UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Power Supply
Model:	1089 Family: GTM21089-0903-A.B-CD GTM21089-1305-A.B-CD GTM21089-1506-A.B-CD GTM21089-1509-A.B-CD GTM21089-1512-A.B-CD GTM21089-1815-A.B-CD GTM21089-1818-A.B-CD GTM21089-1824-A.B-CD 1096 Family: GTM21096-1003-A.B-CD GTM21096-1505-A.B-CD GTM21096-1506-A.B-CD GTM21096-1509-A.B-CD GTM21096-1512-A.B-CD GTM21096-1815-A.B-CD GTM21096-1818-A.B-CD GTM21096-1824-A.B-CD The models listed here are the standard models which the custom versions are based on. Custom units are obtained using the optional "A.B" modifier. The "CD" modifier describes type of input connection. See Model Differences for details.
Rating:	Input (all models, both families): 100-240 V ac, 50-60 Hz, 0.5 A max Output:

1089 Model	Vdc	A
GTM21089-0903-A.B-CD	3.3	2.6
GTM21089-1305-A.B-CD	5.0	2.6
GTM21089-1506-A.B-CD	6.0	2.5
GTM21089-1509-A.B-CD	9.0	1.7
GTM21089-1512-A.B-CD	12.0	1.25
GTM21089-1815-A.B-CD	15.0	1.2
GTM21089-1818-A.B-CD	18.0	1.0
GTM21089-1824-A.B-CD	24.0	0.75

1096 Model	Vdc	A
GTM21096-1003-A.B-CD	3.3	2.6

	GTM21096-1505-A.B-CD	5.0	2.6
	GTM21096-1506-A.B-CD	6.0	2.5
	GTM21096-1509-A.B-CD	9.0	1.7
	GTM21096-1512-A.B-CD	12.0	1.25
	GTM21096-1815-A.B-CD	15.0	1.2
	GTM21096-1818-A.B-CD	18.0	1.0
	GTM21096-1824-A.B-CD	24.0	0.75
	See Model Differences for further details.		
Applicant Name and Address:	GLOBTEK (HONG KONG) LTD UNIT 1402, BENSON TOWER 74 HUNG TO RD KWUN TONG KOWLOON HONG KONG		

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Conga Chen Reviewed by: Calvin Tang

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.

ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.

iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Product Description

The product covered by this report is a unit intended to provide power to and intended for use with Medical Electrical equipment.

Model Differences

Differences within the families are limited to minor component changes to determine output voltage and current.

The 1096 Family is identical to the 1089 Family except for the following:
1) The 1089 Family is provided w/ an enclosure; the 1096 Family is open-frame.
2) The 1096 Family is provided with Molex connectors for input and output connections.

The 1089 Family models are represented by the following nomenclature:

GTM21089-YYZZ-A.B-CD

where:
GTM2 designates versions with UL 60601-1 Medical safety approval;
1089 is the family designation;
YYZZ output parameter designations as seen in the standard model list for both families;
-A.B designates the optional deviation, subtracted from standard output voltage in 0.1 volt increments;
C designates physical configuration - W = wall plug-in model, T = desktop model;
D designates the input plug configuration - 2 = Class II type (2-prong), 3 = Class I type (3-prong) (See Note 1.)

Note 1 - Despite the Class I type appliance inlet, these units remain classified as Class II with Function Earth only.

The 1096 family models are represented by the following nomenclature:

GTM21096-YYZZ-A.B-CD

where:
GTM2 designates versions with UL 60601-1 Medical safety approval;
1096 is the family designation;
YYZZ output parameter designations as seen in the standard model list for both families;
-A.B designates the optional deviation, subtracted from standard output voltage in 0.1 volt increments;
CD designates physical configuration and input plug configuration - F = open-frame, Class I input connector, FW = open-frame, Class II input connector (See Note 2).

Note 2 - Class I and Class II Input connectors are identical except that the Earth pin is removed on the Class II units.

Technical Considerations

- Classification of installation and use : 1089 Family - Portable; 1096 Family - For building-in
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Recognized power adaptor, shall be determine in end use application.
- Mode of operation : Continuous
- Supply connection : 1089 Family - Appliance coupler/Direct Plug-in; 1096 Family - To be determined

in the end-product

- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) - Edition 1 - Revision Date 2012/01/01, CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) Edition 2 - Revision Date 2011/06/01
- The product was not investigated to the following standards or clauses:: Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 601-1-2) Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is:: Ordinary
- The mode of operation is:: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide:: No
- The product is Classified only to the following hazards: for 1089 Family - Casualty, Fire, Shock; for 1096 Family - Fire, Shock
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. When installed in an end-product, consideration must be given to the following:

- For 1096 Family only - A suitable fire and electrical enclosure shall be provided in the end-product. Further, connection and disconnection to and from MAINS shall be determined in the end-product.
- For 1089 Family only - A Listed detachable Power Supply cord provided with a "Hospital Only" or "Hospital Grade" attachment plug shall be employed in the end-use application in North America.
- This equipment was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The unit provides the following MOOP (means of operator protection): The power supply was evaluated as 2 MOOP between primary and secondary. See insulation diagram for details.
- This equipment has not been evaluated for field wiring.
- This equipment was evaluated for operating altitude up to 3000m above sea level.
- The maximum working voltage measure between primary and secondary is 280 V rms; 496 Vpk. The dielectric strength tests in the end product shall be based on these values.
- The suitability for this equipment to be used in patient care equipment needs to be evaluated in end-product investigation.
- Cleaning, sterilization or disinfection should be considered in the end use application.
- Transformer T1 incorporates a Class B(130 Degree C) insulation system. The Power Supply was evaluated for a maximum ambient temperature of 40 degree C.
- This power supply has been judged on the basis of the required creepage and clearances in the First Edition of the Standard for Medical Electrical Equipment, ANSI/AAMI ES 60601-1(2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1(2008), Sub clause 8.9.
- This power supply has been evaluated as continuous operation, ordinary Equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. An additional evaluation shall be made if the power supply is intended for use in other than these conditioin.

- Legibility of markings test shall be considered in end application.
- Product was power supplies intend to be used with meidical device in end application, the evaluation for allowable touch duration / accessible temperature limit / test corner shall be considered in end application.

Additional Information

N/A

Additional Standards

The product fulfills the requirements of: The product fulfills the requirements of: CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)

Markings and instructions

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Supply Frequency	Rated frequency range in hertz
Class II equipment	
Alternating current	
Direct current	
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.

Special Instructions to UL Representative

Class I product don't have Class II equipment symbol

Production-Line Testing Requirements

Test Exemptions - The following models are exempt from the indicated test

Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
GTM21089-YYZZ-A.B-CD	Exempt	Not exempt	Exempt
GTM21096-YYZZ-A.B-CD	Exempt	Not exempt	Exempt

Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:

Component
--

Sample and Test Specifics for Follow-Up Tests at UL

The following tests shall be conducted in accordance with the Generic Inspection Instructions

Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
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TABLE: List of Critical Components

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
X Capacitor (CX1) (optional)	Pilcor	PCX2	Max.0.22uf, Min.250V, X1 or X2	FOKY2, or FOWX2	UL/cUL R/C
X Capacitor (CX1) – Alternate (optional)	Ultra Tech	HQX	Max.0.22uf, Min.250V, X1 or X2	FOKY2, or FOWX2	UL/cUL R/C
X Capacitor (CX1) – Alternate (optional)	Dain	MPX	Max.0.22uf, Min.250V, X1 or X2	FOKY2, or FOWX2	UL/cUL R/C
X Capacitor (CX1) – Alternate (optional)	Europtronic	MPX	Max.0.22uf, Min.250V, X1 or X2	FOKY2, or FOWX2	UL/cUL R/C
X Capacitor (CX1) – Alternate (optional)	Cheng Tung	CTX	Max.0.22uf, Min.250V, X1 or X2	FOKY2, or FOWX2	UL/cUL R/C
X Capacitor (CX1) – Alternate (optional)	Jiangsu Xinghua Huayu Electronics Co., Ltd.	MPX	Max.0.22uf, Min.250V, X1 or X2	FOKY2, or FOWX2	UL/cUL R/C
X Capacitor (CX1) – Alternate (optional)	Sinhua Electronics (Huzhou) Co. Ltd.	MPX	Max.0.22uf, Min.250V, X1 or X2	FOKY2, or FOWX2	UL/cUL R/C
X Capacitor (CX1) – Alternate (optional)	SHANTOU HIGH-NEW TECHNOLOGY DEVELOPMNT ZONE SONGTIAN ENTERPRISE CO LTD	MPX	Max.0.22uf, Min.250V, X1 or X2	FOKY2, or FOWX2	UL/cUL R/C
Appliance Inlet – "-T3" models only - 1089 Only	In-Always	0711	Min 10A, 250V	AXUT2/8	UL R/C
Appliance Inlet – Alternate - "-T3" models only - 1089 Only	Rich Bay	R-301SN, R-301	Min 10A, 250V	AXUT2/8	UL R/C
Appliance Inlet – Alternate - "-T3" models only - 1089 Only	Sun Fair	S-03	Min 10A, 250V	AXUT2/8	UL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Appliance Inlet – Alternate - "-T3" models only - 1089 Only	Tecx-Unions	TU-301-S, TU-301-SP	Min 10A, 250V	AXUT2/8	UL R/C
Appliance Inlet – Alternate - "-T3" models only - 1089 Only	DLK	CDJ-3K	Min 10A, 250V	AXUT2/8	UL R/C
Appliance Inlet – Alternate - "-T3" models only - 1089 Only	RONG FENG	SS-120	Min 10A, 250V	AXUT2/8	UL R/C
Bulk Capacitor (C9)	--	--	Max.68uF, Min.400V, 105 deg C	--	--
Capacitor, bridging (CY1)(optional)	TDK	CD	4700pf (max), 250V, Y1	FOKY2, or FOWX2	UL/cUL R/C
Capacitor, bridging (CY1) – Alternate (optional)	WALSIN TECHNOLOGY CORP	AH	4700pf (max), 250V, Y1	FOKY2, or FOWX2	UL/cUL R/C
Capacitor, bridging (CY1) – Alternate (optional)	Murata	KX	4700pf (max), 250V, Y1	FOKY2, or FOWX2	UL/cUL R/C
Capacitor, bridging (CY1) – Alternate (optional)	Success	SE, SB	4700pf (max), 250V, Y1	FOKY2, or FOWX2	UL/cUL R/C
Capacitor, bridging (CY1) – Alternate (optional)	JYA-NAY CO LTD	JN	4700pf (max), 250V, Y1	FOKY2, or FOWX2	UL/cUL R/C
Capacitor, bridging (CY1) – Alternate (optional)	HAOHUA ELECTRONIC	CT 7	4700pf (max), 250V, Y1	FOKY2, or FOWX2	UL/cUL R/C
Capacitor, bridging (CY1) – Alternate (optional)	KUNSHAN WANSHENG ELECTRONICS CO LTD	CT7	4700pf (max), 250V, Y1	FOKY2, or FOWX2	UL/cUL R/C
Capacitor, bridging	SHANTOU HIGH-	CD	4700pf (max), 250V, Y1	FOKY2, or	UL/cUL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
(CY1) – Alternate (optional)	NEW TECHNOLOGY DEVELOPMNT ZONE SONGTIAN ENTERPRISE CO LTD			FOWX2	
Capacitor, bridging (CY1) – Alternate (optional)	ZHI WEI ELECTRONICS CO LTD	DJ	4700pf (max), 250V, Y1	FOKY2, or FOWX2	UL/cUL R/C
Capacitor, bridging (CY1) – Alternate (optional)	JERRO ELECTRONICS CORP	JX	4700pf (max), 250V, Y1	FOKY2, or FOWX2	UL/cUL R/C
Capacitor, bridging (CY1) – Alternate (optional)	HONGZHI	Y	4700pf (max), 250V, Y1	FOKY2, or FOWX2	UL/cUL R/C
Enclosure - 1089 Only	Teijin Chemicals	LN-1250G	Rated V-0. Overall wall plug-in measures 74 by 49 by 40.5 mm. Desktop measures 86.5 by 47 by 32 mm. All minimum 2.3 mm thick. Constructed of two parts secured together by ultrasonic welding.	QMFZ2	R/C UL
Enclosure – Alternate - 1089 Only	SABIC	SE100	Same as above.	QMFZ2	UL/cUL R/C
Enclosure – Alternate - 1089 Only	Chi Mei	PA-769	Same as above.	QMFZ2	UL/cUL R/C
Fuse (F1, F2)	Littlefuse	228	250V, T1A. Validate and accept by test.	JDYX2	UL/cUL R/C
Fuse (F1, F2) - Alternate	Wickman	195	250V, T1A. Validate and accept by test.	JDYX2	UL/cUL R/C
Fuse (F1, F2) - Alternate	Walter	TAP	250V, T1A. Validate and accept by test.	JDYX2	UL/cUL R/C
Fuse (F1, F2) - Alternate	Various	Various	250V, T1A. No micro fuse.	JDYX/7	UL/cUL R/C
Insulating Tape (around D8/H1)	YAHUA	PZ, CT, WF	2 layers, min. 1 turn, min. 20mm wide	OANZ2	UL R/C
Insulating Tape (around D8/H1) alternate	JINGJIANGJINGYI	JY25-A	2 layers, min. 1 turn, min. 20mm wide	OANZ2	UL R/C
Insulating Tape (around D8/H1) alternate	SYMBIO INC	35660Y	2 layers, min. 1 turn, min. 20mm wide	OANZ2	UL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Insulating Tape (around D8/H1) alternate	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	2 layers, min. 1 turn, min. 20mm wide	OANZ2	UL R/C
Insulating Tape (around D8/H1) alternate	3M	1350-1	2 layers, min. 1 turn, min. 20mm wide	OANZ2	UL R/C
Insulator - Silpad	DONGGUAN NANJU POLYMER MATERIAL CO LTD	NJ-352H-70	Around D8; 0.4mm thick min.	QMFZ2	UL/cUL (E346848)
Insulator – Heat sink	Formex	Formex-18	Min 0.4mm thick; L-shaped, measuring 27 by 51 mm overall (flat)	QMFZ2	UL/cUL R/C
Insulator – Heat sink Alternate	MIANYANG LONGHUA FILM CO LTD	PP-(i)(j)	Min 0.4mm thick; L-shaped, measuring 27 by 51 mm overall (flat)	QMFZ2	UL/cUL R/C
Optical isolator (U1)	Sharp	PC817	5000 Vac isolation; 0.4mm insulation thickness inside and out (Reinforced)	FPQU2	UL/cUL R/C
Optical isolator (U1) -- Alternate	Liton	LTV-817	5000 Vac isolation; 0.4mm insulation thickness inside and out (Reinforced)	FPQU2	UL/cUL R/C
Optical isolator (U1) -- Alternate	Everlight	EL817	5000 Vac isolation; 0.4mm insulation thickness inside and out (Reinforced)	FPQU2	UL/cUL R/C
Optical isolator (U1) -- Alternate	Cosmo	K1010; KP1010	5000 Vac isolation; 0.4mm insulation thickness inside and out (Reinforced)	FPQU2	UL/cUL R/C
Optical isolator (U1) -- Alternate	BRIGHT LED ELECTRONICS CORP	BPC- 817; BPC-817M; BPC- 817S	5000 Vac isolation; 0.4mm insulation thickness inside and out (Reinforced)	FPQU2	UL/cUL R/C (E236324)
Printed wiring board	Various	Various	Min V-1, 105 deg C	ZPMV2	UL/cUL R/C
Resistor, bleeding (R8, R9)	--	--	470K, min.1/8W, carbon	--	--
Output Strain Relief - 1089 Only	Various	Various	Rated Min HB (See Diagrams enclosure.)	QMFZ2	UL R/C
Transformer (T1)	BOAM	See Diagrams Enclosure for model numbers.	Employs R/C OBJY2 Class B insulation system. See Diagrams Enclosure 4-01 for details.	--	(Tested in power supply.)

