TÜVINDIA

TC-5237

Report Number : TUV/PTL/24-25/SFTY/0066
ULR NUMBER : TC523724000000155F

Date of issue : 26 August 2024

TEST REPORT

Highness Microelectronics Pvt. Ltd

JOB CARD NUMBER: TUV/24-25/SFT/0069
JOB ORDER NUMBER: 8122831148

This test report consists of 127 pages including this cover letter

TESTING LABORATORY:

TUV INDIA PVT. LTD.

ANJANI PALLADIUM, 203 & 204, SECOND FLOOR AND MEZZANINE FLOOR, 104B, SURVEY NO.126/1, BANER MAIN ROAD, BANER, PUNE 411045, MAHARASHTRA, INDIA.
TEL NO: + (91) 20-67113116
EMAIL ID: bekomal@tuv-nord.com
WEBSITE: www.tuv-nord.com

SERVICE REQUESTED BY:

Highness Microelectronics Pvt. Ltd
1C3, Gundecha Onclave, Sakinaka, Mumbai-400072
TEL NO: 022-28507123/ 09619797252
EMAIL ID: gaurav@highnessmicro.com/ Manasvichavan@highnessmicro.com.

REPORT ISSUED TO:

Highness Microelectronics Pvt. Ltd
R-364, TTC industrial area, Rabale, Mumbai-400701 India.
TEL NO: 022-28507123/ 09619797252
EMAIL ID:
kalpeshtambe@highnessmicro.com/ kushalvishwakarma@highnessmicro.com.

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DISCIPLINE: ELECTRONICS
GROUP: MEDICAL ELECTRICAL EQUIPMENT

Product details:

Test item :	10.1" MEDICAL GRADE HAND HELD COMPUTER		
Model Number:	TB101WX001		
Serial No. :	2425TB101WX001-003		
Trademark:	HIGHNESS™		
Make:	**Highness Microelectronics Pvt. Ltd**		
Sample ID:	TUV/PU240807-008		
Number of Samples:	1		
Date of receipt:	7 August 2024		
Condition of EUT on receipt:	Good		
Applicable Standard/ test specification/ regulations:	IEC 60601-1:2005+AMD1:2012+AMD2:2020 2020 (See summary of test result on page No. 06 of 127 of this test report)		
Test Result:	The test item Passed / ~~Failed~~ the test specification(s)		
Declaration of Conformity:	Declaration of conformity of results is based on as per standard limits or criteria.		
Other Aspects:	This test report relates to the test sample submitted only.		
Testing (Start date):	7 August 2024	**End Date**	23 August 2024
Laboratory Ambient Condition :	**Temperature in °C**		(25 ± 3)°C
	Relative humidity in %		(45 to 75) %RH
	Atmospheric pressure in Hpa (If applicable)		(940 to 950) hPa
Date of Issue:	26 August 2024		

Approved By :	**Issued by:**
Mr. Manish Bokade **(AVP – Product Testing Lab)**	**Komal Behaniya** **(Customer Support Engineer)**
Date : 26 August 2024	**Date : 26 August 2024**

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Product Ratings : (#)	Rated I/P voltage and current: 12V DC 5A powered by certified adapter (i.e. Voltage 100-240V AC, Current: 1.5A); Degree of protection: IP20.	
EUT Environment : (#)	operating temperature range: (-20 to +50) °C Relative humidity range: 10% to 90% RH	
Photographs Pages:	Section 6: Photographs of Equipment Under Test (Page No. 126-127)	
Any other Document attached:	N/A	
Test witnessed by (If any):	N/A	
☒ **Testing Laboratory :**	**TUV India Private Limited**	
Testing location/ address :	ANJANI PALLADIUM, 203 & 204, SECOND FLOOR AND MEZZANINE FLOOR, 104B, SURVEY NO.126/1, BANER MAIN ROAD, BANER, PUNE 411045, MAHARASHTRA, INDIA	
Tested by :	**Mr. Akash Chavan (Test Engineer Safety)**	
Reviewed & Authorized by :	**Mr. Praveen Kumar Mishra (Assistant Manager-Safety)**	
Approved By :	**Mr. Manish Bokade (AVP – Product Testing Lab)**	

Note: - # marks represents the details Specified / given by Customer only.
TUV India Private Limited has the following Accreditations/ Recognition:

S.R. No	Accreditation Bodies	Certificate Number
1	National Accreditation Board for Testing and Calibration Laboratories Combined ILAC MRA Mark	TC-5237
2	Bureau of Indian Standards (BIS)	OSL- 7139026
3	Telecommunication Engineering Center (TEC)	TEC/MRA/CAB/IND-D/51

Disclaimer

1. The Released Test Report/s relates ONLY to the specific sample/s submitted for testing and under the stated conditions
2. Any corrections/erasures invalidate the Test Reports. TUV India does not accept any liability whatsoever for the tampering or any unlawful or inadvertent alteration of documents that have been handed over to the Customer.
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8. For any Complaints / Suggestions please email to: bekomal@tuv-nord.com

Reviewed & Authorized by:

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Section 1: Description of equipment under Test: (#)

Medical grade computer for machine control and navigation.

Copy of Marking Label:

Reviewed & Authorized by:

Section 2: Test items particulars	
Test item particulars (see also Clause 6) .....:	Highness Microelectronics Pvt. Ltd.
Classification of installation and use ..... :	~~transportable /~~ portable / ~~stationary~~ / ~~mobile~~ / ~~fixed~~ / ~~permanently installed~~ / ~~hand-held, body-worn~~
Supply Connection.....:	~~Internally powered /permanently installed / appliance coupler / non-detachable cord/~~ Detachable cord with Adaptor
Device type (component/sub-assembly/ equipment/ system).....:	ME Equipment with adaptor.
Intended use (Including type of patient, application location) .....:	Refer Description of Equipment under Test section 1 of this test report
Mode of operation .....:	Continuous / ~~non-continuous~~
Other options include.....:	None
Testing	
Date of receipt of test item(s).....:	07/08/2024
Dates tests performed .....:	07/08/2024 – 23/08/2024
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement.....:	Pass (P)
- test object whose information is not available.....:	NA
- test object was not evaluated for the requirement..... :	N/E (collateral standards only)
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
normal condition.....: N.C.	single fault condition.....: S.F.C.
means of Operator protection .....: MOOP	means of Patient protection .....: MOPP
Instruction for use Manual.....: IFU	Risk management review file ....: RMF
Special Test.....: SP	Equipment under test.....: EUT
General remarks: "(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report. **Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**	

Technical Testing Services TUV India

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Section 3: Summary of Test Results

Test No.	Test Parameter	Standard & Clause Number	Result
1.	Power Input	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 4.11)	Pass
2.	Humidity preconditioning.	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 5.7)	Pass
3.	ACCESSIBLE parts	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 5.9.2)	Pass
4.	Legibility and Durability of markings	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 7.1. 2 and Cl. 7.1.3)	Pass
5.	Means of protection (MOP)	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 8.5.1)	Pass
6.	Working Voltage	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 8.5.4)	Pass
7.	leakage currents and patient auxiliary currents	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 8.7)	Pass
8.	Dielectric strength	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 8.8.3)	Pass
9.	CREEPAGE distances and AIR CLEARANCES	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 8.9)	Pass
10.	Instability – Overbalance	IEC 60601-1:2005+AMD1:2012+AMD2:2020 (Cl. 9.4.2)	Pass
11.	Excessive temperatures in me equipment	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 11.1.1)	Pass
12.	Cleaning and disinfection of ME equipment	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 11.6.6)	Pass
13.	Hazardous situations and fault conditions	IEC 60601-1:2005+AMD1:2012+AMD2 :2020 (Cl. 13)	Pass
14.	Mechanical strength test	IEC 60601-1 : 2005 + AMD1 :2012 + AMD2 :2020 (Cl. 15.3)	Pass
☒ **The product fulfils the requirements of IEC 60601-1:2005+AMD1:2012+AMD2:2020 as specified in summary of test result table above.**			

Reviewed & Authorized by:

Section 4: Equipment used during the tests:

Serial No.	Test Equipment	Unique Equipment ID	Calibration Due Date
1.	Digital power meter	TUV/PTL/SAFETY/217	07/05/2025
2.	Thermohygrometer	TUV/PTL/SAFETY/260	17/05/2025
3.	Stability tester	TUV/PTL/SAFETY/229	-
4.	Level box	TUV/PTL/SAFETY/229-1	21/05/2025
5.	Electrical Safety Analyser	TUV/PTL/SAFETY/258	07/05/2025
6.	Crush Tester	TUV/PTL/SAFETY/350	19/05/2025
7.	Test Probe 'B'	TUV/PTL/SAFETY/276	08/05/2025
8.	Test hook	TUV/PTL/SAFETY/288	07/05/2025
9.	Oscilloscope 500 MHz, 4 Ch	TUV/PTL/SAFETY/224	08/05/2025
10.	high voltage probe	TUV/PTL/SAFETY/224-2	08/05/2025
11.	Leak Current Tester	TUV/PTL/SAFETY/255	05/12/2024
12.	Data Logger	TUV/PTL/SAFETY/223	07/05/2025
13.	Climatic Test Chamber	TUV/PTL/SAFETY/301	08/08/2025
14.	Stop Watch	TUV/PTL/SAFETY/267	20/05/2025
15.	Digimatic Vernier Caliper	TUV/PTL/SAFETY/242	07/05/2025
16.	Impact ball	TUV/PTL/SAFETY/339	08/05/2025
17.	6.5 Digital multimeter	TUV/PTL/SAFETY/225	07/05/2025
18.	Vertical and flammability tester V0-V1	TUV/PTL/SAFETY/329	08/05/2025
19.	Force gauge	TUV/PTL/SAFETY/237	19/05/2025
20.	Test finger probe	TUV/PTL/SAFETY/299	21/05/2025

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

Section 5: Tests

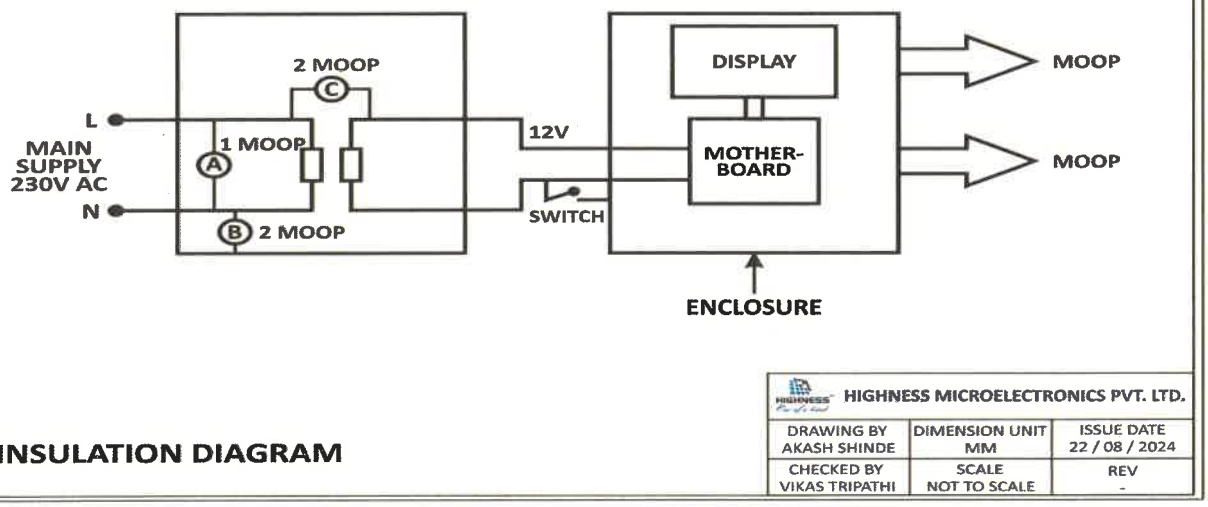
INSULATION DIAGRAM

TABLE: INSULATION DIAGRAM		P
Pollution degree .....:	**2**	—
Overvoltage category .....:	**1**	—
Altitude.....:	**Altitude ≤ 2000 m**	—
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**	**Working voltage**		**Required creepage (mm)**	**Required clearance (mm)**	**Measured creepage (mm)**	**Measured clearance (mm)**	**Remarks**
			V_{rms}/Vdc	**V_{pk}**					
A	1MOOP	IIIb	240 V_{rms}	-	2.0	2.0	12.24	12.24	Between Line and neutral at Power adaptor side.
B	1MOOP	IIIb	240 V_{rms}	-	2.0	2.0	5.40	5.40	Between Line/Neutral to Adaptor body
C	2MOOP	IIIb	12 V DC	-	0.8	0.8	25.97	7.88	Between +ve and –ve terminal at connector at EUT side.

