTEMS**		N/A
	*[Replace the paragraph that starts with "*An ME SYSTEM shall provide:*" with the following]*		N/A
	An ME SYSTEM shall be provided:		N/A
	- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this CSA Group Standard; and		N/A
	- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA Group, IEC, or ISO safety Standards.		N/A
	[Replace the third-last paragraph with the following] Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with the CSA Group, IEC, or ISO safety Standards that are relevant to that equipment.		N/A
16.9	**ME SYSTEM connections and wiring**		N/A
16.9.2.1	**MULTIPLE SOCKET-OUTLET**		N/A
	[Replace the first sentence of Item c) of Clause 16.9.2.1 in the adopted Standard with the following]		N/A
	c) The MULTIPLE SOCKET-OUTLET shall comply with CSA C22.2 No. 308 as applicable and the following requirements.		N/A
	[Add the following note to Item d) in the Canadian deviations in the adopted Standard]		N/A
	d) If the MULTIPLE SOCKET OUTLET is combined with a separating transformer, the following additional requirements shall apply:		N/A
	The separating transformer complies with this Standard.		N/A
	Interchangeablely, the separating transformer may comply with the requirements of CAN/CSA-E61558-2-1, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply.		N/A
	Note 1: As a separating transformer is not a MAINS SUPPLY TRANSFORMER, it does not require more than BASIC INSULATION. Note 2: Limitation of output power is not explained in CAN/CSA-E61558-2-1 and		N/A

ATTACHMENT TO IEC 60601-1 TEST REPORT – CANADA NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
	the RATED output power is defined by the fuse in the installation and by the allowable power supply cable used. However, the characteristics of the separating transformer need to be carefully selected, taking into account the variations in the load current of the ME SYSTEM to ensure that the voltage supplied to the various items of the ME SYSTEM remains within the limits specified for the equipment. Note 3: For additional details refer to the Canadian Electrical Code, Part I, Diagrams 1 and 2.		
	The separating transformer assembly shall be a CLASS I construction.		N/A
	The degree of protection against ingress of water as given in IEC 60529 is specified.		N/A
	The separating transformer assembly shall be marked according to the requirements of 7.2 and 7.3.		N/A
	The MULTIPLE SOCKET OUTLET is permanently connected to the separating transformer or,		N/A
	The socket-outlet of the separating transformer assembly shall be of a type that cannot accept MAINS PLUGS of any of the kinds identified in Canadian Electrical Code, Part I (see Figure I.1 and Figure I.2 of this Standard)		N/A
	[Add the following item] dA) The MULTIPLE SOCKET OUTLET complies with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and Item d) of this Standard, as applicable.		N/A

ATTACHMENT TO IEC 60601-1 TEST REPORT – US NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict

ATTACHMENT TO TEST REPORT

IEC 60601-1
US NATIONAL DIFFERENCES
MEDICAL ELECTRICAL EQUIPMENT - PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE

Differences according to.....: National standard AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021

TRF template used: ..... : IECEE OD-2020-F3, Ed. 1.1

Attachment Form No. .....: US_ND_IEC60601_1U

Attachment Originator .....: UL(US)

Master Attachment .....: 2022-07-01

	National Differences		P
4.8	Components of ME EQUIPMENT		P
	b) where there is no relevant IEC/ISO standard, the relevant ANSI standard applied; if no relevant ANSI standard exists, the requirements of this standard were applied. (*Replacement of clause 4.8 b*)		P
4.10.2	SUPPLY MAINS FOR ME EQUIPMENT AND ME SYSTEMS		P
	(Replacement to reflect agreement with the National Electrical Code (NEC): The reference to "500 V" replaced with "600 V" in the second and third dashes.	Up to 240V	P
	(Addition to reflect agreement with the NEC) In the text of the second-to-last dash of this sub-clause, "and the NEC" added after reference to "IEC 60364-4-41"		P
6.0	**Classification of ME EQUIPMENT and ME SYSTEMS**		N/A
6.6	Mode of operation		N/A
	(Addition to reflect agreement with NFPA 70) X-Ray systems are classified as long time operation (> 5 min) or momentary operation (< 5 sec).		N/A
7.0	**ME EQUIPMENT identification, marking and documents**		P
7.2.11	Mode of operation		P
	(Addition to reflect agreement with NFPA 70) X-Ray systems are marked as long time operation or momentary operation.		N/A

ATTACHMENT TO IEC 60601-1 TEST REPORT – US NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.22	(*Addition of new item*) Colours of medical gas cylinders		N/A
	To reflect agreement with NFPA 99: Cylinders containing medical gases and their connection points are coloured in accordance with the requirements of NFPA 99.		N/A
8.0	**Protection against electrical hazards from ME EQUIPMENT**		P
8.2	Requirements related to power sources		P
	(Addition to reflect agreement with the NEC) All FIXED ME EQUIPMENT and PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT.	Not fixed or permanently installed	N/A
8.6.1	Application of requirements		N/A
	(Addition to reflect agreement with NFPA 99) The enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850 Vdc 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.		N/A
	(Addition to reflect agreement with NFPA 99) Non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized are PROTECTIVELY EARTHED		N/A
8.7.3	Allowable values		P
	(Deletion to reflect agreement with NFPA 99 which does not allow for allowance greater than the stated values) Delete the second sentence and note to sub-clause 8.7.3 d) so that it reads: d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION		P
8.11	MAINS PARTS, components and layout		P
	(Addition to reflect agreement with the NEC) Permanently connected ME EQUIPMENT has provision for the connection of one of the wiring systems that is in accordance with the NEC.		N/A
	Exception: Fixed and stationary X-ray ME EQUIPMENT supplied from a branch circuit rated at 30 A or less, and ME EQUIPMENT that is not strictly portable but obviously is intended to be stationary, may be acceptable if provided with a length of attached hard service flexible cord - such as Type S, or the equivalent, for supply connection.		N/A