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Insulation System	BOAM	BOAM-01	Class B (130 deg C)	OBJY2	UL R/C
-Primary winding used in T1	Various	Various	Polyurethane with or without overcoat Polyamide, 130 deg C min. MW -75 or MW28 Type.	OBMW2	UL R/C
-Secondary winding used in T1	Furukawa Electric Co Ltd	TEX-E	Rated 130 deg C Triple insulated wire	OBJT2	UL R/C
-Bobbin used in T1	Sumitomo Bakelite Co., Ltd.	PM-9820	Phenolic, rated V-0, 150 deg C	QMFZ2	UL R/C
-Insulation Tape used in T1	YAHUA	PZ, CT	Rated 130 deg C	OANZ2	UL R/C
-Varnish used in T1	NOROO PAINT&COATINGS CO.,LTD	DVB-2085(C) DVB-2085(1)	Rated 130 deg C	OBOR2	UL R/C
-Tube	GREATHOLDING INDUSTRIAL CO LTD	TFL TFT	Rated 150V, 200 deg C	YDPU2	UL R/C
Transformer (T1)- Alternate	GlobTek/ ZhongTong	See Diagrams Enclosure for model numbers.	Employs R/C OBJY2 Class B insulation system. See Diagrams Enclosure 4-02 for details.	--	(Tested in power supply.)
Insulation System	GlobTek	GTX-130-TM	Class B, table VII (130 deg C)	OBJY2	UL R/C
-Primary winding used in T1	Various	Various	Polyurethane with or without overcoat Polyamide, 130 deg C min. MW -75 or MW28 Type.	OBMW2	UL R/C
-Secondary winding used in T1	GREATLEOFLON INDUSTRIAL CO LTD	TRWB	Rated 130 deg C Triple insulated wire	OBJT2	UL R/C
-Secondary winding used in T1 Alternate	TOTOKU ELECTRIC CO LTD	TIW-2	Rated 130 deg C Triple insulated wire	OBJT2	UL R/C
-Bobbin used in T1	Sumitomo Bakelite Co., Ltd.	PM-9820	Phenolic, rated V-0, 150 deg C	QMFZ2	UL R/C
-Bobbin used in T1 Alternate	CHANGCHUN	T375J, T375HF	Phenolic, rated V-0, 150 deg C	QMFZ2	UL R/C
-Insulation Tape used in	YAHUA	PZ, CT, WF	Rated 130 deg C	OANZ2	UL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
T1					
-Insulation Tape used in T1 Alternate	JINGJIANGJINGYI	JY25-A	Rated 130 deg C	OANZ2	UL R/C
-Insulation Tape used in T1 Alternate	SYMBIO INC	35660Y	Rated 130 deg C	OANZ2	UL R/C
-Insulation Tape used in T1 Alternate	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	Rated 130 deg C	OANZ2	UL R/C
-Varnish used in T1	SUZHOU TAIHU ELECTRIC ADVANCED MATERIAL CO LTD	T-4260(a)	Rated 130 deg C	OBOR2	UL R/C
-Tube	NanTong Baishiling Plastic Electronics Co., Ltd	TFL-201 TFT-201	Rated 150V, 200 deg C	YDPU2	UL R/C
-Tube Alternate	SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD	WF	Rated 600V, 200 deg C	YDPU2/8	UL R/C
- Tube (Alternate)	CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD	CB-TT-L CB-TT-S CB-TT-T	VW-1. Rated Min.150V,Min. 200 Vdc	YDPU2	UL R/C
Insulation System, alternate	GlobTek	GTX-130-TM	Class B, table IV (130 deg C)	OBJY2	UL R/C
-Primary winding used in T1	Various	Various	Polyurethane with or without overcoat Polyamide, 130 deg C min. MW -75 or MW28 Type.	OBMW2	UL R/C
-Secondary winding used in T1	GREATLEOFLON INDUSTRIAL CO LTD	TRWB	Rated 130 deg C Triple insulated wire	OBJT2	UL R/C
-Bobbin used in T1	Sumitomo Bakelite	PM-9820	Phenolic, rated V-0, 150 deg C	QMFZ2	UL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
	Co., Ltd.				
-Bobbin used in T1 Alternate	CHANGCHUN	T375J	Phenolic, rated V-0, 150 deg C	QMFZ2	UL R/C
-Insulation Tape used in T1	YAHUA	PZ, CT, WF	Rated 130 deg C	OANZ2	UL R/C
-Insulation Tape used in T1 Alternate	JINGJIANGJINGYI	JY25-A	Rated 130 deg C	OANZ2	UL R/C
-Insulation Tape used in T1 Alternate	SYMBIO INC	35660Y	Rated 130 deg C	OANZ2	UL R/C
-Insulation Tape used in T1 Alternate	CHANG SHU LIANG YI TAPE INDUSTRY CO LTD	LY-XX	Rated 130 deg C	OANZ2	UL R/C
-Varnish used in T1	SUZHOU TAIHU ELECTRIC ADVANCED MATERIAL CO LTD	T-4260(a)	Rated 130 deg C	OBOR2	UL R/C
-Tube	Great Holding Industrial Co Ltd	TFL, TFT	Rated 150V, 200 deg C	YDPU2	UL R/C
-Tube Alternate	SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD	WF	Rated 600V, 200 deg C	YDPU2/8	UL R/C
Transformer (T1)		See Diagrams Enclosure for model numbers.	Employs R/C OBJY2 Class B insulation system. See Diagrams Enclosure 4-03 for details.	--	(Tested in power supply.)
-Insulation System		DASH 2 B-19	Class B (130 deg C)	OBJY2	UL R/C
-Primary winding used in T1	Various	Various	Polyurethane with or without overcoat Polyamide, 130 deg C min. MW -75 or MW28 Type.	OBMW2	UL R/C
-Secondary winding used in T1	Furukawa Electric Co Ltd	TEX-E	Rated 130 deg C Triple insulated wire	OBJT2	UL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
-Bobbin used in T1	CHANGCHUN	T375J	Phenolic, rated V-0, 150 deg C	QMFZ2	UL R/C
-Insulation Tape used in T1	3M	1350-1	Rated 130 deg C	OANZ2	UL R/C
-Varnish used in T1	ELANTAS	468-2FC	Rated 130 deg C	OBOR2	UL R/C
-Tube	GREAT HOLDING INDUSTRIAL CO LTD	TFL	Rated 150V, 200 deg C	YDPU2	UL R/C
Wiring, internal – functional earth lead - 1089 with 3-prong construciton only	Various	Various	VW-1; 105 deg C, 18 gauge; shrink tubing around wire is necessary for compliance	AVLV2	UL/cUL R/C
Tube on function earth lead	SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD	RSFR-H	Min. 0.4mm, min.125 deg C,min.300V	YDPU2	UL/cUL (E203950)
Output Cord	Various	Various	No. 22 AWG min., VW-1, 80 deg C, 300V, one end soldered to pwb and the other end molded with connector barrel type.	AVLV2, ZJCZ	UL/cUL R/C
Heat Sink	--	--	Copper, L-shaped. Top dimensions 36 mm by 40 mm, 0.8 mm thick. Side dimensions 23mm by 25mm, 0.8 mm thick. Rear edge covered in 1 layer, 8.0mm of R/C OANZ2 Mylar tape on both top and bottom.	--	--
Diode Bridge (D3 to D6)	--	--	Rated min.600V, min.1.5A.	--	--
Transistor (U3)	--	--	Rated min.500V, 2A min. Secured to heatsink by metal screw.	--	--
Input connector - 1096 Only	Molex	09-65-2038	Rated min 250V, min 1A; 3 pin version for Class I units, 3rd pin cut for Class 2 units, material rated V-2	ECBT2	UL, cUL R/C
Input connector - 1096 Only	Weli Sheng	M2/3-I39601	Rated min 250V, 7A; 3 pin version for Class I units, 3rd pin cut for Class 2 units, material rated V-2	ECBT2	UL, cUL R/C
Switch (Optional for 21089 Output Cord)	Various	Various	250 V, 2 A; 120 V, 3 A. V-2	WNWV2	UL/cUL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Line Choke (LF1)	Various	Various	Rating 130 deg. C	--	--
- Bobbin	Changchun	T375J T375HF	Rated minimum 94V-1, and 130 deg. C, minimum	QMFZ2	UL/cUL R/C
-Bobbin (alternate)	Sumitomo Bakelite Co., Ltd	PM-9820	Rated minimum 94V-1, and 130 deg. C, minimum	QMFZ2	UL/cUL R/C
- Wire	Various	Various	Rating 130 deg. C	OBMW2	UL/cUL R/C
Label (Provided if not using engraving or silkscreen)	Dongguan Xianquan Printing Co Ltd	XQ03, XQ004-B	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2	UL/cUL R/C
Label (Provided if not using engraving or silkscreen) (alternate)	Fan JA Paper Printing Co Ltd	FJ-03-3, FJ-07, FJ-03-1	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2	UL/cUL R/C
Label (Provided if not using engraving or silkscreen) (alternate)	E-Lin Adhesive Co Ltd	EL-15	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2	UL/cUL R/C
Label (Provided if not using engraving or silkscreen) (alternate)	DONGGUAN SHANGMAO PRINTING CO LTD	C-004, C-019	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2	UL/cUL R/C
Label (Provided if not using engraving or silkscreen) (alternate)	SUZHOU HAIRONG PACKING PRODUCTION CO LTD	HR-01, HR-04	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2	UL/cUL R/C
Label (Provided if not using engraving or silkscreen) (alternate)	CORWIN	CW-01	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2	UL/cUL R/C
Label (Provided if not using engraving or silkscreen) (alternate)	YUEN CHANG	JL-08, JL-02	Rated min 80 deg C Suitable for use on the plastic enclosure	PGDQ2	UL/cUL R/C