Supplementary Information: Area A, B, C are shown in insulation diagram below

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



Insulation Diagram

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**	The ME equipment is tested in normal use and reasonable foreseeable misuse	**P**
4.2	**RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS**		**P**
4.2.2	General requirement for risk management - process complies with ISO14971 (2019).....:	See Appended RM Results Table 4.2.2.	P
4.2.3	Evaluating risk		P
4.2.3.1	a) Compliance with the standard reduces residual risk to an acceptable level	All the risks are reduced to acceptable level, complies the standard requirements	P
	b) Manufacturer has defined risk acceptability criteria in the risk management plan..... :	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
	c) When no specific technical requirements provided manufacturer has determined hazards or hazardous situations exists.	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
	- hazards or hazardous situations have been evaluated using the risk management process.	Evaluated	P
4.2.3.2	manufacturer has addressed hazards or hazardous situations not specifically addressed in the IEC 60601-1 series.	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
4.3	Performance of clinical functions necessary to achieve intended use or that could affect the safety of the me equipment or me system were identified during risk analysis.	See below	p
	- Performance limits were identified in both normal condition and single fault condition.	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
	- Loss or degradation of performance beyond the limits specified by the manufacturer were evaluated	EUT evaluated as per IEC 60601-1 standard	P
	- Functions with unacceptable risks are identified as essential performance.....:	Essential performance defined in risk management report	P
	- Risk control measures implemented	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	- Methods used to verify the effectiveness of risk control measures implemented	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
4.4	Expected service life stated in risk management file.....:	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
4.5	Alternative RISK CONTROL methods utilized:	See below	P
	residual risk resulting from the alternative risk control measures or tests is acceptable and comparable to residual risk resulting from application of this standard.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
	Alternative means based scientific data or clinical opinion or comparative studies .....:	See above	P
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 .....:	EUT is not comming in contact with patient.	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)	See above	N/A
	Assessment identified the applied part type requirements .....:	Type B Applied Part	P
4.7	Me equipment remained single fault safe, or the risk remained acceptable as determined by Clause 4.2.....:	Evaluated by test. The equipment remains single fault safe	P
	manufacturer risk analysis was used to determine failures to be tested.....: (ISO 14971 Cl. 4.2-4.4)	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
	Failure of any one component at a time that could result in a hazardous situation, including those in 13.1, simulated physically or theoretically.....:	See appended Table 13.2 for simulated physical test	P
4.8	All components and wiring whose failure could result in a hazardous situation used according to their applicable ratings, unless specified .....:	See appended Table 8.10 and 8.10.b	P
	Components and wiring exception in the standard or by risk management process	No such case	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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 above	N/A
	manufacturer identified components where the failure results in a hazardous situation .....:	See Table 8.10 b.	P
	Components determined to be acceptable where used as a means of protection .....:	See Table 8.10 b.	P
	Reliability of components used as means of protection assessed for conditions of use in me equipment, and they complied with one of the following	Complied	P
	a) Applicable safety requirements of a relevant IEC or ISO standard	Complied	P
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard	Complied	P
4.9	A component with high-integrity characteristics provided and selected appropriately.....:	See appended Table 8.10 b	P
	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)	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
	Components identified and required to be components with high integrity characteristic:	See Table 8.10 b	P
4.10	**Power supply**		**P**
4.10.1	ME EQUIPMENT is suitable for connection to indicated power source (select applicable) .....:	EUT is connected to supply mains.	P
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:	The EUT is portable device and operated by 12 Vdc supplied by certified Adapter.	P
	- 250 V for HAND-HELD ME EQUIPMENT (V) .....:	No such construction	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).....:	See above	N/A
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS	See above	N/A
4.11	**Power input**		**P**

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%.....:	See appended Table 4.11	P
5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		**P**
5.1	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods .....:	Tests conducted within the specified conditions	P
	RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. (ISO 14971 Cl. 5.2-5.5)	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01 All applicable test conducted	P
5.3	Tests conducted within the environmental conditions specified in technical description	See below	P
	Temperature (°C), Relative Humidity (%) .....:	Operating temperature: (-20 to +50) °C Humidity: (10% to 90%) RH	P
	Atmospheric Pressure (kPa) .....:	-	-
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).....:	Operated by 12 Vdc supplied by certified Adapter voltage (100-240V AC)	P
	b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz).....:	EUT is DC operated but the certified adapter frequency is 50/60Hz.	P
	c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current.....:	See above	P
	d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered :	The Standard connectors used.	P
	e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favorable conditions.....:	EUT tested with all the accessories & components connected	P
	f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use	No such construction	N/A

IEC 60601-1			
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.....:	Humidity preconditioning test conducted	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 +30°C for indicated time	T = 25°C, Humidity: 93%RH Time = 48Hr	**P**
5.9	**Determination of APPLIED PARTS and ACCESSIBLE PARTS**		**P**
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS.....:	TYPE B applied part	P
5.9.2	**ACCESSIBLE PARTS**		**P**
5.9.2.1	Accessibility determined using standard test finger of Fig. 6	See Appended Table 5.9.2	P
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	See Appended Table 5.9.2	P
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS :	No such parts	N/A
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, required use of a TOOL.....:	See Above	N/A
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		**P**
6.2	CLASS I ME EQUIPMENT, externally powered	See below	N/A
	CLASS II ME EQUIPMENT, externally powered	EUT is Class II device	P
	INTERNALLY POWERED ME EQUIPMENT	See above	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	EUT is Class II device	p
	TYPE B APPLIED PART	Type B applied part	P
	TYPE BF APPLIED PART	No such part	N/A
	TYPE CF APPLIED PART	No such part	N/A
	DEFIBRILLATION-PROOF APPLIED PARTS	No such parts	N/A

IEC 60601-1			
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.....:	IP 20 rated	N/A
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use.....:	No sterilization required Mentioned in user manual	P
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	No such use	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 Appended Table 7.1.2	P
7.1.3	Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE	See appended Tables 7.1.3	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 .....:	Refer clause 7.2.2 to 7.2.20	P
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS .....:	Refer user manual	P
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	Complied	P
	Single use item marked.....:	See above	P
7.2.2	ME EQUIPMENT marked with:	See below	P
	– the name or trademark and contact information of the MANUFACTURER	Trade mark and manufacturer information evident name plate	P
	– a MODEL OR TYPE REFERENCE	TB101WX001	P
	– a serial number or lot or batch identifier; and	2425TB101WX001-003	P
	– the date of manufacture or use by date	Information given on the marking label	P
	Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or	Complied	P

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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)	See below	N/A
	Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and	Complied	P
	– a MODEL OR TYPE REFERENCE	See above	P
	Software forming part of a PEMS identified with a unique identifier.....:	Refer software validation document Document number: HM2425-TB101WX-SVR01	P
7.2.3	Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS	See below	P
	SAFETY SIGN 10 on Table D.2) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	Complied	P
7.2.4	ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and .....:	Complied	P
	- with a MODEL or TYPE REFERENCE	See above	P
	– a serial number or lot or batch identifier	See above	P
	– the date of manufacture or use by date	See above	P
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	See above	P
7.2.5	ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following	No such construction	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	See above	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	See above	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.	See above	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	Mentioned on the Name plate	P

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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	No such construction	N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V).....:	12V DC mentioned on Name plate	N/A
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V).....:	See Above	N/A
	– Nature of supply and type of current.....:	Mentioned on name plate	P
	Symbols 1-5, Table D.1 (used for same parameters.....:	See above	N/A
	– RATED supply frequency or RATED frequency range in hertz.....:	See above	N/A
	– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT.....:	No such construction	N/A
7.2.7	RATED input in amps or volt-amps, (A, VA).....:	Current mentioned in A.	P
	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W).....:	See above	N/A
	RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A,VA,W).....:	See above	N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W).....:	See above	N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA).....:	See above	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).....:	See above	N/A
7.2.8	**Output connectors**		N/A
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment	No such output connectors are used in EUT	N/A
	Rated Voltage (V), Rated Current (A).....:	See above	–
	Rated Power (W), Output Frequency (Hz).....:	See above	–

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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....:	IP 20 rated. see table 5.9.2	P
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols .....:	IP 20 rated. see table 5.9.2	P
	TYPE B APPLIED PARTS with symbol 19 of Table D.1.....:	EUT is Type B applied part	P
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1:	No such applied parts	N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1.....:	No such applied parts	N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1.....:	No such applied parts	N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART.....:	Complied	P
	SAFETY SIGN 2 of Table D.2 placed near relevant outlet.....:	Symbol marked on name plate	P
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use.....:	No such parts	N/A
7.2.11	ME EQUIPMENT suitable for CONTINUOUS OPERATION	EUT is continous operation	P
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time.....:	See above	N/A
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	There is no such fuse holder	N/A
	Fuse type.....:	See above	N/A
	Voltage (V) and Current (A) rating.....:	See above	N/A
	Operating speed (s) and Breaking capacity.....:	See above	N/A
7.2.13	Physiological effects – SAFETY SIGN and warning statements .....:	No such construction	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)	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1	No such construction	N/A
7.2.15	Requirements for cooling provisions marked.....:	No such construction	N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage.....:	No such marking	N/A
	Permissible environmental conditions marked on outside of packaging.....:	See above	N/A
	Packaging marked with a suitable SAFETY SIGN indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK.....:	See above	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)	See above	N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization	Complied, Also mentioned on packaging.	P
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and .....:	No such construction	N/A
	- the RATED flow rate also marked	See Above	N/A
7.2.19	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL.....:	No such construction	N/A
7.2.20	Removable protective means marked to indicate the necessity for replacement when the function is no longer needed.....:	No such protective means was provided	N/A
7.2.21	MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms .....:	EUT is portable device	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).....:	No such construction	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	See Above	N/A
7.3.2	Symbol 24 of Table D.1, or SAFETY SIGN No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts.....:	No such construction of EUT	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.3.3	Type of battery and mode of insertion marked..:	No such construction	N/A
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL.....:	See above	N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK .....:	See above	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)	See above	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.....:	See above	N/A
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified .....:	No such fuse are used	N/A
	Voltage (V) and Current (A) rating.....	See above	N/A
	Operating speed(s), size & breaking capacity....:	No such construction	N/A
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1	EUT is class II device, Earth is part of certified adapter	N/A
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	See above	N/A
7.3.6	Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS	No such construction	N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals.....:	Certified adaptor is used	P
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	No such case	N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3	No such construction	N/A
	Marking for connection to a 3-phase supply, complies with IEC 60445	No such construction	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	No Such Removable Part	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	No Such case	N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made	See Above	N/A
7.4	**Marking of controls and instruments**		P
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 such construction	N/A
	– indicated by an adjacent indicator light, or	See above	N/A
	– indicated by other unambiguous means	No such construction	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	No such construction	N/A
	- marked with symbols 16 and 17 of Table D.1 or	No such construction	N/A
	– indicated by an adjacent indicator light, or	See Above	N/A
	– indicated by other unambiguous means	See Above	N/A
	Switches that brings ME EQUIPMENT into "stand-by" may be indicated by symbol 29 of Table D.1	Complied, symbol marked on device	P
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, and	No such construction	N/A
	– status indicated by adjacent indicator light	See Above	N/A
	– status indicated by other unambiguous means	See Above	N/A
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 or	No such construction	N/A
	– status indicated by adjacent indicator light	See Above	N/A
	– status indicated by other unambiguous means	See Above	N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	No such controling position	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)	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE.....:	No such condition	N/A
	– or an indication of direction in which magnitude of the function changes	See above	N/A
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units	There is such measurement	N/A
	ISO 80000-1 applied for application of SI units, their multiples, and certain other units	See above	N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3.....:	See above	N/A
7.5	**SAFETY SIGNs**		P
	SAFETY SIGN with established meaning used	See below	P
	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)	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
	Affirmative statement together with SAFETY SIGN placed in instructions for use if insufficient space on ME EQUIPMENT	Complied	P
	Specified colours in ISO 3864-1 used for SAFETY SIGNs.....:	Complied	P
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	Complied	P
	SAFETY SIGNs including any supplementary text or symbols described in instructions for use	Safety signs supplementary text provided in user manual	P
	- and in a language acceptable to the intended OPERATOR	English	P
7.6	**Symbols**		P
7.6.1	Meanings of symbols used for marking described in instructions for use.....:	Refer the user manual	P
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable	See Above	P
7.7	Colours of the insulation of conductors		P