ATTACHMENT TO IEC 60601-1 TEST REPORT – US NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
	The installation of connecting cords between EQUIPMENT parts meets the requirements of the NEC, as applicable. Cable used as external interconnection between units are as follows:		N/A
	1) If exposed to abuse, the cables are Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable		N/A
	2) If not exposed to abuse, the cables are as indicated in item 1) above or are: i) Type SPT-2, SP-2, or SPE-2, or equivalent, ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material, or iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, 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 or ME SYSTEMS for use in the patient care areas of paediatric wards, rooms, or areas are listed tamper resistant or employ a listed tamper resistant cover in accordance with the NEC.		N/A
	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 to reflect agreement with the NEC)* The flexible cord is of a type that is acceptable for the particular application. It is acceptable for use at a voltage not less than the rated voltage of the appliance and has an ampacity, as given in the NEC, not less than the current rating of the appliance.....:		N/A
8.11.3.3	Cross-sectional area of POWER SUPPLY CORDS		N/A
	(Addition to reflect agreement with NFPA 99) For X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug should be 2X the maximum input current of the equipment.		N/A
	1) If exposed to abuse, the cables are Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable.		N/A

ATTACHMENT TO IEC 60601-1 TEST REPORT – US NATIONAL DIFFERENCES			
Clause	Requirement + Test	Result - Remark	Verdict
	2) If not exposed to abuse, the cables are as indicated in item 1) above or are: i) Type SPT-2, SP-2, or SPE-2, or equivalent, ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material, or iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, 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 or ME SYSTEMS for use in the patient care areas of paediatric wards, rooms, or areas are listed tamper resistant or employ a listed tamper resistant cover in accordance with the NEC.		N/A
	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

ATTACHMENT TO IEC 60601-1 TEST REPORT – MEASUREMENT UNCERTAINTY

Statement concerning the measurement uncertainty and decision rules.

			Max overall uncertainty k=2
Voltage	≤ 7000V	DC	±0,5%
	≤ 1500V	45Hz - 66Hz	±4,6%
	1500V – 4000V	45Hz - 66Hz	±3,3%
Current	50mA - 63A	DC	±0,7%
	50mA - 63A	10-45Hz	±0,8%
	50mA - 63A	45-66 Hz	±0,4%
	50mA - 63A	66-1000Hz	±0,8%
	50mA - 63A	1-10 kHz	±0,9%
	50mA - 63A	10-50 kHz	±1,6%
Resistance	< 200mΩ		±2,0%
	200mΩ - 20Ω		±0,7%
	> 20 Ω		±0,2%
	2mΩ - 20kΩ	Four-wire resistance	±1,2%
Electric power	≤ 3kW	DC	±1,4%
		10-45 Hz	±1,6%
		45-65 Hz	±0,7%
		66Hz-1kHz	±1,6%
		1-10kHz	±2,0%
		10-20kHz	±3,6%
		20-50kHz	±3,8%
	≥ 3kW	45 Hz ≤f ≤66 Hz	±0,4%
Electric power (precision power meter)	≤ 3kW	45 Hz ≤f ≤66 Hz	±0,2%
Oscilloscopes	peak value	1mV – 35 V	±3,8%
		35 V – 7kV	±4,4%
Leakage current	0- 30mA	10Hz-1MHz	±11,8%
Temperature	-40 ≤ 900°C		±3,8°C
Enviroment Kista	23°C ±5°C		±2,7°C
Linear dimensions			
Micrometer	0 - 25mm		±0,1%
Caliper	0 - 150mm		±0,1%
Meas. tape	5m		±0,1%
Steel rule	1m		±0,2%
Gauge rods (Inst. of caliper)	≤10mm		±1,2%
Mass, scale resolution	Resolution 0,001g		±0,02g
	Resolution 0,01g		±0,1g
	Resolution 0,1g		±0,5g
	Resolution 1g		±4,8g
Relative humidity, Kista	10-95%RH		±6,5%
Time	100ms – 1s		±1,3%
	> 1s – 1min		±2,0%
	> 1min		±3,2%
Ph value	4-7Ph		±0,1Ph
Flow	l/min		±8,4%
Pressure	Pa		±3,3%

Revision: 2022-06-10

Decision rule applied

"Simple Acceptance" rule, also called "Shared Risk Approach" of ILAC-G8:09/2019 guide

The statements of conformity are reported as:

Passed – When the measured values are within the specified limits

Failed – When one or more measures values are outside the specified limits