Enclosures

Type	Supplement Id	Description
Collateral		
Particular		
Photographs	3-01	1089 Desktop, Enclosure
Photographs	3-02	1089 Desktop, internal, top
Photographs	3-03	1086 Desktop, internal, bottom
Photographs	3-04	1089 Wall Plug-in, Enclosure
Photographs	3-05	1089 Wall Plug-in, internal, top
Photographs	3-06	1089 Wall Plug-in, internal, bottom
Photographs	3-07	1096 Open-frame (all) Models, top
Photographs	3-08	1096 Open-frame (all) Models, bottom
Diagrams	4-01	Output Strain Relief Spec
Diagrams	4-02	Transformer Construction Diagram_BOAM
Diagrams	4-03	Transformer Construction Diagram_Globtek
Diagrams	4-04	Transformer Construction Diagram_SUNNY
Schematics + PWB	5-01	1089 Desktop Models
Schematics + PWB	5-02	1089 Wall Plug-in Models
Schematics + PWB	5-03	1096 Open-Frame (all) Models
Manuals		
Miscellaneous	7-01	1089 Family Label
Miscellaneous	7-02	1096 Family Label

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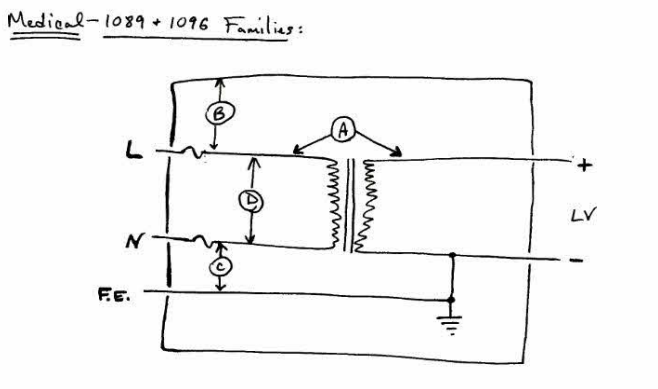
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM



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Clause	Requirement + Test	Result - Remark	Verdict

Table: to insulation diagram

Pollution Degree	Overvoltage Category	Altitude	Additional details on parts considered as applied parts (See clause 4.6 for details)
2	II	3000m	None

Area	Number and type of Means of Protection (MOOP/MOPP)	CTI (IIIb, unless is known)	Working Voltage Vrms	Working Voltage, Vpk	Required Creepage (mm)	Required Clearance (mm)	Measured Creepage (mm)	Measured Clearance (mm)	Remarks
D	BOP	IIIb	250	354	3.0	1.6	3.6	3.6	Trace L to N before fuse
A	2MOOP	IIIb	280	496	5.9	5.0	8.0	8.0	T1 primary to secondary via PWB trace
A	2MOOP	IIIb	280	496	5.9	5.0	--	--	T1 primary windings/core to secondary windings (secondary use TIW)
A	2MOOP	IIIb	250	354	5.0	4.7	5.7	5.7	T1 core to CY1 secondary pin through PWB via core tape
A	2MOOP	IIIb	250	354	5.0	4.7	--	--	T1 to secondary C2/C3 via T1 external tape (2 layers)
A	2MOOP	IIIb	250	354	5.0	4.7	5.2	5.2	Primary H1 to secondary C2/C3 via insulator (min. 0.4mm thick)
A	2MOOP	IIIb	250	354	5.0	4.7	--	--	Primary H1 to secondary C3 via tapes around D8 (1 layer around

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Clause	Requirement + Test	Result - Remark	Verdict

									D8/H1 + 1 layer on the side of D8 adjacent to C3)
A	2MOOP	IIIb	221	356	5.0	4.7	8.0	5.7	Under CY1
A	2MOOP	IIIb	239	380	5.0	4.7	8.0	5.7	Under U1
B	2MOOP	IIIb	250	354	5.0	4.7	5.7	5.7	Primary C9 to enclsoure
C	2MOOP	IIIb	250	354	5.0	4.7	8.0	8.0	Primary trace to Functional Earth trace (same as primary to secondary locations)
C	2MOOP	IIIb	250	354	5.0	4.7	--	--	Functional earth wire to primary circuits via tubing
Supplementary information: Refer to CTL Decision DSH 0791 for circumstances when > (greater than) or < (less than) symbols are permitted.									

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

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

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

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

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Clause	Requirement + Test	Result - Remark	Verdict
4	**GENERAL REQUIREMENTS**		Pass
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		N/A
4.2	A RISK MANAGEMENT PROCESS complying with ISO 14971 was performed ..... :	See Appended RM Results Table 4.2	Pass
4.3	ESSENTIAL PERFORMANCE functions identified according to MANUFACTURER'S policy for RISK acceptability in RISK MANAGEMENT FILE ..... :	No essential performance other than power rating is defined. Essential performance other than power rating is to be evaluated in end application.	N/A
	ESSENTIAL PERFORMANCE functions maintained following particular tests as applicable	No essential performance other than power rating is defined. Essential performance other than power rating is to be evaluated in end application.	N/A
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE ..... :	5 yesrs	Pass
4.5	Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means equal to or less than RESIDUAL RISKS resulting from requirements of this standard ..... :	No alternative means applied in the evaluation of RM report.	N/A
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10 ..... :	No parts that are not applied parts that need to be treated as applied parts used	N/A
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2..... :	See Appended RM Results Table 4.7	N/A
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically :	See Appended Table 13.2 for simulated physical test.	N/A
	RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation	Single fault condition considered. See appended RM result Table 4.7 and appended Table 13.2 for failure simulation.	N/A
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, except as specified, or by RISK MANAGEMENT PROCESS :	See Appended RM Results Table 4.8	N/A
	Reliability of components used as MEANS OF		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following:		
	a) Applicable safety requirements of a relevant IEC or ISO standard	See table Critical component table list of critical components	N/A
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		N/A
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK..... :	No high-integrity was used	N/A
	COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS selected and evaluated consistent with their conditions of use and reasonable foreseeable misuse during EXPECTED SERVICE LIFE of ME EQUIPMENT by reviewing RISK MANAGEMENT FILE ..... :		N/A
4.10	Power supply		N/A
4.10.1	ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three ..... :	The product is suitable to connect to SUPPLIED MAINS	N/A
4.10.2	Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS is 250 V for HAND-HELD ME EQUIPMENT (V) ..... :	No hand-held parts	N/A
	- 250 V d.c. or single-phase a.c., or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V) ..... :	100-240Vac; max 0.5 A	N/A
	- 500 V for all other ME EQUIPMENT and ME SYSTEMS	100-240Vac; max 0.5 A	N/A
4.11	Power input		Pass
	Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use did not exceed marked rating by more than 10%.. :	Test conducted in previous 2nd Edition evaluation (Ref.: E341350-A4-UL).	Pass
	- Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range..... :	Test conducted in previous 2nd Edition evaluation (Ref.: E341350-A4-UL).	Pass
	Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of	No such marking. Rated voltage: 100-240Vac.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	relevant voltage range		
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage..... :	Power Input is expressed in Amp. See Appended Table 4.11	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