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Clause	Requirement + Test	Result - Remark	Verdict
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	Certified Power adaptor is used with certified Power cord.	P
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations	Complied	P
7.7.3	Green and yellow insulation identify only following conductors:	Certified Power adaptor is used with certified Power cord.	P
	– PROTECTIVE EARTH CONDUCTORS	Complied	P
	– conductors specified in 7.7.2	Complied	P
	– POTENTIAL EQUALIZATION CONDUCTORS	No such construction	N/A
	– FUNCTIONAL EARTH CONDUCTORS	No such construction	N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are "light blue"	Certified Power adaptor is used with certified Power cord.	P
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	Certified Power adaptor is used with certified Power cord.	P
7.8	Indicator lights and controls		P
7.8.1	Red indicator lights, not flashing used only for Warning	No such indication	N/A
	Yellow indicator lights, not flashing used only for Caution	No such indication	N/A
	Green indicator lights used only for Ready for use	No such indication	N/A
	Red flashing used only for HIGH PRIORITY ALARM CONDITION, interruption of current workflow needed	No such indication	N/A
	Yellow flashing used only MEDIUM PRIORITY ALARM CONDITION, re-planning of workflow needed	No such indication	N/A
	Yellow or Cyan, not flashing used for LOW PRIORITY ALARM CONDITION, planning of future workflow needed.	No such indication	N/A
	Other colours: Meaning other than red, yellow, cyan or green (colour, meaning).....:	No such indication	N/A
7.8.2	Red used only for emergency control	No such indication	N/A
7.9	**ACCOMPANYING DOCUMENTS**		P
7.9.1	ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description	Complied Refer user manual of EUT	P
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:	See below	P
	– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to.....:	Complied	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– MODEL or TYPE REFERENCE.....:	Mentioned in the user's manual	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	Soft copy provided	P
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	Information about the same are mentioned in user manual and RMR	P
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	Complied	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:	Complied	P
	– frequently used functions,	No such functions	N/A
	– known contraindication(s) to use of ME EQUIPMENT	See below	N/A
	- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient	No such functions	N/A
	– name or trademark and address of the MANUFACTURER	Complied	P
	– MODEL OR TYPE REFERENCE	Complied	P
	Instruction for use included the following when the PATIENT is an intended OPERATOR:	No such construction	N/A
	– the PATIENT is an intended OPERATOR	See above	N/A
	– warning against servicing and maintenance while the ME EQUIPMENT is in use	See above	N/A
	- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and	See above	N/A
	–maintenance the PATIENT can perform	See above	N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of SAFETY SIGNs and symbols marked on ME EQUIPMENT	See above	N/A
	Instructions for use are in a language acceptable to the intended operator	English	P
7.9.2.2	Instructions for use include all warning and safety notices	Complied	P
	Warning statement for CLASS I ME EQUIPMENT included	No such construction	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	Complied	P
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	Complied	P
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided	No such construction	N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	See Above	N/A
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions	There is no such construction	N/A
7.9.2.4	Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source	No such construction	N/A
	RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.2)	No such construction	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 ..... :	There is no such battery in the EUT	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided.....:	See above	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.....:	See above	N/A
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	Information provided in user manual	P
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to	See above	P
	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 such construction	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	APPLIED PARTS specified	Type B applied part Information provided in user manual	P
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation	Information provided in the user manual	P
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device	EUT is portable device	N/A
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation	Information provided in user manual	P
7.9.2.9	Information provided to operate ME EQUIPMENT	Information provided in user manual	P
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	See above	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	Information provided in user manual`	N/A
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	Information provided in user manual	P
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	Information provided in user manual	P
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	See above	P
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	Complied	P
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	Complied	P
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	Provided in user manual	P
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	No such batteries	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	Provided in user manual	P
	Other equipment providing power to ME SYSTEM sufficiently described	See above	P
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.....:	Provided in user manual	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)	Refer 7.9.3	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	No such condition	N/A
7.9.2.18	The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization	No sterile	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	See above	N/A
7.9.2.19	The instructions for use contain a unique version identifier.....:	Complied, Document number: HM2425-TB101WX-USRM01	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	See Below	P
	-information required in 7.2	Information provided in user manual	P
	-permissible environmental conditions of use including conditions for transport and storage..... :	Information provided in user manual	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 below	N/A
	-special installation requirements such as the maximum permissible apparent impedance of SUPPLY MAINS	No special installation requirement.	N/A
	-permissible range of values of inlet pressure and flow, and the chemical composition of cooling liquid	No such construction	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	-description of the means for checking the oil level in partially sealed oil filled ME EQUIPMENT or its parts	No such condition	N/A
	-warning statement that addresses the HAZARDS that can result from unauthorized modification of the ME EQUIPMENT	Provided in user manual	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	Provided in user manual	P
	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	Technical description is provided in user manual itself	N/A
	- brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and	See above	N/A
	a unique version identifier.....:	See above	N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	See above	N/A
7.9.3.2	**The technical description contains the following required information**		N/A
	-type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT.....:	The certfied Power adaptor is used	N/A
	- a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and	See above	N/A
	- instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	Provided in user manual	P
	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)	Refer risk management report Document number: HM2425-TB101WX-RMR01	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– 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	Provided in user manual	P
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	See above	P
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	Refer clause 8.11.1	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	Values are with in the limit as per standard requirements	P
	RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION.....: (ISO 14971 Cl. 4.3)	Refer risk management report Document number: HM2425-TB101WX-RMR01	P
8.2	**Requirements related to power sources**		N/A
8.2.1	**Connection to a separate power source**		N/A
	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	EUT is connected only to supply mains through the certified adaptor.	N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified	See above	N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	See above	N/A
8.2.2	**Connection to an external d.c. power source**		N/A
	No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	Certified power adaptor used	N/A
	ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE	See above	N/A
	Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset	No such construction	N/A
8.3	**Classification of APPLIED PARTS**		P

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Clause	Requirement + Test	Result - Remark	Verdict

	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	No such parts	N/A
	b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART	No such part	N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	Type B applied Part	P
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.....:	See appended Table 8.7	P
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT.....:	See appended Table 8.7	P
	c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed	No such condition	N/A
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.).....:	EUT do not have any live accessible parts without use of tool	N/A
	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 above	N/A
	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	No such construction	N/A
	d) Voltage and energy limits specified in c) above also applied to the following:	See below	N/A
	– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and	No such parts are accessible	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	No such parts are accessible	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	No such parts are accessible	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	See above	N/A
	Test repeated with a TOOL specified in instructions for use	See above	N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	See above	N/A
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION	No such construction	N/A
	A TOOL is required when it is possible to prevent the devices from operating	See above	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).....:	Refer Table 8.4.3	P
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45µC.....:	See above	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.....:	Measured voltage is less than 60V	N/A
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL	See above	N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description.....:	See above	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	Complied	P

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Clause	Requirement + Test	Result - Remark	Verdict
	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.....:	Complied	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	Sterlization methode provided in user manual	P
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10	See clause 8.10	P
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)	See below	N/A
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test.....:	Device only accessible by Operator	N/A
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12	Refer insulation diagram	N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6	No such construction	N/A
	Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION .....:	No such construction	N/A
	Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c.....:	See above	N/A
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	See above	N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF).....:	See above	N/A
	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 above	N/A
	Measurement of Air Clearance and Creepage distance on the outside	See above	N/A
	Dielectric strength test across optocoupler	See above	N/A
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	See below	P
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:	See below	P
	– dielectric strength test .....:	See appended Table 8.8.3	P

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Clause	Requirement + Test	Result - Remark	Verdict