5	**GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT**		Pass
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2	TYPE TESTS determined in consideration of Clause 4, in particular 4.2	Pass
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods ..... :		N/A
	Results of RISK ANALYSIS used to determine combination(s) of simultaneous faults to be tested	The all tests described in RM report are TYPE TESTS (TYPE TESTS was according to IEC60601-1:2005, clause 5.1). For the selection of the tests to be performed, is according to risk management process of ISO14971:2007.	Pass
5.2	TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected ..... :	The product was tested with multiple samples.	Pass
5.3	a) Tests conducted within the environmental conditions specified in technical description		Pass
	Temperature (°C), Relative Humidity (%) ..... :	0-40 degree C 0-93% RH	-
	Atmospheric Pressure (kPa)..... :	700-1060 hPa(up to 3000m)	-
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests	No such situation	N/A
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained ..... :	No such situation	N/A
5.4	a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use and identified during RISK ANALYSIS, except as noted..... :	See Appended RM Results Table 5.4a	Pass
	b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favourable for the relevant test per instructions for use	The product is switching power adapter, the application of this clause shall be evaluated in end application	N/A
	c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits in technical description ..... :	The product is switching power adapter, the application of this clause shall be evaluated in end application	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	d) Potable water used for cooling	The product is switching power adapter, the application of this clause shall be evaluated in end application	N/A
5.5	Supply voltage during tests was the least favourable of the voltages specified in 4.10 or voltages marked on ME EQUIPMENT (V) ..... :	Rated voltage: 100-240Vac Tested at 90/100/240/264Vac	Pass
	ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz) ..... :	50-60 Hz	Pass
	ME EQUIPMENT with more than one RATED voltage, or both a.c./ d.c. tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current ..... :	Tested at 90/100/240/264Vac, Single phase supply, AC current.	Pass
	ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions ..... :	The product is switching power adapter, the application of this clause shall be evaluated in end application.	N/A
	ME EQUIPMENT connected to a separate power supply as specified in instructions for use	The product is switching power adapter, the application of this clause shall be evaluated in end application.	N/A
5.6	When failure occurred or probability of future failure detected during sequence of tests, per agreement with manufacturer, all tests affecting results conducted on a new sample		Pass
	Alternatively, upon repair and modification of the sample, only the relevant tests conducted		Pass
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3..... :	See Appended RM Results Table 5.7 and Appended Table 5.7.	Pass
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened and detached	No such construction	N/A
	ME EQUIPMENT heated to a temperature between T and T + 4 °C for at least 4 h and placed in a humidity chamber with a relative humidity of 93 % ± 3 % and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 48 h	Humidity test at 25 degree C in R.H. 95% duration 48 hours.	Pass
	When RISK MANAGEMENT PROCESS indicated ME EQUIPMENT can be exposed to high humidity	No such declaration.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	for extended periods (i.e., out-door use), test time extended proportionally (h)..... :		
5.8	Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent results of one test on a subsequent test		Pass
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		Pass
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS .... :	No applied parts used	N/A
5.9.2	ACCESSIBLE PARTS		N/A
5.9.2.1	Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position		N/A
	Openings preventing entry of test finger of Fig. 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N		N/A
	When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening		N/A
5.9.2.2	Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s		N/A
	All additional parts that became accessible checked using standard test finger and by inspection		N/A
5.9.2.3	Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS..... :	No such parts	N/A
	Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL, and inspection of RISK MANAGEMENT FILE indicated the relevant part is unlikely to detach unintentionally during EXPECTED SERVICE LIFE of ME EQUIPMENT..... :	No such parts	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
6	**CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS**		Pass
6.2	CLASS I ME EQUIPMENT, externally powered		N/A
	CLASS II ME EQUIPMENT, externally powered	See model differences for construction	Pass
	INTERNALLY POWERED ME EQUIPMENT	Not internally powered	N/A
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements		N/A
	TYPE B APPLIED PART	No applied parts used	N/A
	TYPE BF APPLIED PART	No applied parts used	N/A
	TYPE CF APPLIED PART	No applied parts used	N/A
	DEFIBRILLATION-PROOF APPLIED PARTS	No applied parts used	N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN1N2) as per IEC 60529 ..... :	IPX0	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 such function	N/A
6.5	ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2	Not used with oxygen or oxygen enriched environments	N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION ..... :	Continuous	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
7	**ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS**		Pass
7.1.1	RISK of poor USABILITY associated with the design of ME EQUIPMENT'S identification and marking addressed in a USABILITY ENGINEERING PROCESS..... :		N/E
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6 ..... :	The product is certified as a component, and the installation method is unclear. The application of this clause should be evaluated in end application. However, the test is done for reference. Please see Appended Table 7.1.2.	N/A
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		Pass
	a) After tests, adhesive labels didn't loosen up or curl up at edges and markings complied with requirements in Clause 7.1.2..... :	See Appended Tables 7.1.3 and 8.10	Pass
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test.. :	See Appended Tables 7.1.3 and 8.10	Pass
7.2	Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts		Pass
7.2.1	At least markings in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ..... :	See attached copy of Marking Plate	Pass
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS..... :	To be evaluated in end application	N/A
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	To be evaluated in end application	N/A
	A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01)..... :	No such construction	N/A
7.2.2	MANUFACTURER's name or trademark marked on ME EQUIPMENT and detachable components :	See Appended RM Results Table 7.2.2	Pass
	Misidentification does not present an unacceptable risk	See Appended RM Results Table 7.2.2	Pass
	MODEL OR TYPE REFERENCE also marked,	See enclosure 7-01 and 7-02	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	except when misidentification would not present an unacceptable RISK..... :	for details	
	Software forming part of a PEMS identified with a unique identifier, such as revision level or date of release/issue, and identification are available to designated persons ..... :	No such part	N/A
7.2.3	Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS	No instruction for use provided. To be evaluated in end application	N/A
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	No instruction for use provided. To be evaluated in end application	N/A
7.2.4	ACCESSORIES marked with name or trademark of MANUFACTURER or supplier, and with a MODEL or TYPE REFERENCE..... :	No accessories.	N/A
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	No accessories.	N/A
7.2.5	MODEL or TYPE REFERENCE of equipment to be connected to ME EQUIPMENT to provide power, is marked adjacent to the relevant connection point when this connection could result in an unacceptable RISK..... :	Not intend to receive its power from other equipment.	N/A
7.2.6	Connection to the Supply Mains		Pass
	Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	Rated input voltage: 100-240Vac	Pass
	For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to supply connection terminals	Not permanently installed	N/A
	- RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V)..... :	100-240Vac	Pass
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)..... :	No Multiple rated supply voltages or multiple rated supply voltage	N/A
	- Nature of supply (e.g., No. of phases, except single-phase) and type of current..... :	Single phase. Rated input voltage: 100-240Vac, max 0.5A.	Pass
	Symbols 1-5, Table D.1 (symbols of IEC 60417-	Symbol was used	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	5032, 5032-1, 5032-2, 5031, and 5033, all DB: 2002-10) used, optionally, for same parameters... :		
	- RATED supply frequency or RATED frequency range in hertz..... :	50-60 Hz	Pass
	- Symbol 9 of Table D.1 (symbol IEC 60417-5172, DB: 2003-02) used for CLASS II ME EQUIPMENT:	Class II or Class II with functional earth	Pass
7.2.7	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)..... :	Input rating: 100-240Vac, max 0.5A	Pass
	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)..... :	Rated input was given in Ampere by maximum	N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) ..... :		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA) ..... :	No such design.	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) ..... :	To be evaluated in end application	N/A
7.2.8	Output connectors		Pass
7.2.8.1	See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT	No multiple socket outlets used	N/A
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment		Pass
	Rated Voltage (V), Rated Current (A) ..... :	Input rating: 100-240Vac, max 0.5A	-
	Rated Power (W), Output Frequency (Hz) ..... :	Input: 50-60Hz DC output	-
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)..... :	Rated with no ingress protection (IPX0)	N/A
7.2.10	Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6):	No applied parts used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	TYPE B APPLIED PARTS with symbol 19 of Table D.1 (IEC 60417-5840, DB: 2002-10), not applied in such a way as to give the impression of being inscribed within a square in order to distinguish it from symbol IEC 60417-5333 ..... :	No applied parts used	N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 (IEC 60417-5333, DB: 2002-10) ..... :	No applied parts used	N/A
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 (IEC 60417-5335, DB: 2002-10) ..... :	No applied parts used	N/A
	DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1 (IEC 60417-5841, IEC 60417-5334, or IEC 60417-5336, all DB: 2002-10) ..... :	No applied parts used	N/A
	Proper symbol marked adjacent to or on connector for APPLIED PART, except marked on APPLIED PART when there is no connector, or connector used for more than one APPLIED PART and different APPLIED PARTS with different classifications ..... :	No applied parts used	N/A
	Safety sign 2 of Table D.2 (ISO 7010-W001) placed near relevant outlet when protection against effect of discharge of a cardiac defibrillator is partly in the PATIENT cable ..... :	No applied parts used	N/A
	An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use ..... :	No applied parts used	N/A
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION	Continuous operation	Pass
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time ... :	Not non-continuous operation	N/A
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	No fuse holder	N/A
	Fuse type ..... :	--	-
	Voltage (V) and Current (A) rating ..... :	--	-
	Operating speed (s) and Breaking capacity ..... :	--	-
7.2.13	A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to	To be evaluated in end application	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	OPERATOR..... :		
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use ..... :	To be evaluated in end application.	N/A
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10)	To be evaluated in end application	N/A
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air)..... :	No cooling device provided	N/A
7.2.16	ME EQUIPMENT with limited mechanical stability	To be evaluated in end application	N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage	Recognized component, final package should be evaluated in end application	N/A
	Permissible environmental conditions for transport and storage marked on outside of packaging ..... :	Recognized component, final package should be evaluated in end application	N/A
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK ..... :		N/A
	Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile		N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector ..... :	No such construction	N/A
7.2.19	Symbol 7 of Table D.1 (IEC 60417-5017, DB:2002-10) marked on FUNCTIONAL EARTH TERMINAL	Marked on Class I appliance inlet for product with functional earth	N/A
7.2.20	Protective means, required to be removed to use a particular function of ME EQUIPMENT with alternate applications, marked to indicate the necessity for replacement when the function is no longer needed..... :	The protective means was not provided.	N/A
	No marking applied when an interlock provided	The protective means was not provided.	N/A
7.3	Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts		Pass
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W) ..... :	No heating elements or lamp-holders provided	N/A
	A marking referring to ACCOMPANYING	No heating elements or lamp-	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL	holders provided	
7.3.2	Symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts..... :	No high parts provided	N/A
7.3.3	Type of battery and mode of insertion when applicable is marked..... :	No batteries used	N/A
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL..... :	No batteries used	N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement by inadequately trained personnel would result in an unacceptable RISK (e.g., excessive temperatures, fire or explosion)..... :	No batteries used	N/A
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS.. :	No batteries used	N/A
7.3.4	Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL, marked by type and full rating at the component or by reference to ACCOMPANYING DOCUMENTS	The primary fuses are identified by rating with type reference: Fuse: F1, F2 Type = Time Delay fuses Voltage = 250V Ampere = 1A	Pass
	Type ..... :	UL recognized and listed fuses were used	-
	Voltage (V) and Current (A) rating..... :	T1A,250V	-
	Operating speed (s) and Breaking capacity ..... :	Time delay type. Breaking capacity of UL recognized fuses were validated and accepted by test in product, UL listed fuse with no micro type can be alternatively used	-
7.3.5	PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, DB: 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1	For 1089 family, symbol 6 of table D.1 marked in Class I appliance inlet when Class II with function earth construction used	N/A
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after	For 1089 family, symbol 6 of table D.1 marked in Class I appliance inlet when Class II	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	connection made	with function earth construction used	
7.3.6	Symbol 7 of Table D.1 (IEC 60417-5017, DB: 2002 -10) marked on FUNCTIONAL EARTH TERMINALS	For 1089 family, symbol 6 of table D.1 marked in Class I appliance inlet when Class II with function earth construction used	N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals, except when no HAZARD would result when interchanging connections	For 1096 family provided with connectors as fool-proof	N/A
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	For 1089 family, provided with connector as fool-proof function	N/A
	Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 (Code in IEC 60445)		N/A
	Marking for connection to a 3-phase supply, if necessary, complies with IEC 60445	Not connected to a multiphase AC input source	N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	For supply connections, use wiring materials suitable for at least X °C (where X > than max temperature measured in terminal box or wiring compartment under NORMAL USE), or equivalent, marked at the point of supply connections		N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made		N/A
7.4	Marking of controls and instruments		N/A
7.4.1	The "on" & "off" positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 (IEC 60417-5007, DB: 2002-10, and IEC 60417-5008, DB: 2002-10), or	The control device was not provided on the product, the application of this clause should be evaluated as part of end application.	N/A
	- indicated by an adjacent indicator light, or		N/A
	- indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 DB: 2002-10), and		N/A
	- status indicated by adjacent indicator light		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- status indicated by other unambiguous means		N/A
	The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 DB: 2002-10), or		N/A
	- status indicated by adjacent indicator light		N/A
	- status indicated by other unambiguous means		N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means		N/A
	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, or		N/A
	- an indication of direction in which magnitude of the function changes		N/A
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 31 except the base quantities listed in Table 1 expressed in the indicated units		N/A
	ISO 1000 applied for application of SI units, their multiples, and certain other units		N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3		N/A
7.5	Safety signs		N/A
	Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010	No such situation. The application of this clause should be evaluated as part of end application.	N/A
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT		N/A
	Specified colours in ISO 3864-1 used for safety signs ..... :		N/A
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)		N/A
	Safety signs including any supplementary text or symbols described in instructions for use		N/A
7.6	Symbols		Pass
7.6.1	Meanings of symbols used for marking described in instructions for use ..... :	To be evaluated in end application	N/A
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced	Complied with table D.1	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable	The application of this clause should be evaluated as part of end application.	N/A
7.7	Colours of the insulation of conductors		Pass
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	Class II with functional earth wire, provided by green and yellow insulation	N/A
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations		N/A
7.7.3	Green and yellow insulation identify only following conductors:		Pass
	- PROTECTIVE EARTH CONDUCTORS		N/A
	- conductors specified in 7.7.2		N/A
	- POTENTIAL EQUALIZATION CONDUCTORS	No potential equalization terminals used	N/A
	- FUNCTIONAL EARTH CONDUCTORS	Class II with functional earth wire, provided by green and yellow insulation	Pass
7.7.4	Neutral conductors of POWER SUPPLY CORDS are "light blue" specified in IEC 60227-1 or IEC 60245-1	Power supply cord is optional, to be considered in end application	N/A
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	Power supply cord is optional, to be considered in end application	N/A
7.8	Indicator lights and controls		N/A
7.8.1	Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required)	No such part. The application of this clause shall be evaluated in end product application	N/A
	Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required)	No such part. The application of this clause shall be evaluated in end product application	N/A
	Green indicator lights mean: Ready for use	The application of this clause shall be evaluated in end product application	N/A
	Other colours, if used: Meaning other than red, yellow, or green (colour, meaning) ..... :	The application of this clause shall be evaluated in end product application	N/A
7.8.2	Red used only for emergency control	The application of this clause	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
		shall be evaluated in end product application	
7.9	ACCOMPANYING DOCUMENTS		N/A
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description	The application of this clause shall be evaluated in end product application	N/A
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:	The application of this clause shall be evaluated in end product application	N/A
	- Name or trade-Name of MANUFACTURER and an address the RESPONSIBLE ORGANIZATION can be referred to ..... :	The application of this clause shall be evaluated in end product application	N/A
	- MODEL or TYPE REFERENCE..... :	The application of this clause shall be evaluated in end product application	N/A
	When ACCOMPANYING DOCUMENTS provided electronically (e.g., on CDROM), RISK MANAGEMENT PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT (for emergency operation)	The application of this clause shall be evaluated in end product application	N/A
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	The application of this clause shall be evaluated in end product application	N/A
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	The application of this clause shall be evaluated in end product application	N/A
7.9.2	Instructions for use include the required information		N/A
7.9.2.1	- intended use of ME EQUIPMENT,	Recognized component - to be evaluated in end product	N/A
	- frequently used functions, and	Recognized component - to be evaluated in end product	N/A
	- known contraindication(s) to use of ME EQUIPMENT	Recognized component - to be evaluated in end product.	N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	Recognized component - to be evaluated in end product.	N/A
	Instructions for use are in a language acceptable to the intended operator	Recognized component - to be evaluated in end product.	N/A
7.9.2.2	Instructions for use include all warning and safety notices	Recognized component - to be evaluated in end product.	N/A
	Warning statement for CLASS I ME EQUIPMENT	Recognized component - to be	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	indicating: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"	evaluated in end product.	
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	Recognized component - to be evaluated in end product.	N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	Recognized component - to be evaluated in end product.	N/A
	Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET indicating, "connecting electrical equipment to MSO effectively leads to creating an ME SYSTEM, and can result in a reduced level of safety"	Recognized component - to be evaluated in end product.	N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	Recognized component - to be evaluated in end product.	N/A
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating "power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM"	Recognized component - to be evaluated in end product.	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	The product is switching power supply, a component not powered with additional source. This part will need to be evaluated with end product.	N/A
	Warning to remove primary batteries when ME EQUIPMENT is not likely to be used for some time when leakage from battery would result in an unacceptable RISK..... :	No batteries.	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided. :	No such part and design.	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..... :	Recognized component - to be evaluated in end product	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	Recognized component - to be evaluated in end product	N/A
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to when such	Recognized component - to be evaluated in end product	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	exposure can constitute an unacceptable RISK		
	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	Recognized component - to be evaluated in end product	N/A
	APPLIED PARTS specified	No such parts.	N/A
7.9.2.6	Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation	Recognized component - to be evaluated in end product	N/A
7.9.2.7	Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device when an APPLIANCE COUPLER or separable plug is used as isolation means to meet 8.11.1 a)	Recognized component - to be evaluated in end product	N/A
7.9.2.8	Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation including initial control settings, and connection to or positioning of PATIENT prior to use of ME EQUIPMENT, its parts, or ACCESSORIES	Recognized component - to be evaluated in end product	N/A
7.9.2.9	Information provided to operate ME EQUIPMENT including explanation of controls, displays and signals, sequence of operation, connection of detachable parts or ACCESSORIES, replacement of material consumed during operation	Recognized component - to be evaluated in end product	N/A
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	Recognized component - to be evaluated in end product	N/A
7.9.2.10	A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message	Recognized component - to be evaluated in end product	N/A
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	Recognized component - to be evaluated in end product	N/A
7.9.2.12	Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified	Recognized component - to be evaluated in end product	N/A
	Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use	Recognized component - to be evaluated in end product	N/A
7.9.2.13	Instructions provided on preventive inspection,	Recognized component - to be	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	calibration, maintenance and its frequency	evaluated in end product	
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	Recognized component - to be evaluated in end product	N/A
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	Recognized component - to be evaluated in end product	N/A
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	Recognized component - to be evaluated in end product	N/A
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	Recognized component - to be evaluated in end product	N/A
	Other equipment providing power to ME SYSTEM sufficiently described (e.g. part number, RATED VOLTAGE, max or min power, protection class, intermittent or continuous service)	Recognized component - to be evaluated in end product	N/A
7.9.2.15	RISKS associated with disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified, and instructions provided on minimizing these RISKS ..... :	Recognized component - to be evaluated in end product	N/A
7.9.2.16	Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)	Recognized component - to be evaluated in end product	N/A
7.9.3	Technical description		N/A
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including the following:	Recognized component - to be evaluated in end product	N/A
	- information as in clause 7.2		N/A
	- permissible environmental conditions of use including conditions for transport and storage		N/A
	- all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found		N/A
	- special installation requirements such as max. permissible apparent impedance of supply MAINS		N/A
	- permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- a description of means of isolating ME EQUIPMENT from supply MAINS, when such means not in ME EQUIPMENT		N/A
	- a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable		N/A
	- a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples		N/A
	WARNING: No modification of this equipment is allowed		N/A
	WARNING: Do not modify this equipment without authorization of the manufacturer		N/A
	WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment		N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	- information as in clause 7.2		N/A
	- all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT		N/A
	- a brief description of ME EQUIPMENT, how it functions, and its significant physical and performance characteristics		N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description		N/A
7.9.3.2	The technical description contains the following required information		N/A
	-TYPE and full rating of fuses used in supply MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, when TYPE and rating of fuses are not apparent from information on RATED current and mode of operation of ME EQUIPMENT		N/A
	- a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure compliance with 8.11.3		N/A
	- instructions for correct replacement of interchangeable or DETACHABLE parts specified		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	by MANUFACTURER as replaceable by SERVICE PERSONNEL, and		
	- warnings identifying Nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component		N/A
7.9.3.3	Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair		N/A
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8	**PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT**		Pass
8.1	Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS		Pass
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in 8.1a)		Pass
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)..... :	See Appended RM Results Tables 8.1b(1), (2), (3)	Pass
	ACCESSIBLE PARTS determined according to 5.9		Pass
	LEAKAGE CURRENTS measured according to 8.7		Pass
8.2	Requirements related to power sources		N/A
8.2.1	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	Not connect to separate power source Recognized component. To be evaluated in end product.	N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified		N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined		N/A
8.2.2	No HAZARDOUS SITUATION other than absence of ESSENTIAL PERFORMANCE developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source	Not connected to an external DC supply source	N/A
	ME EQUIPMENT connected with correct polarity did not present an unacceptable RISK	Not connected to an external DC supply source	N/A
	Protective devices that can be reset by anyone without a TOOL restore correct operation on reset	Not connected to an external DC supply source	N/A
8.3	Classification of APPLIED PARTS		N/A
	a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF	No applied parts used	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 applied parts used	N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF	No applied parts used	N/A
	d) Requirements of a TYPE B APPLIED PART applied to a part in 4.6 to be subjected to	No parts that are not applied parts that need to be treated	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	requirements for an APPLIED PART (except marking)	as applied parts used	
	Requirements for a TYPE BF or CF APPLIED PART applied as in RISK MANAGEMENT PROCESS	No parts that are not applied parts that need to be treated as applied parts used	N/A
8.4	Limitation of voltage, current or energy		Pass
8.4.1	PATIENT CONNECTIONS intended to deliver Current		N/A
	Limits in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE	No applied parts used	N/A
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS		Pass
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT per Tables 3 and 4 when measured according to Clause 8.7.4..... :	Recognized component, and not provided with Patient connection -To be evaluated in end product	N/A
	b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA) ..... :	See appended Table 8.7	Pass
	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	Unit complied with 8.4.2 (b)	N/A
	- accessible contacts of connectors		N/A
	- contacts of fuseholders accessible during replacement of fuse		N/A
	- contacts of lampholders accessible after removal of lamp		N/A
	- parts inside an ACCESS COVER that can be opened without a TOOL, or where a TOOL is needed but the instructions for use instruct an OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER		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.)..... :		N/A
	Limit of 60 V d.c. applied with no more than 10% peak-to-peak ripple, and when ripple larger than specified value, 42.4 V peak limit applied (V d.c.). :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V (VA or J) ..... :		N/A
	LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA) ..... :		N/A
	d) Voltage and energy limits specified in c) above also applied to the following:	Recognized power - To be evaluated in end product	N/A
	- internal parts, other than contacts of plugs, connectors and socket-outlets, touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and		N/A
	- internal parts touchable by a metal test rod with a diameter of 4 mm and a length of 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls using a TOOL		N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N		N/A
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N		N/A
	Test repeated with a TOOL specified in instructions for use		N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE		N/A
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION	No such construction	N/A
	A TOOL is required when it is possible to prevent the devices from operating		N/A
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one s after disconnecting the plug of ME EQUIPMENT or its parts (V) ..... :	See appended Table 8.4.3	Pass
	A triggering circuit used to ensure disconnection occurred at peak of supply voltage waveform		Pass
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 uC..... :	See appended Table 8.4.3	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
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 45uC ..... :		N/A
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL		N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, DB: 2002-10), and manual discharging device specified in technical description ..... :		N/A
8.5	Separation of parts		Pass
8.5.1	MEANS OF PROTECTION (MOP)		Pass
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	No Applied part	N/A
	Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account Clause 4.6, and flow chart in Fig A.12	2MOOP provided between primary to secondary circuit	Pass
	Varnishing, enameling, oxidation, and similar protective finishes and coatings with sealing compounds replasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION	No such situation	N/A
	Coatings and other insulation intended as a MEANS OF PROTECTION complying with IEC 60950-1:2001 considered acceptable as a MEANS OF OPERATOR PROTECTION but not automatically as a MEANS OF PATIENT PROTECTION		N/A
	RISK MANAGEMENT PROCESS taken into consideration for MEANS OF PATIENT PROTECTION		N/A
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10		Pass
	Insulation, CREEPAGE, CLEARANCES, components or earth connections not complying with 8.5.1.2 and 8.5.1.3 not considered as MEANS OF PROTECTION, and failure of these parts regarded as NORMAL CONDITION		Pass
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6		N/A
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12		N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		N/A
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF PATIENT PROTECTION considered equivalent to one MEANS OF PATIENT PROTECTION		N/A
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A
	Voltage Total Working (V) and C Nominal (uF)..... :		-
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	2MOOP provided between primary to secondary circuit	Pass
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:		Pass
	- dielectric strength test of 8.8 at test voltage of Table 6; or		Pass
	- requirements of IEC 60950-1 for INSULATION CO-ORDINATION		Pass
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:		Pass
	- limits of Tables 13 to 16 (inclusive); or		Pass
	- requirements of IEC 60950-1 for INSULATION CO-ORDINATION		Pass
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6, or		N/A
	- requirements and tests of IEC 60950-1 for protective earthing ..... :		N/A
	A Y2 capacitor complying with IEC 60384-14 and passing dielectric strength test for one MEANS OF OPERATOR PROTECTION considered equivalent to one MEANS OF OPERATOR PROTECTION... :		N/A
	A Y1 capacitor complying with IEC 60384-14 and	A Y1 class capacitor used	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	having passed dielectric strength test for two MEANS OF OPERATOR PROTECTION considered equivalent to two MEANS OF OPERATOR PROTECTION..... :		
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance		N/A
	Voltage Total Working (V) and C Nominal (uF)..... :	See Appended Table Critical component table	-
	Points at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION		N/A
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION..... :		N/A
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION ..... :	MOOP considered	Pass
8.5.2	Separation of PATIENT CONNECTIONS		N/A
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to maximum MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT at 110 % of max. MAINS VOLTAGE ..... :	No type F applied parts used or parts needed to be treated as type F applied parts	N/A
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART	No type F applied parts used or parts needed to be treated as type F applied parts	N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function	No type F applied parts used or parts needed to be treated as type F applied parts	N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS ..... :	No type F applied parts used or parts needed to be treated as type F applied parts	N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	No type F applied parts used or parts needed to be treated as type F applied parts	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	LEAKAGE CURRENT tests conducted per 8.7.4.. :	No type F applied parts used or parts needed to be treated as type F applied parts	N/A
	Dielectric strength test conducted per 8.8.3 ..... :	No type F applied parts used or parts needed to be treated as type F applied parts	N/A
	CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable	No type F applied parts used or parts needed to be treated as type F applied parts	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 type F applied parts used or parts needed to be treated as type F applied parts	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 type B applied parts or parts needed to be treated as type B applied parts	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 type B applied parts or parts needed to be treated as type B applied parts	N/A
	- RISK that metal accessible PART will make contact with a source of voltage or LEAKAGE current above permitted limits is acceptably low	No type B applied parts or parts needed to be treated as type B applied parts	N/A
	LEAKAGE CURRENT tests conducted per 8.7.4.. :	No type B applied parts or parts needed to be treated as type B applied parts	N/A
	Dielectric strength test conducted per 8.8.3 ..... :	No type B applied parts or parts needed to be treated as type B applied parts	N/A
	Relevant CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable	No type B applied parts or parts needed to be treated as type B applied parts	N/A
	The RISK MANAGEMENT FILE reviewed	No type B applied parts or parts needed to be treated as type B applied parts	N/A
8.5.2.3	A connector on a PATIENT lead located at the end of the lead remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE		N/A
	- cannot be connected to EARTH or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter		N/A
	- CLEARANCE between connector pins and a flat surface is at least 0.5 mm		N/A
	- conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1		N/A
	- required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N, except when RISK MANAGEMENT PROCESS indicated no unacceptable RISK existed from contact with objects other than a mains ..... :		N/A
8.5.3	MAXIMUM MAINS VOLTAGE		Pass
	- MAXIMUM MAINS voltage determined to be the highest RATED supply voltage for single-phase or d.c. supply MAINS powered ME EQUIPMENT, as well as INTERNALLY powered ME EQUIPMENT with a means of connection to a supply MAINS (V)	250Vac	Pass
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V		N/A
	- MAXIMUM MAINS voltage was the highest RATED phase to neutral supply voltage for poly-phase ME EQUIPMENT (V)	Not connected to a multiphase AC input source	N/A
	- for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V	Not internally powered	N/A
8.5.4	WORKING VOLTAGE		Pass
	- Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V)..... :	240Vac	Pass
	- 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) ..... :		N/A
	- WORKING voltage for each means of PROTECTION forming DOUBLE insulation was voltage DOUBLE insulation, as a whole, subjected to (V)	See Insulation Diagram and Insulation Table See Table Additional test.	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	- Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING voltage involving a PATIENT connection not connected to EARTH	To be evaluated in end product	N/A
	- WORKING voltage between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL use including earthing of any PART of APPLIED PART (V)	No type F applied parts used	N/A
	- WORKING voltage for DEFIBRILLATION-PROOF APPLIED parts determined disregarding possible presence of DEFIBRILLATION voltages	No defibrillation-protected applied parts or parts needed to be treated as defibrillation-protected applied parts	N/A
	- WORKING voltage was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external CONDUCTORS (V)	No motors used	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS	No defibrillation-protected applied parts or parts needed to be treated as defibrillation-protected applied parts	N/A
8.5.5.1	Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART	No defibrillation-protected applied parts or parts needed to be treated as defibrillation-protected applied parts	N/A
	Possibility of an OPERATOR receiving a shock from such parts taken into consideration in RISK MANAGEMENT PROCESS	No defibrillation-protected applied parts or parts needed to be treated as defibrillation-protected applied parts	N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:	No defibrillation-protected applied parts or parts needed to be treated as defibrillation-protected applied parts	N/A
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :	No defibrillation-protected applied parts or parts needed to be treated as defibrillation-protected applied parts	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 ..... :	No defibrillation-protected applied parts or parts needed to be treated as defibrillation-protected applied parts	N/A
8.5.5.2	Means provided to limit energy delivered to a 100	No defibrillation-protected	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Ohm load to at least 90% of energy delivered to this load with ME EQUIPMENT disconnected ..... :	applied parts or parts needed to be treated as defibrillation-protected applied parts	
8.6	Protective and functional earthing and potential equalization of ME EQUIPMENT		Pass
8.6.1	Requirements of 8.6.2 to 8.6.8 applied		Pass
	Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8		N/A
8.6.2	PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR ..... :	To be evaluated in end product	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	To be evaluated in end product	N/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside ..... :	No screw provided	N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		N/A
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing	To be evaluated in end product	N/A
8.6.3	PROTECTIVE EARTH CONNECTION not used for a moving part, except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE ..... :	To be evaluated in end product	N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop		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..... :	The fault of functional earth terminal was measured. See appeded table 8.7	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
8.6.5	Surface coatings		N/A
	Poorly conducting surface coatings on conductive elements removed at the point of contact	No such construction	N/A
	Coating not removed when requirements for impedance and current-carrying capacity met		N/A
8.6.6	Plugs and sockets		N/A
	PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections	To be evaluated in end product	N/A
	- APPLIED also where interchangeable parts are PROTECTIVELY EARTHED		N/A
8.6.7	Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR		N/A
	- terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL use	No potential equalization terminals used	N/A
	- RISK of accidental disconnection minimized in NORMAL use	No potential equalization terminals used	N/A
	- terminal allows conductor to be detached without a TOOL	No potential equalization terminals used	N/A
	- terminal not used for a PROTECTIVE EARTH connection	No potential equalization terminals used	N/A
	- Terminal marked with symbol 8 of Table D.1 (i.e., symbol IEC 60417-5021)	No potential equalization terminals used	N/A
	- instructions for use contain information on function and use of POTENTIAL EQUALIZATION conductor together with a REFERENCE to requirements of this standard	No potential equalization terminals used	N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR	No potential equalization terminals used	N/A
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION		Pass
8.6.9	Class II ME EQUIPMENT		Pass
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow		Pass
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring	2MOOP provided for this power adapter	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	connected to them with a related explanation in technical description ..... :		
8.7	LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS		Pass
8.7.1	a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3 ..... :	See appended Table 8.7	Pass
	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 Table 8.7	Pass
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except		N/A
	- where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		N/A
	- the only single FAULT CONDITION for EARTH LEAKAGE current was interruption of one supply conductor at a time		N/A
	- LEAKAGE CURRENTS and PATIENT AUXILIARY current not measured in single FAULT CONDITION of short circuiting of one constituent PART of DOUBLE insulation	No applied part	N/A
	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		N/A
8.7.3	Allowable Values		Pass
	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	Pass
	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:	No applied part	N/A
	c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION (ITNC, ITSFC):	See appended Table 8.7	Pass
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (IENC, IESFC)	Leakage current of functional earth terminal was measured for reference. See appeded table 8.7	N/A
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710:..... :		
	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:		N/A
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements:		N/A
8.8	Insulation		Pass
8.8.1	Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION and insulation between parts of opposite polarity of MAINS PART on SUPPLY MAINS side of mains fuse or OVER-CURRENT RELEASE		Pass
	Insulation exempted from test (complies with clause 4.8)		Pass
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8		Pass
8.8.2	Distance through solid insulation or use of thin sheet material		Pass
	Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:		Pass
	a) 0.4 mm, min, distance through insulation, or		Pass
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:		Pass
	- at least two layers of material, each passed the appropriate dielectric strength test, or	See appended Table 8.8.3	Pass
	- three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test	See appended Table 8.8.3	Pass
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		Pass
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		Pass
	BASIC, SUPPLEMENTARY, and REINFORCED		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		
	c) Wire with solid insulation, other than solvent based enamel, complying with a)	No such construction	N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L	UL certified triple insulation wire provided in secondary wire	Pass
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	UL certified triple insulation wire provided in secondary wire	Pass
	- BASIC insulation: minimum two wrapped layers or one extruded layer		N/A
	- SUPPLEMENTARY insulation: minimum two layers, wrapped or extruded		N/A
	- REINFORCED insulation: minimum three layers, wrapped or extruded		Pass
	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	UL certified triple insulation wire provided in secondary wire	Pass
	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	UL certified triple insulation wire provided in secondary wire	Pass
	Finished component complied with routine dielectric strength tests of 8.8.3..... :	UL certified triple insulation wire provided in secondary wire	Pass
	Tests of Annex L not repeated since material data sheets confirm compliance..... :	UL certified triple insulation wire provided in secondary wire	Pass
8.8.3	Dielectric Strength		Pass
	Solid insulating materials with a safety function withstood dielectric strength test voltages ..... :	See appended Table 8.8.3	Pass
8.8.4	Insulation other than wire insulation		Pass
8.8.4.1	Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT and RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests ..... :	See Appended RM Results Table 8.8.4.1	Pass
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :	See Appended RM Results Table 8.8.4.1	Pass
	Tests conducted in absence of satisfactory evidence for resistance to heat		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 apparatus of Fig 21	See Table 8.8.4.1	Pass
	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) ..... :	Phenolic bobbin is used	N/A
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION		N/A
8.8.4.2	Resistance to environmental stress		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 construction	N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No such construction	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 natural latex rubber provided	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		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	16h		
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		Pass
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are to values in Tables 11 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15		Pass
8.9.1.2	Tables 11 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested		N/A
8.9.1.3	Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics	No such material	N/A
8.9.1.4	When min CREEPAGE derived from Tables 11 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE		Pass
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m		N/A
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m)..... :	3000 m	Pass
	Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used to determine multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor		Pass
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE	Multiplication factors used for MOOP	N/A
8.9.1.6	When WORKING VOLTAGE was between those in Tables 11 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:		Pass
	- CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :	See Insulation Diagram/Table	Pass
	- CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) ..... :	Max working voltage: 280 Vrms, not exceeding the value	N/A
	- for AIR CLEARANCES corresponding to PEAK		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied		
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group) ..... :	Not mention the material group, and treated as most worse condition: IIIb	Pass
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112..... :		N/A
	Material of unknown group considered IIIb	Not mention the material group, and treated as most worse condition: IIIb	Pass
8.9.1.8	- Pollution degree 1: Micro-environment sealed to exclude dust and moisture		N/A
	- Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation	PD2	Pass
	- Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation		N/A
	- Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions		N/A
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION		N/A
	Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree		N/A
8.9.1.9	Overvoltage category classification; value of MAINS TRANSIENT VOLTAGE determined from overvoltage category per IEC60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10	OVC II	Pass
	V MT Peak (V) ..... :	2500 Vpk	-
	V MN r.m.s. (V)..... :	300 Vrms	-
8.9.1.10	AIR CLEARANCE for MAINS PARTS (operating on RATED MAINS VOLTAGES up to 300 V) were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE		Pass
8.9.1.11	SUPPLY MAINS overvoltage category II applied according to IEC 60664-1		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used		N/A
	When PATIENT protection (Table 12) is required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for Cl. 8.9 used		N/A
8.9.1.12	A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15)		N/A
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT		N/A
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		N/A
	Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I		N/A
	Table 15 column for circuits not subject to transient overvoltages applied to:		N/A
	- d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and		N/A
	- CIRCUITS in INTERNALLY powered ME EQUIPMENT		N/A
8.9.1.13	For PEAK WORKING VOLTAGES above 1400 V peak or d.c. Table 15 not applied since all the following conditions were met:	Max Vpk working voltage: 496 Vpk	N/A
	- CLEARANCE was at least 5 mm		N/A
	- insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or		N/A
	- a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and		N/A
	- CLEARANCE path was partly or entirely through		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	AIR or along the surface of an insulating material of material group I		
	Dielectric strength test conducted only across part(s) of the path that are through air when CLEARANCE path was also partly along surface of a non- group I material		N/A
8.9.1.14	Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION		Pass
8.9.1.15	CREEPAGE DISTANCES and AIR CLEARANCES for DEFIBRILLATION-PROOF APPLIED PARTS are 4 mm or more to meet 8.5.5.1	No defibrillation-protected applied parts or parts needed to be treated as defibrillation-protected applied parts	N/A
8.9.2	a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied..... :		N/A
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths		Pass
	c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by molding, or there is no reduction of a distance below specified value by deformation or movement of parts		Pass
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE		Pass
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 were such that CLEARANCES and CREEPAGE DISTANCES don't exist	No insulating compound provided	N/A
	Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted		N/A
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	(for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6 ..... :		
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur		N/A
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint		N/A
	A winding of solvent-based enameled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:		N/A
	- One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage ..... :		N/A
	- The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage		N/A
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times ..... :		N/A
8.10	Components and wiring		Pass
8.10.1	Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely as indicated in RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 8.10.1	Pass
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION ..... :	See Appended RM Results Table 8.10.2	Pass
	Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION as indicated in RISK MANAGEMENT FILE		Pass
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION		Pass
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS due to poor contact	No such construction	N/A
8.10.3	Flexible cords detachable without a TOOL used to	No such construction	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as shown by measurement or using test finger		
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N/A
8.10.4.1	Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION		N/A
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple		N/A
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit		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 cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION		N/A
	This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION	No hand-held parts	N/A
8.10.5	Mechanical protection of wiring		Pass
	a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION..... :	See Appended RM Results Table 8.10.5	Pass
	b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION as shown by manual tests and RISK MANAGEMENT FILE		Pass
8.10.6	Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE	No such construction	N/A
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is	See appended Table 8.10	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	used on internal wiring of when needed..... :		
	b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics	No such construction	N/A
	c) Insulated conductors subject to temperatures > 70 °C in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation ..... :	No such construction	N/A
8.11	MAINS PARTS, components and layout		Pass
8.11.1	a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles ..... :	No such means. R/C component, to be evaluated in the end product.	N/A
	PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)	Not Permanently installed me equipment	N/A
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description ..... :	No such means. R/C component, to be evaluated in the end product.	N/A
	c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE and CLEARANCES in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV..... :	Not Permanently installed me equipment	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	Not Permanently installed me equipment	N/A
	e) Direction of movement of actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447	No actuator of a supply mains switch	N/A
	f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a) ..... :	Product is recognized component, the disconnecting method was unknown, to be evaluated in end product	N/A
	g) A fuse or a semiconductor device not used as an isolating means		Pass
	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		Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	To be evaluated in end product	N/A
	A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient)		N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause		N/A
	Standard test finger of Fig 6 applied		N/A
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No such construction	N/A
8.11.3	POWER SUPPLY CORDS		N/A
8.11.3.1	MAINS PLUG not fitted with more than one POWER SUPPLY CORD	Product is recognized component, optional power supply cord provided, to be evaluated in end product	N/A
8.11.3.2	POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design. 53)..... :		N/A
	Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ..... :		N/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm2 Cu) ..... :		N/A
8.11.3.4	APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6..... :		N/A
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		N/A
	a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4:		N/A
	- insulating material, or		N/A
	- metal, insulated from conductive accessible parts non-PROTECTIVELY EARTHED by a means of PROTECTION, or		N/A
	- metal provided with an insulating lining affixed to cord anchorage, except when it is a flexible bushing forming part of the cord guard in 8.11.3.6, and complying with the requirements for one MEANS OF PROTECTION		N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation		N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage		N/A
	e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails		N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR		N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 ..... :		N/A
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests		N/A
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position		N/A
	CREEPAGE and CLEARANCES not reduced below limits in 8.9		N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	the cord or internal parts would be damaged		
8.11.3.6	POWER SUPPLY CORDS other than for STATIONARY ME EQUIPMENT protected against excessive bending at inlet opening of equipment or of MAINS CONNECTOR by means of an insulating cord guard or by means of an appropriately shaped opening		N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or		N/A
	ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D2 gram attached to the free end of cord (g) ..... :		N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance		N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D ..... :		N/A
8.11.4	MAINS TERMINAL DEVICES		N/A
8.11.4.1	PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD replaceable by SERVICE PERSONNEL provided with MAINS TERMINAL DEVICES ensuring reliable connection		N/A
	Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away		N/A
	Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors		N/A
	Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors		N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	Mains connector was provided for 1096 familiy models, to be considered in end application	N/A
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3		N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL		N/A
	e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction		N/A
8.11.4.3	Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times		N/A
8.11.4.4	Terminals with clamping means for a rewirable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by test of 8.11.3.4		N/A
8.11.4.5	Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a re-wirable POWER SUPPLY CORD to allow for connection of conductors, and covers fitted without damage to conductors or their insulation		N/A
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES		Pass
	A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection per clause 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT .... :	See appended Table 8.10 and Appended RM Results Table 8.11.5	Pass
	- neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	Not permanently installed	N/A
	- fuses or OVER-current RELEASES omitted due to provision of two means of PROTECTION between all parts of opposite polarity within MAINS PART, and between all parts of MAINS PART and EARTH, and such provisions continued within all components		N/A
	Effect of short-circuit fault conditions in other circuits taken into consideration before eliminating fuses or OVER-CURRENT RELEASES		N/A
	Protective devices have adequate breaking	See appended Table 8.10	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	capacity to interrupt the maximum fault current including the available short-circuit ..... :		
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR		Pass
	Fuses complying with IEC 60127 have high breaking capacity (1 500 A) and prospective short-circuit current > 35 A or 10 times current rating of the fuse, whichever is greater		N/A
	Justification for omission of fuses or OVER-CURRENT RELEASES is in RISK MANAGEMENT FILE	Not omission of fuses inside	N/A
8.11.6	Internal wiring of the MAINS PART		Pass
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE and protective devices is not less than minimum required for POWER SUPPLY CORD as in clause 8.11.3.3 (mm2 Cu) ..... :	no internal wiring for mains part	N/A
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents ... :	See appended Table 8.10	Pass
	When necessary, ME EQUIPMENT connected to a SUPPLY MAINS with max available short-circuit fault, and subsequent simulation of a fault in a single insulation in MAINS PART did not result in any of the HAZARDOUS SITUATIONS in 13.1.2		Pass