	– 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	No such part	N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:	Refer insulation diagram	P
	– limits of Tables 13 to 16 (inclusive); or	See above	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	See above	N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6	See above	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.....:	No such construction in EUT	N/A
	A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION.....:	No such construction in EUT	N/A
	A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION.....:	No such construction in EUT	N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	No such construction	N/A
	Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF).....:	See above	–
	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 above	N/A
	Measurement of Air Clearance and Creepage distance on the outside	See above	N/A
	Dielectric strength test across optocoupler	See above	N/A
	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	See above	N/A
8.5.2	**Separation of PATIENT CONNECTIONS**		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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 such construction	N/A
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART	See above	N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function	See above	N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS.....:	See above	N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	No such construction	N/A
	LEAKAGE CURRENT tests conducted per 8.7.4....:	See above	N/A
	Dielectric strength test conducted per 8.8.3.....:	See above	N/A
	CREEPAGE and CLEARANCES measured .....:	See above	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	No such construction	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...:	No such construction	N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and	No such case	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	No such case	N/A
	LEAKAGE CURRENT tests conducted per 8.7.4...:	See above	N/A
	Dielectric strength test conducted per 8.8.3 .....:	See above	N/A
	Relevant CREEPAGE and CLEARANCES measured	See above	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)	No such construction	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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.....:	No direct electrical connection to 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	See above	N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm	See above	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	See above	N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,	See above	N/A
	Test finger test (10 N).....:	See above	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)	See above	N/A
8.5.4	**WORKING VOLTAGE**	See below	P
	– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V).....:	12VDC Powered by certified adapter voltage (100-240V AC)	P
	– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V).....:	See above	P
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V).....:	See above	P
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	See above	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V).....:	No direct electrical connection to patient	N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	No such part	N/A
	– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V).....:	No such case	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	No such part	N/A
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety	See above	N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:	See above	N/A
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator .....:	See above	N/A
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS.....:	See above	N/A
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load.....:	See above	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	EUT is Class II device	N/A
	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	See above	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.....:	Certified Power adaptor is used with certified Power cord.	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	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside.....:	See above	N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	See above	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	See above	N/A
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part,	No such construction	N/A
	except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE .....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4)	See above	N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop.....:	EUT is class II device	N/A
	b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits.....:	See above	N/A
	DETACHABLE POWER SUPPLY CORD specified by manufacturer or delivered with product	See above	N/A
8.6.5	**Surface coatings**		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact	EUT is class II device	N/A
	Coating not removed when requirements for impedance and current-carrying capacity met	See above	N/A
8.6.6	**Plugs and sockets**		P
	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	Certified detachable power supply cord used with certified power adaptor	P
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	See above	P
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	EUT is class II device	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	-accidental disconnection avoided in NORMAL USE	See above	N/A
	- Terminal allows conductor to be detached without a TOOL	See above	N/A
	- Terminal not used for a PROTECTIVE EARTH CONNECTION	See above	N/A
	- Terminal marked with symbol 8 of Table D.1	See above	N/A
	- Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard	See above	N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR	See above	N/A
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION	No such case	N/A
8.6.9	**Class II ME EQUIPMENT**		P
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, colored green and yellow	Complied	P
	ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.	See above	P
	Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS	See above	P
8.7	**LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS**		P
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3.....:	See appended Tables 8.7	P
	b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7.....:	See appended Tables 8.7	P
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except	Single fault performed see table 8.7	P
	- where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	See above	P
	- the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time	See above	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION	See above	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	See above	P
8.7.3	**Allowable Values**		P
	a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b.....:	See appended Table 8.7	P
	b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz.....:	See appended Table 8.7	N/A
	c) TOUCH CURRENT did not exceed 100µA in NORMAL CONDITION and 500µA in SINGLE FAULT CONDITION (I_{TNC}, I_{TSFC}).....:	See appended Table 8.7	P
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC}).....:	See appended Table 8.7	N/A
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710.....:	See appended Table 8.7	N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device.....:	See appended Table 8.7	N/A
	f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION....:	See appended Table 8.7	N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements.....:	See appended Table 8.7	N/A
8.8	Insulation		P
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing	See appended table 8.8.3	P
	Insulation exempted from test (complies with clause 4.8)	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	See appended Table 8.8.3	P
8.8.2	**Distance through solid insulation or use of thin sheet material**		N/A
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:	No such construction	N/A
	a) 0.4 mm, min, distance through insulation, or	See above	N/A
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:	See above	N/A
	– at least two layers of material, each passed the appropriate dielectric strength test .....:	See above	N/A
	– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test.....:	See above	N/A
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION	See above	N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION	See above	N/A
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when	See above	N/A
	c) Wire with solid insulation, other than solvent based enamel, complying with a)	See above	N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L	See above	N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	See above	N/A
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer	See above	N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded	See above	N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values	See above	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.....:	See above	N/A
	Finished component complied with routine dielectric strength tests of 8.8.3.....:	See above	N/A
	Tests of Annex L not repeated since material data sheets confirm compliance.....:	See above	N/A
8.8.3	**Dielectric Strength**		P
	Solid insulating materials with a safety function withstood dielectric strength test voltages .....:	See appended Table 8.8.3	P
8.8.4	**Insulation other than wire insulation**		N/A
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT	No such a construction	N/A
	ME EQUIPMENT and design documentation examined.....:	See above	N/A
	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)	See above	N/A
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat.....:	Refer as below	N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat.....:	See above	N/A
	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 such construction	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).....:	No such case	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION	See above	N/A
8.8.4.2	**Resistance to environmental stress**		N/A
	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	No such construction	N/A
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such parts are used	N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No such heating conductors are used	N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	No such part used in EUT	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	See above	N/A
8.9	**CREEPAGE DISTANCES and AIR CLEARANCES**		P
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive).....:	Refer insulation diagram	P
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1	See above	P
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 construction	N/A
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION , min CREEPAGE and CLEARANCES not applied.....:	See insulation diagram	P
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	No such insulating compound is used	N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (cl. 8.8.3 at 1,6 x test voltage).....:	See above	N/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur	See above	N/A
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint	See above	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:	See above	N/A
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage .....:	See above	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	See above	N/A
8.9.4	Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree .....:	No such construction	N/A
	Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES	No such construction	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.....:	Complied	P
	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)	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment.....	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS	See above	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 above	N/A
8.10.4	**Cord-connected HAND-HELD parts and cord-connected foot-operated control devices**		N/A
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION	No such construction	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	See above	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	No such construction	N/A
8.10.5	**Mechanical protection of wiring**		P
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges.....:	Complied	P
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS	No such construction	N/A
8.10.6	Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead	No such construction	N/A
8.10.7	a) Insulating sleeve adequately secured.....:	See below	P
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics	Complied	P
	c) Insulated conductors of ME EQUIPMENT subject to temperatures exceeding 70 °C.....:	See above	P
8.11	**MAINS PARTS, components and layout**		N/A
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles.....:	No such construction	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	No such construction	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	EUT is not a permanently installed equipment	N/A
	- the isolation device specified in the ACCOMPANYING DOCUMENTS	Provided	P
	b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description .....:	See above	P
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV.....:	No such construction	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	Complied	P
	e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	No such construction of switch	N/A
	f) A suitable plug device used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH.....:	Complied	P
	g) A fuse or a semiconductor device not used as an isolating means	Complied	P
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device	No such construction	P
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	No such circuit present	N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage	See above	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	No hazardous voltage present in EUT	N/A
	Standard test finger applied	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No such construction	N/A
8.11.3	**POWER SUPPLY CORDS**		P
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	Certifed Mains cord is used with certified power adaptor (See appanded Table 8.10)	P
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53):	See above	P
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE .....:	See above	P
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17.....:	The cross-sectional area is 0.75mm^2	P
	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.	No such construction of EUT	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 .....:	Appliance coupler is part of certified adaptor	P
8.11.3.5	**Cord anchorage**		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage	No such construction	N/A
	b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or	See above	N/A
	- metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or	See above	N/A
	- metal provided with an insulating lining affixed to cord anchorage	See above	N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	See above	N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	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	See above	N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	See above	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:	No such construction	N/A
	Cord subjected to a torque in Table 18 for one minute immediately after pull tests	See above	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	See above	N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9	Refer clause 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	No such construction of EUT	N/A
8.11.3.6	POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment	No such construction of EUT	N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or	No such construction of EUT	N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D^2 gram attached to the free end of cord (g).....:	No such construction of EUT	N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance	No such construction of EUT	N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D .....:	No such construction of EUT	N/A
8.11.4	**MAINS TERMINAL DEVICES**		P
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection	No such construction	N/A
	Terminals alone are not used to keep conductors in position	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors	See above	N/A
	Screws and nuts clamping external conductors do not serve to secure any other component	No such construction	N/A
8.11.4.2	**Arrangement of MAINS TERMINAL DEVICES**		P
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	Appliance inlet provided for detachable power supply cord	N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL	Complied	P
	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	No such construction	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	Complied	P
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	See above	P
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	See above	N/A
	Correct connection and positioning of conductors before ACCESS COVER verified by an installation test	See above	N/A
8.11.5	**Mains fuses and OVER-CURRENT RELEASES**		N/A
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection.....:	No such construction	N/A
	- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT.....:	No such construction	N/A
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	See above	N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Protective devices have adequate breaking capacity based on MANUFACTURER'S expectation of the highest branch circuit current and/or prospective short circuit current:	See above	N/A
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR	See above	N/A
	Justification for omission of fuses or OVER-CURRENT RELEASES documented.....:	See above	N/A
8.11.6	**Internal wiring of the MAINS PART**		P
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable .....:	See appended Table 8.10	P
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient.....:	See above	P
9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		N/A
9.2	**HAZARDS associated with moving parts**		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level.....:	No such construction	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)	See above	N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and	See above	N/A
	RISK CONTROLS implemented.....:	See above	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)	See above	N/A
	All RISKS associated with moving parts have been reduced to an acceptable level	See above	N/A
9.2.2	**TRAPPING ZONE**		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	No such trapping zone present	N/A
	– Gaps in Clause 9.2.2.2, or	See above	N/A
	– Safe distances in Clause 9.2.2.3, or	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– GUARDS and other RISK CONTROL measures in 9.2.2.4, or	See above	N/A
	– Continuous activation in Clause 9.2.2.5	See above	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	See above	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....:	No such trapping zone present	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 ...:	No such trapping zone present	N/A
9.2.2.4	**GUARDS and other RISK CONTROL measures**		N/A
9.2.2.4.1	A TRAPPING ZONE do not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK.....:	No such trapping zone present	N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that can only be dismantled with a TOOL	See above	N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open	See above	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,	See above	N/A
	– absence or failure of one of their components prevents starting, and stops moving parts	See above	N/A
	Movable GUARDS complied with any applicable tests	See above	N/A
9.2.2.4.4	Other RISK CONTROL designed and incorporated into to the control system stops movement and	See above	N/A
	– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or	See above	N/A
	ME EQUIPMENT is SINGLE FAULT SAFE	See above	N/A
9.2.2.5	**Continuous activation**		N/A
	Continuous activation used as a RISK CONTROL, complies with the following	No such trapping zone present	N/A
	a) movement was in OPERATOR's field of view	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR	See above	N/A
	c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or	See above	N/A
	- the continuous activation system is SINGLE FAULT SAFE	See above	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	See above	N/A
	Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK	See above	N/A
9.2.3	**Other MECHANICAL HAZARDS associated with moving parts**		N/A
9.2.3.1	Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated	No such moving parts	N/A
	- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or	See above	N/A
	- activation does not result in an unacceptable RISK	See above	N/A
9.2.3.2	Over travel past range limits of the ME EQUIPMENT prevented.....:	See above	N/A
	Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse.....:	See above	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.....:	There is only On/Off switch is evident	N/A
	a) Emergency stopping device reduced RISK to an acceptable level	See above	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)	See above	N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM	See above	N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT	See above	N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD	See above	N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like	See above	N/A
	g) Means for stopping of movements operate as a result of one single action	See above	N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls	See above	N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"	See above	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	See above	N/A
	k) Emergency stopping device is suitable for its application	See above	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.....:	No such construction	N/A
	– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented	See above	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	No such case	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	No such case	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)	No such case	N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered.....:	Complied	P

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Clause	Requirement + Test	Result - Remark	Verdict
9.4	**Instability HAZARDS**		P
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	See clauses from 9.4.2 to 9.4.4	P
9.4.2	**Instability – overbalance**		P
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested .....:	See appended Table 9.4.2.1	P
9.4.2.2	**Instability excluding transport**		P
	ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE, ... :	See appended Table 9.4.2.2	P
	A warning provided when overbalance occurred during 10° inclined plane test	No overbalance occurred during 10° inclined plane test	P
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	Weight is less than 25 Kg	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	No such marking available on the equipment	N/A
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)	No such construction	N/A
	b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping	No such construction	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 ..... :	No such condition	N/A
	ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b).....:	No such construction	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	No such construction of EUT	N/A
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT did not exceed 200 N .....:	No such construction of EUT	N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold .....:	No such construction of EUT	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	No such type of EUT	N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1	See above	N/A
9.4.3.2	**Instability excluding transport**		N/A
	a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test .....:	See above	N/A
	b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test	See above	N/A
9.4.4	**Grips and other handling devices**		N/A
	a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method	Weight of EUT is less than 20 kg.	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	See above	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	Weight of EUT is less than 20 kg.	N/A
	c) Carrying handles and grips and their means of attachment withstood loading test .....:	No such construction provided	N/A
9.5	**Expelled parts HAZARD**		N/A
9.5.1	Suitability of means of protecting against x parts determined by assessment and examination of RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No such requirements	N/A
	All identified RISKS associated with expelled parts mitigated to an acceptable level	See above	N/A
9.5.2	Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965.....:	No such construction	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	No such construction	N/A
	If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity .....:	No such construction	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)	No such construction	N/A
	All identified RISKS mitigated to an acceptable level	No such construction	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

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	No such construction	N/A
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....:	See below	N/A
	- 83 dBA (when halving the cumulative exposure time) (dBA).....:	See below	N/A
	– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB) .....:	See below	N/A
9.6.2.2	RISK MANAGEMENT FILE examined.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See above	N/A
	– 2.5 m/s2 for a cumulative time of 8 h during a 24 h period (m/s2) .....:	See above	N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s2).....:	See above	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	No such construction	N/A
	– 2.5 m/s^2 for a cumulative time of 8 h during a 24 h period (m/s^2) .....:	See above	N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s^2).....:	See above	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)	There are no such Pressure vessel present.	N/A
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum	See above	N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure	See above	N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects	See above	N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible	There are no such Pressure vessel present	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	See above	N/A
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.....:	There are no such Pressure vessel present	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.....:	There are no such Pressure vessel present	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 :	There are no such Pressure vessel present	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 :	See above	N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect	See above	N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair	See above	N/A
	c) Could be adjusted or rendered inoperative without a TOOL	See above	N/A
	d) With discharge opening located and directed as to not to release material towards any person	See above	N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK	See above	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	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect	See above	N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)	See above	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)	See above	N/A
9.8	**HAZARDS associated with support systems**		N/A
9.8.1	ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK .....:	No such Support system present in EUT	N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD	See above	N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK	See above	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)	See above	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	See above	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	See above	N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to	See above	N/A
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest	No such Support system present in equipment	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing..... :	See above	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)	See above	N/A
	All identified RISKS are mitigated to an acceptable level	See above	N/A
	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 ..... :	See above	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)	See above	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 ..... :	No such support or suspension part is present in equipment	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)	See above	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	See above	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	See above	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	See above	N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS	See above	N/A
	Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance .....:	See above	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.....:	No such support or suspension part is present in equipment	N/A
	Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests .....:	See above	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	See above	N/A
	Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test .....:	See above	N/A
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test	See above	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	No such part present in equipment	N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:	See above	N/A
	– Designed based on TOTAL LOAD	See above	N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7	See above	N/A
	– Activated before travel produced an unacceptable RISK	See above	N/A
	– Considers Clauses 9.2.5 and 9.8.4.3	See above	N/A
	Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests :	See above	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	See above	N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced	See above	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 .....:	No such part present in equipment	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal	See above	N/A
	– ME EQUIPMENT permanently marked with SAFETY SIGN 2 of Table D.	See above	N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE	See above	N/A
	– Compliance confirmed by examination and following test .....:	See above	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	See above	N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR	See above	N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function	See above	N/A
9.8.5	**Systems without MECHANICAL PROTECTIVE DEVICES**		N/A
	Support Systems does not require MECHANICAL PROTECTIVE DEVICES.....:	No such construction	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)	See above	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 .....:	No such radiations are generated from equipment	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	See above	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.....:	See above	N/A
	RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT ILE.....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See above	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)	No such radiations are generated from equipment	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	No such radiations are generated from equipment	N/A
	Microwave radiation is propagated intentionally	See above	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.	No such radiations are generated from equipment	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)	No such radiations are generated from equipment	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)	No such radiations are generated from equipment	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)	No such radiations are generated from equipment	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 appended Table 11.1.1	P
	Surfaces of test corner did not exceed 90 °C	Complied	P
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	No such part	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)	See appended Table 11.1.1 Refer RMR	P
11.1.2	**Temperature of APPLIED PARTS**		P
11.1.2.1	APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply .....:	See appended Table 11.1.1	P
	Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See above	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use	No such part used	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 ..... :	Complied	P
	APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:	Applied part surface temperature not exceeds 41°C	P
	Maximum Temperature ..... :	See above	—
	Conditions for safe contact, e.g. duration or condition of the PATIENT ..... :	See above	—
	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)	See above	N/A
	APPLIED PARTS surface temperature of equal to or less than 41°C	Less than 41°C	P
	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 ..... :	Test 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)	No such case	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)	Measurements are made, See appended Table 11.1.1	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)	Test corner used	N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	No such requirement	N/A
	e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE ..... :	No such case	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No such part	N/A
11.2	**Fire prevention**		P
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3	Refer clause 15.3	P
11.2.2	**Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS**		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of .....:	EUT is not used in such environment	N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions	See below	N/A
	1) when temperature of material raised to its ignition temperature	No such case	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	No such case	N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating	No such case	N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton	No such case	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	No such case	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)	See above	N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively.....:	See above	N/A
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three ..... :	See above	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)	See above	N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3.....:	See above	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 (%).....:	No such case	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	No such case	N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE.....:	See above	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 .....:	No such case	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	No such construction of EUT	N/A
11.2.2.3	Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks	Operating voltage and power is very less below the hazardous level	N/A
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques	No such construction	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	See above	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).....:	No such construction	N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3).....:	No such construction	N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a).....:	No such case	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).....:	No such case	N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas.....:	No such case	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.....:	Refer clause 13.1.2	P
	Constructional requirements were met, or	See above	P
	- Constructional requirements specifically analyzed in RISK MANAGEMENT FILE ..... : (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	See Below	P
	Justification, when requirement not met.....:	Refer risk management report Document number: HM2425-TB101WX-RMR01	P
	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 :	Certified wires are used Refer Table 8.10	P
	insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide as determined by examination of data on materials.....:	See Above	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 below	P

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Clause	Requirement + Test	Result - Remark	Verdict
	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	PCB is tested as per IEC 60695-11-10 and complies the requirments	P
	b) Fire ENCLOSURE met following:		N/A
	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	No such construction	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	See above	N/A
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials.....:	See above	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	No such construction of EUT	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)	No such construction of EUT	N/A
11.6	**Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT**		N/A
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT.....:	There is no such construction	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.....:	No such construction	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.	See above	N/A
	No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.	See above	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)	No such construction	N/A
	RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill.....:	See above	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).....:	IP 20 rated	N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION..... :	See above	N/A
11.6.6	**Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS**		P
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use.....:	provided in user manual	P
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER.....	See above	P

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Clause	Requirement + Test	Result - Remark	Verdict
11.6.7	**Sterilization of ME EQUIPMENT and ME SYSTEMS**		P
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests.....:	Complied, Sterilization provided in user manual	P
	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)	Refer risk management report Document number: HM2425-TB101WX-RMR01	P
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)	See above	P
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented	No such construction	N/A
11.8	Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE	Complied	P
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		P
12.1	RISKS associated with accuracy of controls and instruments stated .....: (ISO 14971 Cl. 5.3-5.5, 6, 7.1-7.4)	Refer risk management report Document number: HM2425-TB101WX-RMR01	P
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING.....:	Refer Usability engineering file Document number: HM2425-TB101WX-TEST01	P
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.....:	No such construction in ME equipment	N/A
12.4	**Protection against hazardous output**		N/A
12.4.1	RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	No such hazardous output	N/A
12.4.2	- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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)	See above	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)	See above	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	No Diagnostic or theraptic radiation from EUT	N/A
	Radiation safety ensured by compliance with requirements of appropriate standards	No Diagnostic or theraptic radiation from EUT	N/A
12.4.5.2	ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3.....:	EUT is not designed to produce X-ray	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)	EUT is not intended for radiotherapy	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)	EUT is not producing diagnostic or therapeutic radiations	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)	No such construction of EUT	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	Refer table 13.2	P
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur	See above	P
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24.....:	Refer clause 13.2	P
	– Temperatures of Accessible PARTS THAT ARE LIKELY TO BE TOUCHED, but not intended to be touched did not exceed limits in Table 34.....:	Table 11.1.1	P
	- Temperatures of ACCESSIBLE PARTS intended to be touched did not exceed limits in Table 23	See above	P

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Clause	Requirement + Test	Result - Remark	Verdict
	-Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded	Table 22 Applied	P
	Limits for windings in Tables 26, 27, and 31 not exceeded	Certified component used	P
	Table 22 not exceeded in all other cases	Complied	P
	Temperatures measured according to 11.1.3	Complied	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:	Refer clause 13.2	P
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION ..... :	EUT do not have fire enclosure	N/A
	- or secondary circuits mounted on materials with a minimum flame rating of -V1, and	EUT do not have fire enclosure	N/A
	- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and	Complied, Refer table 8.10	P
	- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and	See above	P
	- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide	See above	P
	- or components in the circuit have HIGH INTEGRITY CHARACTERISTICS..... :	Refer table 8.10(b)	P
	– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation	Complied	P
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function	No such construction	N/A
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed.....:	See appended Table 8.7	P
	– voltage limits for ACCESSIBLE PARTS and APPLIED PARTS did not exceed.....:	See appended Table 8.4.2	N/A
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	Refer clause 13.2.2 to 13.2.13	P
	ME EQUIPMENT complied with 13.2.2 -13.2.12.....:	See appended Table 13.2	P

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Clause	Requirement + Test	Result - Remark	Verdict
	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)	No such liquid is used in equipment	N/A
	RISK MANAGEMENT FILE defines the appropriate test conditions.....:	See above	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	There is no such construction	N/A
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted	There is no such construction	N/A
13.2.13.2	**ME EQUIPMENT with heating elements**		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests	No such heating element is used in equipment	N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests	See above	N/A
	a 3) other ME EQUIPMENT with heating elements met test	See above	N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively	See above	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	See above	N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part	See above	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	See above	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) :	See above	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	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted	See above	N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION	See above	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	See above	N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS	See above	N/A
	2) When more than one control provided, they were disabled in turn	See above	N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time	See above	N/A
13.2.13.3	**ME EQUIPMENT with motors**		P
	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	See appended Table 13.2	P
	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	See above	P
	a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition	No such heating element is used in equipment	N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT	No such requirement	N/A
	b) Motor met running overload protection test of this clause when:	Complied	P
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or	Motor is part of certified fan, no automatic control.	N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended	Complied	P
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) :	Motor is part of certified fan	P
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps:	See above	P

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Clause	Requirement + Test	Result - Remark	Verdict
	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	No such construction	N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current	See above	N/A
	Test not conducted based on other justifications (justification) ..... :	See above	N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10	No such part used in EUT	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	EUT is continuous operation	N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle	See above	N/A
	Motor winding temperatures did not exceed values in 13.2.10.....:	No such construction	N/A
	Insulation Class.....:	See above	N/A
	Maximum temperature measured (°C).....:	See above	N/A
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		P
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	Refer clause 14.2 to 14.12	P
	- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK.....:	See above	P
	RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 5.2-5.5, 6)	See above	P
	Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK	Refer Software validation documents Document number : HM2425-TB101WX-SVR01	P
	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	See above	P

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Clause	Requirement + Test	Result - Remark	Verdict
	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.....:	See above	P
	Software development process applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015.....:	See above	P
	Software development process for Software risk management applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015.....:	See above	P
	Software development process Configuration Management applied according to Clause 8 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015.....:	See above	P
	Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/AMD1:2015.....:	See above	P
14.2	Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process.....:	Refer Software validation documents Document number : HM2425-TB101WX-SVR01	P
14.3	RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan	Complied	P
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	Refer Software validation documents Document number : HM2425-TB101WX-SVR01	P
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	See above	P
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	See above	P
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones	See above	P
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	See above	P

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Clause	Requirement + Test	Result - Remark	Verdict
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	See above	P
14.6	**RISK MANAGEMENT PROCESS**		P
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.....:	Refer Software validation documents Document number : HM2425-TB101WX-SVR01	P
	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)	See above	P
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...:	See above	P
	RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure.....: (ISO 14971 Cl. 7.1)	Refer Risk management Document number : HM2425-TB101WX-RMR01	P
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)	Refer Software validation documents Document number : HM2425-TB101WX-SVR01	P
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems .....: (ISO 14971 Cl. 7.2)	Refer Software validation documents Document number : HM2425-TB101WX-SVR01	P
14.9	Design is broken up into sub systems and descriptive data on design environment documented.....:	See above	P
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)	Refer Software validation documents Document number : HM2425-TB101WX-SVR01	P

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Clause	Requirement + Test	Result - Remark	Verdict
	– milestone(s) when VERIFICATION is to be performed for each function	See above	P
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION	See above	P
	– selection and utilization of VERIFICATION tools	See above	P
	– coverage criteria for VERIFICATION	See above	P
	The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented	See above	P
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE ..... :	Refer Software validation documents Document number : HM2425-TB101WX-SVR01	P
	The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented	See above	P
	The person with overall responsibility for PEMS VALIDATION is independent	See above	P
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 7.2)	Refer Risk management Document number : HM2425-TB101WX-RMR01	P
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	Refer Software validation documents Document number : HM2425-TB101WX-SVR01	P
	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.....:	See above	P
	Software Process for Software changes applied according to Clause 5 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015 ..... :	See above	P
	RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015 ..... :	See above	P
	Configuration management of software changes applied per Clause 8 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015.....:	See above	P

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Clause	Requirement + Test	Result - Remark	Verdict
	Problem resolution for Software changes applied according to Clause 9 of IEC 62304:2006 and IEC 62304:2006/ AMD1:2015 ..... :	See above	P
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..... :	Refer Software validation documents Document number : HM2425-TB101WX-SVR01	P
	a) Purpose of the PEMS connection to an IT-NETWORK	See above	P
	b) required characteristics of the IT-NETWORK	See above	P
	c) required configuration of the IT-NETWORK	See above	P
	d) technical specifications of the network connection, including security specifications	See above	P
	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	See above	P
	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)	See above	P
	ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:		P
	– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties	See above	P
	– Notification that the RESPONSIBLE ORGANIZATION identify, analyse, evaluate and control these RISKS	See above	P
	– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis	See above	P
	- Changes to the IT-NETWORK include: - changes in network configuration - connection of additional items - disconnection of items - update of equipment - upgrade of equipment	See above	P
15	**CONSTRUCTION OF ME EQUIPMENT**		P
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS..... :	Refer Usability engineering file Document number: HM2425-TB101WX-TEST01	P