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Clause	Requirement + Test	Result - Remark	Verdict

9	**PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS**		Pass
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)		Pass
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level ..... :	No moving part	N/A
	RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)		N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its function		N/A
	Warnings marked on ME EQUIPMENT or included in instructions for use when HAZARDS persisted after implementing all reasonable protective measures ..... :		N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:		N/A
	- Gaps in Clause 9.2.2.2, or		N/A
	- Safe distances in Clause 9.2.2.3, or		N/A
	- GUARDS and protective measures in 9.2.2.4, or		N/A
	- Continuous activation in Clause 9.2.2.5		N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM		N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20 ..... :		N/A
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13852 ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse		N/A
9.2.2.4	GUARDS and protective measures		N/A
9.2.2.4.1	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when GUARDS and protective measures were of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK based on results of applicable tests in 15.3 for ENCLOSURES ..... :		N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that cannot be dismantled without a TOOL		N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open		N/A
	- they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,		N/A
	- absence or failure of one of their components prevents starting, and stops moving parts		N/A
	Movable GUARDS complied with all applicable tests as confirmed by review of RISK MANAGEMENT FILE		N/A
9.2.2.4.4	Protective measures provided in control system prevented moving parts from starting to move while in reach of persons ..... :		N/A
	- PROTECTIVE measures prevented TRAPPING ZONE from reach, or, when it was reached, SYSTEM movement stopped once ME EQUIPMENT started to move, and in the latter case, no HAZARD or damage resulted		N/A
	- when PROTECTIVE measure was in a single FAULT CONDITION, and an unacceptable RISK could arise, one or more emergency stopping device(s) provided		N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed		N/A
9.2.2.5	Continuous activation		N/A
	TRAPPING ZONE not considered to present a MECHANICAL HAZARD where impractical to make TRAPPING ZONE inaccessible when:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	a) movement was in OPERATOR'S field of view		N/A
	b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR as long as OPERATOR response to deactivate device relied upon to prevent HARM		N/A
	Manually operated movements complied with this clause since mass and velocity allowed adequate control of positioning without causing an unacceptable RISK		N/A
	c) when in a SINGLE FAULT CONDITION of continuous activation system an unacceptable RISK could arise, one or more emergency stopping device(s) provided in ME EQUIPMENT ..... :		N/A
9.2.2.6	Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT, when contact with ME EQUIPMENT could result in a HAZARDOUS SITUATION, limited to allow OPERATOR control of positioning without resulting in an unacceptable RISK ..... :		N/A
	Over travel (stopping distance) of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK		N/A
9.2.3	Other HAZARDS associated with moving parts		N/A
9.2.3.1	Controls positioned, recessed, or protected by other means and could not be accidentally actuated to result in unacceptable RISK, except when ergonomic considerations for a PATIENT with special needs require otherwise		N/A
9.2.3.2	RISK due to over travel (past range limits) of ME EQUIPMENT parts reduced to an acceptable level, and stops or other means with mechanical strength to withstand intended loading in NORMAL USE and foreseeable misuse provided limiting measure in NORMAL and SINGLE FAULT CONDITION .... :		N/A
9.2.4	Emergency stopping devices		N/A
	Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power ..... :		N/A
	a) Emergency stopping device reduced RISK to an acceptable level		N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Emergency stopping device actuator was readily accessible to OPERATOR		N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT		N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original HAZARD		N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like		N/A
	g) Means for stopping of movements operate as a result of one single action		N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls		N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 (symbol IEC 60417-5638, DB:2002-10) or "STOP"		N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed		N/A
	k) Emergency stopping device is suitable for its application		N/A
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a protective measure, or emergency stopping, and		N/A
	- Uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented		N/A
	- Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of NORMAL exit routes, or other HAZARDS prevented		N/A
	- measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way		N/A
9.3	Rough surfaces, sharp corners and edges of ME	See Appended RM Results	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	EQUIPMENT that could result in an unacceptable RISK avoided or covered ..... :	Table 9.3	
9.4	Instability HAZARDS		N/A
9.4.1	ME EQUIPMENT, other than FIXED and hand-held, for placement on a surface did not overbalance (tip over) or move unexpectedly, to the degree that it could present an unacceptable RISK to PATIENT, or OPERATOR as tested in 9.4.2 to 9.4.4	Recognized component - to be evaluated in the end application	N/A
9.4.2	Instability - overbalance		N/A
9.4.2.1	ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when not specified, as in 9.4.2.2, and placed on a 10° inclined plane from horizontal consisting of a hard and flat surface (e.g., concrete floor covered with 2 to 4 mm thick vinyl material).. :		N/A
9.4.2.2	Instability excluding transport		N/A
	ME EQUIPMENT or its parts prepared based on a) to g), inclusive, did not overbalance when placed in different positions of NORMAL USE, except transport positions, on a 5° inclined plane from horizontal (hard and flat surface)		N/A
	A warning provided, stating "Transport only under conditions described in instructions for use or marked on ME EQUIPMENT with an indication of RESIDUAL RISK if ME EQUIPMENT or its parts overbalances" when overbalance occurred during 10° inclined plane test		N/A
9.4.2.3	Instability from horizontal and vertical forces		N/A
	a) ME EQUIPMENT with a mass of 25 kg or more, other than FIXED ME EQUIPMENT for use on floor, did not overbalance due to pushing or resting		N/A
	Surfaces of ME EQUIPMENT where a RISK of overbalancing exists from pushing, leaning, resting etc., permanently marked with a CLEARLY LEGIBLE warning of the RISK (e.g., safety sign 5 of Table D.2, safety sign ISO 7010-P017)		N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a force of 25% of its weight, but not more than 220 N, applied in different directions, except a direction with an upward component		N/A
	b) ME EQUIPMENT, other than FIXED ME EQUIPMENT, for use on the floor or on a table, did		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	not overbalance due to sitting or stepping, except when a legible warning of this RISK provided on ME EQUIPMENT (e.g., safety signs 6 and 7 of Table D.2, safety signs ISO 7010-P018, or ISO 7010-P019 as appropriate)		
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a constant force of 800 N applied at the point of maximum moment to working surfaces, offering an foothold or sitting surface of a min 20 x 20 cm area, and at a height 1 m from the floor ..... :		N/A
9.4.2.4	Castors and wheels		N/A
9.4.2.4.1	Means used for transportation of MOBILE ME EQUIPMENT (e.g., castors or wheels) did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE	Not mobile equipment	N/A
9.4.2.4.2	Force required to move MOBILE ME EQUIPMENT along a hard and flat horizontal surface did not exceed 200 N applied at a height of 1 m above floor or highest point on ME EQUIPMENT when < 1 m high, except when instructions indicated more than one person needed (N)..... :	Not mobile equipment	N/A
9.4.2.4.3	MOBILE ME EQUIPMENT exceeding 45 kg configured with a SAFE WORKING LOAD, moved 10 times in forward direction over a solid vertical plane obstruction with wheels impacting the obstruction at a speed of 0.4 m/s ± 0.1 m/s for manual or with max speed for motor driven MOBILE ME EQUIPMENT ..... :	Not mobile equipment	N/A
	ME EQUIPMENT went up the obstruction without overbalancing or any other unacceptable RISK as determined by examination of RISK MANAGEMENT FILE, ME EQUIPMENT and its parts..... :	Not mobile equipment	N/A
	There was no reduction of CREEPAGE and CLEARANCES below 8.9, no access to parts exceeding limits in 8.4, and no access to moving parts capable of causing HARM, and	Not mobile equipment	N/A
	- Assessment criteria in Clause 9 and 11.6 used	Not mobile equipment	N/A
	- Dielectric strength test of 8.8.3 conducted to evaluate integrity of solid SUPPLEMENTARY or REINFORCED INSULATION	Not mobile equipment	N/A
	- CREEPAGE DISTANCES and AIR CLEARANCES measured compared favourably with min distances in clause 8.9	Not mobile equipment	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Small chips not adversely affecting protection against electric shock or moisture, disregarded	Not mobile equipment	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	Not mobile equipment	N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements of ME EQUIPMENT or its parts in transport position	Not mobile equipment	N/A
	c) No unacceptable RISK due to unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position or worst case NORMAL USE position with SAFE WORKING LOAD, and locking device activated, on a 10° inclined hard flat surface with castors in the worst-case position	Not mobile equipment	N/A
	Following initial elastic movement, creepage, and pivoting of castors, no further movement of MOBILE ME EQUIPMENT > 50 mm (in relation to inclined plane) occurred (mm)	Not mobile equipment	N/A
	RISK due to any initial movement assessed taking into consideration NORMAL USE of ME EQUIPMENT	Not mobile equipment	N/A
9.4.3.2	Instability excluding transport		N/A
	a) Further movement of ME EQUIPMENT (after initial elastic movement) was less than 50 mm when MOBILE ME EQUIPMENT with a SAFE WORKING LOAD positioned on a 5 inclined hard flat surface with wheel locked or braking system activated (mm) ..... :	Not mobile equipment	N/A
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT	Not mobile equipment	N/A
	b) TRANSPORTABLE or STATIONARY ME EQUIPMENT for use on the floor and with a SAFE WORKING LOAD prepared as in 9.4.2.2 and placed on a horizontal plane with locking device activated and castors, when supplied, in their worst -case position		N/A
	Further movement of ME EQUIPMENT (after initial elastic movement), was no more than 50 mm when a force of 25 % of weight of unit, but less than 220 N, applied in different directions, except a direction with an upwards component, at highest point of ME EQUIPMENT but 1.5 m from floor ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT		N/A
9.4.4	Grips and other handling devices		N/A
	a) ME EQUIPMENT other than PORTABLE EQUIPMENT or its part 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, except when handling is obvious and causing HAZARDS	Portable equipment only	N/A
	Handles, when supplied, 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	Portable equipment only	N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying		N/A
	c) Carrying handles and grips and their means of attachment withstood loading test ..... :	See Appended Table 9.4.4	N/A
9.5	Expelled parts HAZARD		N/A
9.5.1	Suitability of means of protecting against unacceptable RISK of expelled parts determined by assessment and examination of RISK MANAGEMENT FILE ..... :	No expelled part	N/A
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965 ..... :		N/A
9.6	Acoustic energy (including infra- and ultrasound) and vibration		N/A
9.6.1	Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK as confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and tests of 9.6.2 and 9.6.3 ..... :	No Acoustic energy	N/A
9.6.2	Acoustic energy		N/A
9.6.2.1	PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE, except for auditory alarm signals		N/A
	- 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA) ..... :	-	-
	- 83 dBA (when halving the cumulative exposure time) (dBA)..... :	-	-

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Clause	Requirement + Test	Result - Remark	Verdict
	- 140 dB un-weighted sound pressure level for impulsive or impact acoustic energy (dB)..... :	-	-
9.6.2.2	RISK MANAGEMENT FILE examined for RISKS associated with infrasound or ultrasound, when present, addressed in RISK MANAGEMENT PROCESS		N/A
9.6.3	Hand-transmitted vibration		N/A
	Means provided, except for INTENDED USE vibrations, to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values measured at points of hand contact with PATIENT or OPERATOR		N/A
	- 2.5 m/s2 for a cumulative time of 8 h during a 24 h period (m/s2) ..... :		N/A
	- Accelerations for different times, inversely proportional to square root of time (m/s2) ..... :		N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.1	Requirements of this clause applied to vessels and parts of ME EQUIPMENT subject to pressure resulting in rupture and unacceptable RISK	No Pressure vessels and parts subject to pneumatic and hydraulic pressure	N/A
	Parts of a pneumatic or hydraulic system used as a support system, comply with 9.8		N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met following requirements based on examination of RISK MANAGEMENT FILE ..... :		N/A
	- no unacceptable RISK resulted from loss of pressure or loss of vacuum		N/A
	- no unacceptable RISK resulted from a fluid jet caused by LEAKAGE or a component failure		N/A
	- Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects		N/A
	- Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its POWER supply		N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- all Elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its POWER supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these Elements before setting or maintenance activity		N/A
9.7.3	Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:		N/A
	a) RATED maximum supply pressure from an external source		N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly		N/A
	c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device		N/A
9.7.4	Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by examination of ME EQUIPMENT and RISK MANAGEMENT FILE, and by functional tests ..... :		N/A
9.7.5	A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was > 50 kPa, and product of pressure and volume was more than 200 kPaI..... :	See Appended Table 9.7.5	N/A
9.7.6	Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE ..... :		N/A
9.7.7	Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests..... :		N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect		N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Could be adjusted or rendered inoperative without a TOOL		N/A
	d) With discharge opening located and directed as to not to release material towards any person		N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK		N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure		N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect		N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)		N/A
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 support systems used	N/A
	- Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD	No support systems used	N/A
	- means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK	No support systems used	N/A
	- RISK ANALYSIS of support systems included HAZARDS from static, dynamic, vibration, impact and pressure loading, foundation and other movements, temperature, environmental, manufacture and SERVICE conditions	No support systems used	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	No support systems used	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	No support systems used	N/A
	Additional instructions provided on checking	No support systems used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	adequacy of surface of structure parts will be attached to		
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 support systems used	N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing ..... :	No support systems used	N/A
	When test results were part of information, 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..... :	No support systems used	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 minimize RISK of physical injuries and accidental loosening of secured joints	No support systems used	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	No support systems used	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	No support systems used	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	No support systems used	N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS	No support systems used	N/A
	Max allowable PATIENT mass > 135 kg stated in ACCOMPANYING DOCUMENTS	No support systems used	N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE	No support systems used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	confirmed compliance ..... :		
9.8.3.2	Part of SAFE WORKING LOAD representing mass of PATIENTS or OPERATORS is distributed on support/suspension surface representing human body as in Fig A.19	No support systems used	N/A
	Part of SAFE WORKING LOAD representing mass of ACCESSORIES deployed as in NORMAL USE and, when not defined, at worst case position permitted by configuration or ACCESSORIES attachment on support/suspension parts	No support systems used	N/A
	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m2 on a foot rest temporarily supporting a standing PATIENT or OPERATOR:	No support systems used	N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and tests	No support systems used	N/A
	PATIENT support/suspension system positioned horizontally in most disadvantageous position in NORMAL USE, and a mass 2 x 135 kg or twice intended person's load (the greater used), applied to foot rest over an area of 0.1 m2 for 1 min (Kg):	No support systems used	N/A
	Damage or deflection resulting in an unacceptable RISK did not occur on foot rest and its secured joints	No support systems used	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..... :	No support systems used	N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and by a test ..... :	No support systems used	N/A
	PATIENT support/suspension system set in most unfavourable NORMAL USE position, and a mass of 60 % of part of SAFE WORKING LOAD simulating PATIENT or OPERATOR, or a min 80 kg, placed on support or suspension system with centre of load 60 mm from outer edge of support or suspension system for at least one minute (Kg) ... :	No support systems used	N/A
	Deflection of support/suspension system resulting in an unacceptable RISK not occur	No support systems used	N/A
9.8.3.3	Dynamic forces that can be exerted on equipment	No support systems used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE did not result in an unacceptable RISK as confirmed by following test:		
	PATIENT support/suspension system set in most unfavourable NORMAL USE position, and a mass equal to SAFE WORKING LOAD simulating PATIENT or OPERATOR dropped from 150 mm above seat area on an area of support/ suspension a PATIENT or OPERATOR can sit ..... :	No support systems used	N/A
9.8.4	Systems with MECHANICAL PROTECTIVE DEVICES		N/A
9.8.4.1	a) A MECHANICAL PROTECTIVE DEVICE provided when a support system or its parts impaired by wear have a TENSILE SAFETY FACTOR to values in Table 21, rows 5 and 6, but less than 3 and 4 ..... :	No support systems used	N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:	No support systems used	N/A
	- Designed based on TOTAL LOAD, and includes effects of Safe WORKING LOAD when applicable	No support systems used	N/A
	- Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7	No support systems used	N/A
	- Activated before travel (movement) produced an unacceptable RISK	No support systems used	N/A
	- Takes into account Clauses 9.2.5 and 9.8.4.3	No support systems used	N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing ... :	No support systems used	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 (e.g., a secondary cable)	No support systems used	N/A
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced	No support systems used	N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	- Further use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE device	No support systems used	N/A
	- ACCOMPANYING DOCUMENTS instruct once MECHANICAL PROTECTIVE device is Activated, SERVICE PERSONNEL shall be called, and MECHANICAL PROTECTIVE device must be	No support systems used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	replaced before ME EQUIPMENT can be used		
	- ME EQUIPMENT permanently marked with safety sign 2 of Table D.2 (i.e., safety sign 7010-W001)	No support systems used	N/A
	- Marking is adjacent to MECHANICAL PROTECTIVE device or its location relative to MECHANICAL PROTECTIVE device is obvious to SERVICE PERSONNEL	No support systems used	N/A
	- compliance confirmed by examination of ME EQUIPMENT, ACCOMPANYING DOCUMENTS, RISK MANAGEMENT FILE, specifications and processing of materials, and following test	No support systems used	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	No support systems used	N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR	No support systems used	N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function	No support systems used	N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N/A
	Support system parts have TENSILE SAFETY FACTORS to values in Table 21, rows 1 and 2, and are not impaired by wear:	No support systems used	N/A
	Support system parts impaired by wear, however, they have TENSILE SAFETY FACTORS to values in Table 21, rows 3 and 4	No support systems used	N/A
	Examination of ME EQUIPMENT and RISK MANAGEMENT FILE confirmed compliance	No support systems used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
10	**PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS**		N/A
10.1	X-Radiation		N/A
10.1.1	X-radiation dose-rate was ≤ 36 pA/kg (5 µSv/h) (0.5 mR/h) 5 cm from surface of ME EQUIPMENT including background radiation for ME EQUIPMENT not producing therapeutic/diagnostic X-radiation but producing ionizing radiation ..... :	No X-radiation	N/A
	Amount of radiation measured by means of an ionizing chamber radiation monitor with an effective area of 10 cm2 or by other instruments producing equal results		N/A
	ME EQUIPMENT operated as in NORMAL USE at most unfavourable RATED MAINS VOLTAGE and controls adjusted to emit maximum radiation		N/A
	Internal pre-set controls not intended for adjustment during EXPECTED SERVICE LIFE of ME EQUIPMENT not taken into consideration		N/A
10.1.2	RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE (see IEC 60601-1-3 & 1.3) :		N/A
10.2	RISK associated with alpha, beta, gamma, neutron, and other particle radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE ..... :	No alpha, beta, gamma, neutron, and other particle radiation	N/A
10.3	RISK associated with microwave radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... :	No microwave radiation	N/A
10.4	Relevant requirements of IEC 60825-1:1993 applied to lasers, light emitting diodes (LEDs), and laser light barriers or similar products	No lasers, light emitting diodes (LEDs), and laser light barriers or similar products	N/A
10.5	RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... :	Not evaluated by Underwriters Laboratories Inc.	N/A
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... :	No such hazard	N/A
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS, as applicable,	No UV	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE ..... :		