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Clause	Requirement + Test	Result - Remark	Verdict
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance	Refer risk management report and IFU Document: Document number: HM2425-TB101WX-RMR01 & HM2425-TB101WX-USRM01	P
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring	See above	P
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	See below	P
15.3.2	Push test conducted .....:	Complied, See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained	See above	P
15.3.3	Impact test conducted.....:	Complied, See Appended Table 15.3	P
	No damage resulting in an unacceptable RISK sustained	See above	P
15.3.4	**Drop test**		P
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested .....:	EUT is not hand held device	N/A
	No unacceptable RISK resulted	See above	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.....:	Complied, See appended table 15.3	P
	No damage resulting in an unacceptable RISK sustained	See above	P
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	No such construction	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.....:	See above	N/A
	No damage resulting in an unacceptable RISK	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
	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	See above	P
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)	Refer risk management report Document: Document number: HM2425-TB101WX-RMR01	P
	a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions,.....:	Complied	P
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection.....:	No such a construction	N/A
15.4.2	**Temperature and overload control devices**		N/A
15.4.2.1	a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION.....: (ISO 14971 Cl. 5.2-5.5, 6)	No such part used	N/A
	b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT	No such construction	N/A
	c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided.....: (ISO 14971 Cl. 5.2-5.5)	See above	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)	See above	N/A
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS	No such part used	N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests	No such part used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17	See above	N/A
	- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13.....:	See above	N/A
	- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards.....:	See above	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	See above	N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards	See above	N/A
	manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times	See above	N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted	See above	N/A
	g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating	No such case	N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating.....: (ISO 14971 Cl. 5.2-5.5)	No such construction	N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS	No such construction	N/A
15.4.3	**Batteries**		N/A
15.4.3.1	Battery housings provided with ventilation.....: (ISO 14971 Cl. 5.2-5.5)	No such construction	N/A
	Battery compartments designed to prevent accidental short circuiting	See above	N/A
15.4.3.2	Means provided to prevent incorrect connection of polarity	See above	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)	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.3.3	Overcharging of battery prevented by virtue of design.....:	See above	N/A
	RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries.....: (ISO 14971 Cl. 5.2-5.5)	See above	N/A
15.4.3.4	Primary lithium batteries comply with IEC 60086-4	No such part	N/A
	Secondary lithium batteries comply with IEC 62133 or IEC 62133-2	See above	N/A
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire.....:	No such construction	N/A
	Protective device has adequate breaking capacity	No such construction	N/A
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented	No such construction	N/A
	Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPs provided, or	No such construction	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	No such construction	N/A
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for.....:	No such construction	N/A
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,	No such case	N/A
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational	No such construction	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)	No such construction	N/A
	Requirement not applied to heated stylus-pens for recording purposes	No such construction	N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists	See above	N/A
	Colours of indicator lights complied with 7.8.1	No such construction	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Charging mode visibly indicated	No such construction	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)	No such construction	N/A
15.4.6	**Actuating parts of controls of ME EQUIPMENT**		P
15.4.6.1	a) Actuating parts cannot be pulled off or loosened during NORMAL USE	Complied	P
	b) Controls secured so that the indication of any scale always corresponds to the position of the control	Complied	P
	c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL	No such construction	N/A
	When torque values per Table 30 applied knobs did not rotate .....:	Complied	P
	Tests conducted with no unacceptable RISK .....:	Complied	P
15.4.6.2	Stops on rotating/ movable parts of controls are of adequate mechanical strength .....:	No such parts	N/A
	Torque values in Table 30 applied.....:	See above	N/A
	No unexpected change of the controlled parameter when tested.....:	See above	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	There is no such construction	N/A
	b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage.....:	No such construction	N/A
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface.....:	No such construction	N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position	No such construction	N/A
15.4.7.3	a) Foot-operated control device is at least rated IPX1.....:	No such construction	N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.....:	No such construction	N/A
15.4.8	Aluminium wires less than 16 mm^2 in cross-sectional area are not used	Copper wire are used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed	No such construction	N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	No oil container is used in equipment	N/A
	A pressure-release device operating during NORMAL USE is provided	No oil container is used in equipment	N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage	No oil container is used in equipment	N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements	No oil container is used in equipment	N/A
15.5	**MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5**		N/A
15.5.1	**Overheating**		N/A
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating.....:	No such construction	N/A
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31	See above	N/A
	Dielectric strength test conducted after short circuit and overload tests .....:	NO such construction	N/A
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved .....:	See above	N/A
	Short circuit applied directly across output windings	See above	N/A
15.5.1.3	Multiple overload tests conducted on windings:	See above	N/A
15.5.2	Transformers operating at a frequency above 1kHz tested according to clause 8.8.3.....:	See above	N/A
	Transformer windings provided with adequate insulation	See above	N/A
	Dielectric strength tests were conducted .....:	See above	N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with.....:	See above	N/A
	- Means provided to prevent displacement of end turns	See above	N/A
	- protective earth screens with a single turn have insulated overlap	See above	N/A
	- Exit of wires form internal windings of toroid transformers protected with double sleeving	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- insulation between primary and secondary windings complies with 8.8.2	See above	N/A
	- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4	See above	N/A
16	**ME SYSTEMS**		N/A
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	EUT is not a ME system	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)	See above	N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered	See above	N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard	See above	N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards	See above	N/A
	– tests performed in NORMAL CONDITION, except as specified	See above	N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM	See above	N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated	See above	N/A
	RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR	See above	N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards	See above	N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	See above	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	EUT is not a ME system	N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM	See above	N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER	See above	N/A
	c) the required information is provided:	See above	N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM	See above	N/A
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard	See above	N/A
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM	See above	N/A
	– additional safety measures to be applied during installation of ME SYSTEM	See above	N/A
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT	See above	N/A
	– additional measures to be applied during preventive maintenance	See above	N/A
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor	See above	N/A
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM	See above	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	See above	N/A
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM	See above	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	See above	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	See above	N/A
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET	See above	N/A
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT	See above	N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:	See above	N/A
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES	See above	N/A
	– assembly of ME SYSTEMS and modifications during actual service life evaluated based on the requirements of this standard	See above	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	EUT is not a ME system	N/A
	Transient currents restricted to allowable levels for the specified IPS or UPS ..... :	See above	N/A
	Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified	See above	N/A
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)	See above	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	See above	N/A
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION	See above	N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V) ..... :	See above	N/A
16.6	**LEAKAGE CURRENTS**		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION did not exceed 100µA :	EUT is not a ME system	N/A
	TOUCH CURRENT did not exceed 500µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR..... :	EUT is not a ME system	N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA..... :	See above	N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values :	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
16.7	ME SYSTEM complied with applicable requirements of Clause 9.....:	See above	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	See above	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.....:	EUT is not a ME system	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)	See above	N/A
	– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results	See above	N/A
	Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable	See above	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	EUT is not a ME system	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	See above	N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer	EUT is not a ME system	N/A
	b) – MULTIPLE SOCKET-OUTLET marked with SAFETY SIGN 2 of Table D.2 visible in NORMAL USE, and	See above	N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or	See above	N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to	See above	N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT	See above	N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– CREEPAGE and CLEARANCES complied with 8.9	See above	N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets	See above	N/A
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:	See above	N/A
	– ENCLOSURE complied with 8.4.2 d)	See above	N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable	See above	N/A
	– RATINGS of components are not in conflict with conditions of use .....:	See above	N/A
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL	See above	N/A
	– POWER SUPPLY CORD complied with 8.11.3	See above	N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:	See above	N/A
	– Separating transformer complied with this standard or IEC 61558-2-1...	See above	N/A
	– Separating transformer is CLASS I	See above	N/A
	– Degree of protection against ingress of water specified as in IEC 60529	See above	N/A
	– Separating transformer assembly marked according to 7.2 and 7.3	See above	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	See above	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	EUT is not a ME system	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	See above	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	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL	EUT is not a ME system	N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage	See above	N/A
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		-
	RISKS associated confirmed by review.....:		-
	- electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS .....:		-
	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)		-
	introduction of electromagnetic phenomena into environment by me equipment or me system that might degrade performance of other devices, electrical equipment, and systems		-

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Clause	Requirement + Test	Result - Remark	Verdict
ANNEX G	**PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES**		N/A
G.2	**Locations and basic requirements**		N/A
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	No such FLAMMABLE ANAESTHETIC MIXTURE used in equipment	N/A
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH	See above	N/A
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE	See above	N/A
G.2.4	ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5	See above	N/A
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6	See above	N/A
	ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.6 conducted after tests of 11.6.6 and 11.6.7	See above	N/A
G.3	**Marking, ACCOMPANYING DOCUMENTS**		N/A
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1)..... :	No such flammable anaesthetic mixture used in equipment	N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case	See above	N/A
	When above marking not possible, relevant information included in instructions for use..... :	See above	N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	See above	N/A
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1) ..... :	See above	N/A
	Marking is as large as possible for the particular case	See above	N/A
	When above marking not possible, the relevant information included in instructions for use ..... :	See above	N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	See above	N/A
G.3.3	The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts	See above	N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG	See above	N/A
G.4	**Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT**		N/A
G.4.1	a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION	No such flammable anaesthetic mixture used in equipment	N/A
	b) Connections protected against accidental disconnection	See above	N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,	See above	N/A
G.4.2	**Construction details**		N/A
	a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL	No such flammable anaesthetic mixture used in equipment	N/A
	b) ENCLOSURE complies with.....:	See above	N/A
	– no openings on top covers of ENCLOSURE,	See above	N/A
	– openings in side-covers prevented penetration of a solid cylindrical test rod	See above	N/A
	– openings in base plates prevented penetration of a solid cylindrical test	See above	N/A
	c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION	See above	N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures	See above	N/A
	– Use of antistatic materials with a limited electrical resistance .....:	See above	N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor	See above	N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882 .....:	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5	See above	N/A
G.5	**Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components**		N/A
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5	No such flammable anaesthetic mixture used in equipment	N/A
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 ..... :	See above	N/A
G.5.2	Temperature limits ..... :	See above	N/A
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:	See above	N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1 ..... :	See above	N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 ..... :	See above	N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1 ..... :	See above	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3 ..... :	See above	N/A
	– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1	See above	N/A
	No extrapolation made for voltages above 42 V	See above	N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2	See above	N/A
	No extrapolation made for voltages above 242V	See above	N/A
	U_{max} determined using actual resistance R	See above	N/A
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3	See above	N/A
	No extrapolation made for inductances larger than 900 mH	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

	– U_{max} was the highest supply voltage occurring in circuit under investigation with sparking contact open	See above	N/A
	– I_{max} was the highest current flowing in circuit under investigation with sparking contact closed	See above	N/A
	– C_{max} and L_{max} taken as values occurring at the component under investigation producing sparks	See above	N/A
	– Peak value considered when a.c. supplied	See above	N/A
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit .....:	See above	N/A
	Temperature measurements made according to 11.1, and U_{max}, I_{max}, R, L_{max}, and C_{max} determined with application of Figs G.1-G.3.....:	See above	N/A
	Alternatively, compliance was verified by examination of design data.....:	See above	N/A
G.5.4	**External ventilation with internal overpressure**		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:	No such flammable anaesthetic mixture used in equipment	N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,	See above	N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa).....:	See above	N/A
	Overpressure maintained at the site of potential ignition	See above	N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE	See above	N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present	See above	N/A
	c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa) .....:	See above	N/A
	d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C.....:	See above	N/A
G.5.5	**ENCLOSURES with restricted breathing**		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:	No such flammable anaesthetic mixture used in equipment	N/A

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

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Clause	Requirement + Test	Result - Remark	Verdict
	Measured $U_{max} \leq U_{zc}$ with C_{max} as in Fig. G.5 ..... :	See above	N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4 ..... :	See above	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.6 ..... :	See above	N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated	See above	N/A
	– U_{max} was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in Cl. 4.10	See above	N/A
	– I_{max} was the highest current flowing in the circuit under investigation, considering MAINS VOLTAGE variations as in Cl. 4.10	See above	N/A
	– C_{max} and L_{max} are values occurring in relevant circuit	See above	N/A
	– U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω	See above	N/A
	– Peak value considered when a.c. supplied	See above	N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and U_{max} and I_{max}, either as d.c. or a.c. peak values in case of a complicated circuit	See above	N/A
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components	See above	N/A
	- requirement not applied to transformers complying with this standard	See above	N/A
	- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture	See above	N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or	See above	N/A
	Temperature measurements made in accordance with 11.1 ..... :	See above	N/A
	- or U_{max}, I_{max}, R, L_{max} and C_{max} determined together with application of Figs G.4-G.6 ..... :	See above	N/A
	Alternatively, compliance verified by comparison with design data ..... :	See above	N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1 ..... :	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	See above	N/A
G.7	Test apparatus for flammable mixtures according to this Clause and Fig G.7	See above	N/A
ANNEX L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		N/A
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex	No such construction	N/A
L.2	**Wire construction**		N/A
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component	See above	N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap	See above	N/A
L.3	**Type Test**		N/A
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified	See above	N/A
	Temperature (°C) ..... :	See above	–
	Humidity (%) ..... :	See above	–
L.3.1	Dielectric strength		N/A
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown:	See above	N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :	See above	N/A
	– 6000 V for REINFORCED INSULATION (V) ..... :	See above	N/A
L.3.2	**Flexibility and adherence**		N/A
	Sample subjected to flexibility and adherence	See above	N/A
	Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown	See above	N/A
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:	See above	N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	– 3000 V for REINFORCED INSULATION (V) ..... :	See above	N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... :	See above	N/A
L.3.3	**Heat Shock**		N/A
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3	See above	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	See above	N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :	See above	N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :	See above	N/A
	Oven temperature based on Table L.2 (°C)..... :	See above	–
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm^2) ..... :	See above	N/A
	Dielectric strength test conducted at room temperature after removal from the oven	See above	N/A
L.3.4	**Retention of electric strength after bending**		N/A
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests	See above	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	See above	N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :	See above	N/A
	– 3000 V for REINFORCED INSULATION (V) ..... :	See above	N/A
	Test voltage applied between the shot and conductor	See above	N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm^2) ..... :	See above	N/A
L.4	**Tests during manufacture**		N/A
L.4.1	Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3 ..... :	See above	N/A
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:	See above	N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See above	N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)..... :	See above	N/A
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)..... :	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:	See above	N/A
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION..... :	See above	N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION ..... :	See above	N/A

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
4.1	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	–	Risk Management Process (excluding production and post-production)	P
4.2	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	–	Adequate Resources	P
4.2	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	–	Assignment of qualified personnel	P
4.2	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	–	Policy for determining criteria for risk acceptability	P
4.3	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Competence of personnel	P
4.4a	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Management Plan - the scope of the planned risk management activities	P
4.4b	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Management Plan - assignment of responsibilities and authorities	P
4.4c	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	–	Risk Management Plan - requirements for review of risk management activities	P
4.4d	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Management Plan - criteria for risk acceptability	P
4.4e	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Management Plan - a method to evaluate the overall residual risk, and criteria for acceptability of the overall residual risk	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
4.4f	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Management Plan - activities for verification of the implementation and effectiveness of risk control measures	P
4.5	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Management File	P
5.1	–		Risk Analysis - Process	P
5.2	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Analysis - Intended use and reasonably foreseeable misuse	P
5.3	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Analysis - Identification of characteristics related to safety	P
5.4	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Analysis - Identification of hazards and hazardous situations	P
5.5	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Analysis - Risk estimation	P
6	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Evaluation	P
7.1	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Control - Risk control option analysis	P
7.2	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Control - Implementation of risk control measures	P
7.3	–	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Control - Residual risk evaluation	P

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Clause	Requirement + Test	Result - Remark	Verdict

4.2.2	RM RESULTS TABLE: General requirements for RISK MANAGEMENT			P
Clause of ISO 14971	Document Ref. in RMF (Document No. paragraph/clause, version)		Result - Remarks	Verdict
	General process	Particular Medical Device		
7.4	—	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Control - Benefit-risk analysis	P
7.5a	—	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Control - Risks arising from risk control measures (new hazards or hazardous situations introduced)	P
7.5b	—	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Control - Risks arising from risk control measures (estimated risks for previously identified hazardous situations affected)	P
7.6	—	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk Control - Completeness of risk control	P
8	—	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Evaluation of overall residual risk	P
9	—	Information evident in the Risk management report: Document number: HM2425-TB101WX-RMR01	Risk management review	P
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**
Case1: Continuous Mode and Intermittent Mode	No such type of equipment	N/A
Case 2: Oxygenation Mode:	No such type of equipment	N/A
Case 3: Combination Mode and Alternating Mode	No such type of equipment	N/A
Supplementary Information: ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in anunacceptable risk.		

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Clause	Requirement + Test	Result - Remark	Verdict

4.11	TABLE: Power Input					P
Operating Conditions / Ratings		**Voltage (V)**	**Frequency (Hz)**	**Current (A)**	**Power (W or ~~VA~~)**	**Power factor (cos ϕ)**
EUT operated in No load operation AC input		100	50	0.3462	34.62	-
		220		0.2052	45.14	-
EUT operated in full load operation AC input		100		0.6120	61.20	-
		220		319.76 mA	70.18	-
EUT operated in No load operation DC input		12 V dc	-	1.0125 A	12.15	-
EUT operated in full load operation DC input		12 V dc	-	2.8148 A	33.77	-
Supplementary Information: Measured input current of equipment did not exceed by more than 10% of marked rating.						

5.9.2	TABLE: Determination of ACCESSIBLE parts	P
Location	**Determination method (NOTE1)**	**Comments**
Openings gap between display and machine	Jointed test finger	No hazardous live parts are accessible
	Test hook	
Supplementary information: The determination methods are: visual; jointed test finger, EUT is declared as IP20.		

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Clause	Requirement + Test	Result - Remark	Verdict

7.1.2	TABLE: Legibility of Marking		P
Markings tested		**Ambient Illuminance (lx)**	**Remarks**
Outside Markings (Clause 7.2)..... :		400	Marking legible
Inside Markings (Clause 7.3)..... :		-	-
Controls & Instruments (Clause 7.4)..... :		-	-
SAFETY SIGNS (Clause 7.5)..... :		400	Marking legible
Symbols (Clause 7.6)..... :		-	-
Supplementary information: Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.			

7.1.3	TABLE: Durability of marking test		P
Characteristics of the Marking Label tested:			**Remarks**
Material of Marking Label ..... :		Sticker	P
Ink/other printing material or process ..... :		-	-
Material (composition) of Warning Label ..... :		Sticker	P
Ink/other printing material or process ..... :		-	-
Other ..... :		-	-
Marking Label Tested:			**Remarks**
Marking label		Marking legible and edges are not curled	
Warning label		Marking legible and edges are not curled	
Supplementary information: --			

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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]: .....: -						-
Location From/To	Measured values					Remarks
	Vrms	Vpk or Vdc	Peak-to-peak ripple[2]	Power W/~~VA~~	Energy (J)	
---	---	---	---	--	---	---

Supplementary Information: Certified power adapter used

[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

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).....:										60V
Voltage measured (V)										
Plug pins 1 & 2	0	0	0	0	0	0	0	0	0	0
Plug pins 1 & Enclosure	0	0	0	0	0	0	0	0	0	0
Plug pins 2 & Enclosure	0	0	0	0	0	0	0	0	0	0
Maximum allowable stored charge when measured voltage exceeded 60 v (µc).....:										-
Calculated stored charge (µc)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
	--	--	--	--	--	--	--	--	--	--
	--	--	--	--	--	--	--	--	--	--
	--	--	--	--	--	--	--	--	--	--
	--	--	--	--	--	--	--	--	--	--
	--	--	--	--	--	--	--	--	--	--

Supplementary information: - voltage measured after 1 second of disconnection of supply.
Measurement taken at the input side of adaptor.

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Clause	Requirement + Test	Result - Remark	Verdict

8.4.4	TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT		N/A
Maximum allowable residual voltage (V) :			**60 V**
Maximum allowable stored charge when residual voltage exceeded 60 V .....:			**45 µC**
Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)	**Measured residual voltage (V)**	**Calculated stored charge (µC)**	**Remarks**
--	--	--	--
--	--	--	--
--	--	--	--
Supplementary information: No such circuit			

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

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

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Clause	Requirement + Test	Result - Remark	Verdict

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

Test Voltage applied to	Measured Energy E1 (Mj)	Measured Energy E2 (Mj)	Energy E1 as % of E2 (%)
PATIENT CONNECTION 1 or APPLIED PART with PATIENT CONNECTIONS 2, 3, and 4 of the same APPLIED PART connected to earth	--	--	--
PATIENT CONNECTION 2 or APPLIED PART with PATIENT CONNECTIONS 1, 3, and 4 of the same APPLIED PART connected to earth	--	--	--
PATIENT CONNECTION 3 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 4 of the same APPLIED PART connected to earth	--	--	--
PATIENT CONNECTION 4 or APPLIED PART with PATIENT CONNECTIONS 1, 2, and 3 of the same APPLIED PART connected to earth	--	--	--

Supplementary information: For compliance: E1 must at least 90% of E2
E1= Measured energy delivered to 100 Ω with ME Equipment connected;
E2= Measured energy delivered to 100 Ω without ME equipment connected.

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

Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (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
-		-	-	-	--
-		-	-	-	
-		-	-	-	
-		-	-	-	
Fig. 14 – Touch Current (TC)		—	—	—	Maximum allowed values: 100 µA NC; 500 µA SFC
Type – Enclosure to earth					
NP - NC		264	50	2.1 µA	Measured touch current is less than 100 µA NC; 500 µA SFC
RP- NC		264	50	2.3 µA	
NP – SFC (Earth cut)		-	-	-	
RP- SFC (Earth cut)		-	-	-	
NP – SFC (Line cut)		264	50	2.6 µA	
RP- SFC (Line cut)		264	50	2.3 µA	
Type – Enclosure to enclosure					
NP - NC		264	50	4.3	Measured touch current is less than 100 µA NC; 500 µA SFC
RP- NC		264	50	5.0	
NP – SFC (Earth cut)		-	-	-	
RP- SFC (Earth cut)		-	-	-	
NP – SFC (Line cut)		264	50	8.9	
RP- SFC (Line cut)		264	50	8.7	
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)~~
Type – Patient to earth					
NP – NC DC			-	-	

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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**
-		-	-	-	Measured current is less than 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.)
-		-	-	-	
-		-	-	-	
-		-	-	-	
-		-	-	-	
-		-	-	-	
-		-	-	-	
-		-	-	-	
-		-	-	-	
-		-	-	-	
-		-	-	-	
-		-	-	-	
Fig. 16 – Patient leakage current with mains on the F-type applied parts (PM)		—	—	—	Maximum allowed values: ~~Type B: N/A~~ Type BF AP: 500 µA ~~Type CF AP: 50 µA~~
-		-	-	-	Measured current is less than 100 µA NC; 500 µA SFC
-		-	-	-	
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

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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. 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)
-		-	-	-	Measured current is less than 50 µA NC; 100 µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.)
-		-	-	-	
-		-	-	-	
-		-	-	-	
-		-	-	-	
-		-	-	-	
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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. 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	
---	---	---	---	N/A	
---	---	---	---	N/A	
Function Earth Conductor Leakage Current (FECLC)	–	–	–	Maximum allowed values: 5 Ma NC; 10 Ma SFC	
---	---	---	---	N/A	
---	---	---	---	N/A	

Supplementary information:

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

Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7
Note 4: Total PATIENT LEAKAGE CURRENT values are only relative to equipment with multiple APPLIED PARTS of the same type. See 8.7.4.7 h). The individual APPLIED PARTS complied with the PATIENT LEAKAGE CURRENT values.

Note 5: In addition to conditions indicated in the Table, tests conducted at operating temperature and after humidity preconditioning of 5.7, EQUIPMENT energized in stand-by condition and fully operating, max rated supply frequency, at 110 % of the max RATED MAINS VOLTAGE, and after relevant tests of Clause 11.6 (i.e., overflow, spillage, leakage, ingress of water and particulate matter, cleaning & disinfection, & sterilization).

ER – Earth leakage current
TC – Touch current
P – Patient leakage current
PA – Patient auxiliary current
TP – Total Patient current
PM – Patient leakage current with mains on the applied parts
MD – Measuring device

A – After humidity conditioning
B – Before humidity conditioning
1 – Switch closed or set to normal polarity
0 – Switch open or set to reversed polarity
NC – Normal condition
SFC – Single fault condition
NP – Normal Polarity
RP- Reverse Polarity

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8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)	P

Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s[1)]	Dielectric breakdown after 1 minute Yes/No[2)]
		PEAK WORKING VOLTAGE (U) V_{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
A	1 MOOP	212 < U ≤354	-	1500	NO
B	1 MOOP	212 < U ≤354	-	1500	NO
C	2 MOOP	-	U <60	-	-

Supplementary information:

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

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

Part/material	Test temperature (°C)	Impression diameter (mm)
-	-	-

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 125 °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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Clause	Requirement + Test	Result - Remark	Verdict

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

Supplementary information:
[1)] Note: AC – AIR CLEARANCE CD – CREEPAGE DISTANCE

8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts			N/A
Part Test	**8.9.3.4 - Test duration and temperature for 10 cycles after which the sample was subjected to Humidity Preconditioning per Cl. 5.7**	**Dielectric test voltage**	**Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No**	**Crack or voids in the insulating compound: Yes/No**
---	**68 h at T1 ± 2 °C = ___°C [1)]**	---	---	---
	1 h at 25 °C ± 2 °C			
	2 h at 0 °C ± 2 °C			
	1 or more h at 25 °C ± 2 °C			
---	---	---	---	---

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

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Clause	Requirement + Test	Result - Remark	Verdict

8.9.3.3	Table: Thermal cycling tests on one sample of cemented joint with other insulating parts (see 8.9.3.3)			N/A
Part tested	**Sample**	**Each test duration and temperature**	**Dielectric test voltage**	**Dielectric strength test Breakdown: Yes/No**
---	1	**10 Cycles conducted of the following:**	---	---
		1 - 68 h at T1 ± 2 °C = ____°C[1]		
		2 - 1 h at 25 °C ± 2 °C		
		3 - 2 h at 0 °C ± 2 °C		
		4 - 1 or more h at 25 °C ± 2 °C		
	2	**Humidity Conditioning per 5.7**		---
	3	**Humidity Conditioning per 5.7**		---

Supplementary information:

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

8.10	TABLE: Critical components information (#)				P
Unique component reference or location/ Component Name	Manufacturer / trademark	Type / model	Technical data	Standard	Mark(s) of conformity evidence of acceptance
Mains Plug	Taiwan Line Tek In China Everfull Electronic (Huizhou) Co. Ltd.,	PE361L	6A, 250V~	IS 1293:2005	ISI (CM/L : 4013635)
Power Cord	Taiwan Line Tek In China Everfull Electronic (Huizhou) Co. Ltd.	Circular PVC insulated	3X0.75sqmm, 1100V	IS 694:2010	ISI (CM/L : 4013534)
Appliance coupler	Longwell Company	LS-60	10A, 250V~	IEC 60320-1:2015	VDE: 40029578

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Clause	Requirement + Test	Result - Remark	Verdict

8.10	TABLE: Critical components information (#)				P
Unique component reference or location/ Component Name	Manufacturer / trademark	Type / model	Technical data	Standard	Mark(s) of conformity evidence of acceptance
AC adapter	LI SHIN INTERNATIONAL ENTERPRISE CORP	LSE9901B1260	Input: 100-240V~, 50/60Hz, 1.5A. Output: 12V DC 5A.	IEC 60065:2001	Certified by TUV SUD with CB certificate number : CB 07 05 37190 038
Primary connectors	CIXI KEFA ELECTRONICS CO LTD	KF2EDGKAM-3.81	300V, 8A	UN 60947-7-1, Harmonized with IEC 60947-7-1	UL (E306245)
Mother Board (PCB)	HIGHNESS MICROELECTRONICS PVT. LTD	EPIC-HM-i7FL-V1.0RU	Thickness: 1.6mm	IEC 60601-1:2005 +A1:2012+A2:2020	Tested with unit.
On/Off switch	ITC	ITC 12MM PUSHBUTTON	12mm; 2A/DC36V	EN 55032:2015+ A11:2020, EN 55035:2017/A11:2020	CE certified
LCD display	HIGHNESS MICROELECTRONICS PVT. LTD	HM101WX101B-OB-PT	3.6V, 330mA	IEC 60601-1:2005 +A1:2012+A2:2020	Tested with appliance
(#): As declared by manufacturer :					

8.10 b	TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS (#)				P
Object / part No.	**Manufacturer/ trademark**	**Type / model**	**Technical data**	**Standard**	**Mark(s) of conformity[1)]**
AC adapter	LI SHIN INTERNATIONAL ENTERPRISE CORP	LSE9901B1260	Input: 100-240V~, 50/60Hz, 1.5A. Output: 12V DC 5A.	IEC 60065:2001	Certified by TUV SUD with CB certificate number : CB 07 05 37190 038
Supplementary information: --- 1) Provided evidence ensures the agreed level of compliance. (#): As declared by manufacturer					

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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Clause	Requirement + Test	Result - Remark	Verdict

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

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

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

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

9.4.2.1	TABLE: Instability--overbalance in transport position	P
ME EQUIPMENT preparation	Test Condition (transport position)	Remarks
EUT in full assembled condition	Transport position	EUT not overbalanced during the test
--	--	--
Supplementary information: Nil		

9.4.2.2	TABLE: Instability—overbalance excluding transport position	P
ME EQUIPMENT preparation	Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)	Remarks
EUT in full assembled condition	Excluding Transport position (10 ° incline)	EUT not overbalanced during the test
--	--	--
Supplementary information: Nil		

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

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Clause	Requirement + Test	Result - Remark	Verdict

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

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

10.1.1	TABLE: Measurement of X - radiation		N/A
Maximum allowable radiation pA/kg (µSv/h) (mR/h)		**36 (5 µSv/h) (0.5 mR/h)**	
Surface area under test Surface no./ Description[1)]		**Measured Radiation, pA/kg (µSv/h) (mR/h)**	**Remarks**
1/ /		---	---
2/ /		---	---
3/ /		---	---
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			

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Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				P
Model No.....:			TB101WX001		---
Test ambient (°C) .....:			27.1		---
Test supply voltage/frequency (V/Hz)[4] .:			12 Vdc		---
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**
Top enclosure	34	Top enclosure	56	54	OK
Bottom enclosure	40	Bottom enclosure	56	55.1	OK
LHS	37	LHS	56	48.4	OK
RHS	39	RHS	56	54.4	OK
Rear enclosure	35	Rear enclosure	56	55	OK
Display	31	Display	66	54.8	OK
ON/OFF switch	33	ON/OFF switch	56	54.7	OK
Supply connector at I/P side	16	Supply connector at I/P side	71	55.8	OK

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

[5] **APPLIED PARTS** intended to supply heat to a **PATIENT - See** RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.
Information from Risk Management, as applicable: **Rated maximum temperature is 50°C.**

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11.1.3d	TABLE: Temperature of windings by change-of-resistance method							N/A
Temperature T of winding:	**t_1 (°C)**	**R_1 (Ω)**	**t_2 (°C)**	**R_2 (Ω)**	**T (°C)**	**Allowed T_{max} (°C)**	**Insulation class**	
---	---	---	---	---	---	---	---	
---	---	---	---	---	---	---	---	
Supplementary information:								

11.2.2.1	TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source	N/A
Areas where sparking might cause ignition:		**Remarks**
1.		---
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):		**Remarks**
1.		---
Test parameters selected representing worst case conditions for ME EQUIPMENT:		**Remarks**
Oxygen concentration (%) ..... :	---	---
Fuel ..... :	---	---
Current (A) ..... :	---	---
Voltage (V) ..... :	---	---
Capacitance (µF) ..... :	---	---
Inductance or resistance (h or Ω) ..... :	---	---
No. of trials (300 Min) ..... :	---	---
Sparks resulted in ignition (Yes/No) :	---	---
Supplementary information:		

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:-			

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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: Certified insulated components are used in EUT				

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:	SEE BELOW	No
	Disconnection of Supply	EUT Turned OFF, No hazard observed in EUT	No
		USB short circuited No hazard observed in EUT	NO
13.2.3	Overheating of transformers per Clause 15.5:	–	–
		EUT is operated with certified adaptor	---
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	–	–
		No such part	–
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	–	–
		No such part	---

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Clause	Requirement + Test	Result - Remark	Verdict
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
		No such part	---
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	SEE BELOW	No
	-	-	-
	---	---	---
	---	---	---
	---	---	---
	---	---	---
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	---	---
	FAN HAS BEEN BLOCKED (TEMPERATURE OF ACCESSIBLE PART METALLIC ENCLOSURE)	No such construction	--
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10	—	—
		V measured =	---
		V measured =	---
		No such case	---
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	-	-

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	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:	—	—
		No such case	---
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	SEE BELOW	No
		No such mechanical hazard is present in EUT	No
Supplementary information: 1) Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10. Information from Risk Management, as applicable: --			

15.3	TABLE: Mechanical Strength tests 1)		P
Clause	**Name of Test**	**Test conditions**	**Observed results/Remarks**
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No damage found
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	No damage found
15.3.4.1	Drop Test (hand-held)	Free fall height (m) =	-
15.3.4.2	Drop Test (portable)	Drop height (cm) = 5 cm	No damage found
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) =	-
Supplementary information: As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows or state N/A in Remarks field).			

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Clause	Requirement + Test	Result - Remark	Verdict

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 (°C)**	**Maximum winding temp measured (°C)**	**Ambient (°C)**	
---	---	---	---	---	---	---	---	
---	---	---	---	---	---	---	---	
---	---	---	---	---	---	---	---	

Supplementary information: Nil

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Clause	Requirement + Test	Result - Remark	Verdict

15.5.1.3	TABLE: transformer overload test – conducted only when protective device under short-circuit test operated	N/A
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 (°C)	Maximum winding temp measured (°C)	Ambient (°C)
---	---	---	---	---	---
---	---	---	---	---	---
---	---	---	---	---	---

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

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
	Primary & secondary windings	---	---	---	---
	Primary winding & frame	---	---	---	---
	Secondary winding & frame	---	---	---	---

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

Reviewed & Authorized by:

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

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)**	

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

Section 6:

PHOTOGRAPS OF EQUIPMENT UNDER TEST

Fig.1 Front View of EUT

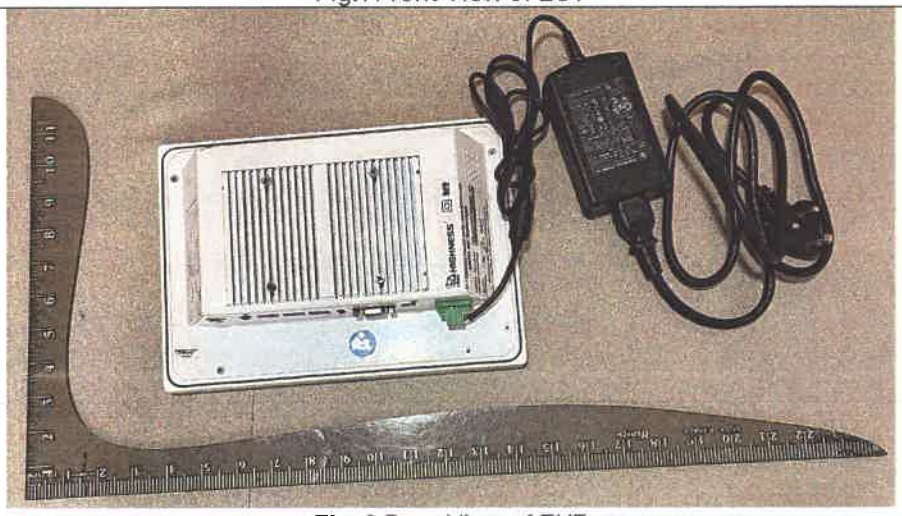

Fig. 2 Rear View of EUT

Fig. 3 Adapter

******END OF TEST REPORT******