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Clause	Requirement + Test	Result - Remark	Verdict
11	**PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS**		Pass
11.1	Excessive temperatures in ME EQUIPMENT		Pass
11.1.1	Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T ..... :	See appended Table 11.1.1 and appended RM Results Table 11.1.1	Pass
	Surfaces of test corner did not exceed 90 °C	Recognized component. To be considered in end application.	N/A
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	No thermal cut-outs used	N/A
11.1.2	Temperature of APPLIED PARTS		N/A
11.1.2.1	Temperatures, hot or cold surfaces, and when appropriate, clinical effects of APPLIED PARTS supplying heat to a PATIENT determined and documented in RISK MANAGEMENT FILE and instructions for use ..... :		N/A
11.1.2.2	APPLIED PARTS not supplying heat to a PATIENT met Table 24 with max surface temperatures > 41 °C disclosed in instructions for use, and clinical effects regarding maturity of PATIENTS, body surface, surface pressure, medications taken, as shown in RISK MANAGEMENT FILE ..... :		N/A
	Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS		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 ..... :	Temperature was conducted. No such condition.	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	The test corner to be evaluated in end application	N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE	The maximum temperature of enclosure was 82.9 degree C during temperature measurements for 1089 familiy. The acceptance of risk to be evaluated in end application.	N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No such condition.	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
11.2	Fire prevention		Pass
11.2.1	ENCLOSURE has strength and rigidity necessary to prevent a fire caused by reasonably foreseeable misuse and met mechanical strength tests for ENCLOSURES in 15.3		Pass
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 fire under NORMAL or SINGLE FAULT CONDITIONS when source of ignition in contact with ignitable material :	Not used with oxygen or oxygen enriched environments	N/A
	Requirements of 13.1.1 applied to oxygen concentrations up to 25 % at one atmosphere or partial pressures up to 27.5 kPa for higher atmospheric pressures	Not used with oxygen or oxygen enriched environments	N/A
	a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT in NORMAL and SINGLE FAULT CONDITIONS under any of the following conditions ..... :	Not used with oxygen or oxygen enriched environments	N/A
	1) when temperature of material raised to its ignition temperature	Not used with oxygen or oxygen enriched environments	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	Not used with oxygen or oxygen enriched environments	N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating	Not used with oxygen or oxygen enriched environments	N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton	Not used with oxygen or oxygen enriched environments	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	Not used with oxygen or oxygen enriched environments	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	Not used with oxygen or oxygen enriched environments	N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ..... :	Not used with oxygen or oxygen enriched environments	N/A
	A safe upper limit determined by dividing upper	Not used with oxygen or	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	limit of voltage or current, respectively, with safety margin factor of three ..... :	oxygen enriched environments	
	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 ..... :	Not used with oxygen or oxygen enriched environments	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 ..... :	Not used with oxygen or oxygen enriched environments	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 (%) ..... :	Not used with oxygen or oxygen enriched environments	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	Not used with oxygen or oxygen enriched environments	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... :	Not used with oxygen or oxygen enriched environments	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 ..... :	Not used with oxygen or oxygen enriched environments	N/A
11.2.2.2	RISK of ignition under least favourable conditions 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 when electrical components mounted outside of ME EQUIPMENT or ME SYSTEM	Not used with oxygen or oxygen enriched environments	N/A
11.2.2.3	Electrical connections within a compartment	Not used with oxygen or	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks due to loosening or breaking, except when limited in power and energy to values in 11.2.2.1 a) 5)	oxygen enriched environments	
	- Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques	Not used with oxygen or oxygen enriched environments	N/A
	- Soldered, crimped, and pin-and-socket CONNECTIONS of cables exiting ENCLOSURE include additional MECHANICAL securing means	Not used with oxygen or oxygen enriched environments	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) ..... :	Not used with oxygen or oxygen enriched environments	N/A
	- Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) ..... :	Not used with oxygen or oxygen enriched environments	N/A
	- Failure of a component creating a source of ignition (as defined in 11.2.2.1 a) ..... :	Not used with oxygen or oxygen enriched environments	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)..... :	Not used with oxygen or oxygen enriched environments	N/A
	- failure of a pneumatic component resulting in LEAKAGE of oxygen-enriched gas ..... :	Not used with oxygen or oxygen enriched environments	N/A
11.3	Constructional requirements for fire ENCLOSURES of ME EQUIPMENT		Pass
	ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 ..... :	See Appended RM Results Table 11.3	Pass
	Constructional requirements were met, or		Pass
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE	The constructional requirements were met	N/A
	Justification, when requirement not met:		N/A
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials	See appended Table 8.10	Pass
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of	See appended Table 8.10	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	materials data:		
	If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings		N/A
	b) Fire ENCLOSURE met following:	Fire enclosure provided for 1089 family	Pass
	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 x 2 mm centre to centre and wire diameter of at least 0.45 mm	No opening	Pass
	2) No openings on the sides within the area included within the inclined line C in Fig 39		Pass
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and made of appropriate metal or of non-metallic materials, except constructions based on Table 25 and a mesh; FV-2 or better for TRANSPORTABLE ME EQUIPMENT, FV-1 or better for fixed EQUIPMENT, or STATIONARY EQUIPMENT per IEC 60695-11-10, determined by ENCLOSURE examination or flammability classification based on 11.3a) ..... :	See appended Table 8.10	Pass
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 anaesthetics (CATEGORY AP) or anaesthetics with oxidants (CATEGORY APG) comply with Annex G	Not rated AP or APG	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 ..... :	Recognized component, the environment of end application is unclear, to be evaluated in end product	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..... :	Recognized component, the environment of end application is unclear, to be evaluated in end product	N/A
11.6.2	Overflow in ME EQUIPMENT		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Liquid reservoir liable to overflow in NORMAL USE completely filled and 15 % of its capacity poured in for over 1 min, and except when restricted, TRANSPORTABLE ME EQUIPMENT tilted through an angle of 15° in least favourable direction(s), and when necessary refilled starting from position of NORMAL USE ..... :		N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet ..... :		N/A
11.6. 3	Spillage on ME EQUIPMENT and ME SYSTEM		N/A
	ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE positioned as in 5.4 a) and liquid with composition, volume, duration of spill, point of contact, and test conditions based on RISK MANAGEMENT PROCESS poured steadily on a point on top of ME EQUIPMENT ..... :		N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and uninsulated electrical parts or electrical insulation of parts that could result in a HAZARDOUS SITUATION were not wet ..... :		N/A
11.6.4	Leakage		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) ..... :		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 a HAZARDOUS SITUATION in NORMAL CONDITION or in a SINGLE FAULT CONDITION		N/A
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected once using methods specified in instructions for use including any cooling or drying period ..... :		N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests, with no deterioration resulting in an unacceptable RISK present ..... :		N/A
	Effects of multiple cleanings/disinfections during		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER and assurance that no unacceptable RISK will occur verified by RISK MANAGEMENT FILE review ..... :		
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented according to ISO 11134, ISO 11135, or ISO 11137 as appropriate ..... :		N/A
	After the test, ME EQUIPMENT complied with the appropriate dielectric strength and LEAKAGE CURRENT tests and there was no deterioration resulting in an unacceptable RISK ..... :		N/A
11.6.8	RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS as confirmed by examination of RISK MANAGEMENT FILE ..... :		N/A
11.7	ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented per ISO 10993		N/E
11.8	Interruption and restoration of power supply did not result in a HAZARDOUS SITUATION, except interruption of its intended function	Refer to report E341350 -A4, identified models that evaluated in 2nd edition	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
12	**ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS**		N/A
12.1	RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review..... :	No function for ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS	N/A
12.2	RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING PROCESS as confirmed by review of provided records..... :		N/A
12.3	The need for alarm systems as a means of RISK CONTROL and RISKS associated with operation or failure of alarm system addressed in RISK MANAGEMENT PROCESS ..... :		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 as confirmed in RISK MANAGEMENT FILE ..... :		N/A
12.4.2	When applicable, need for indication of parameters associated with hazardous output addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE..... :		N/A
12.4.3	RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit designed to provide low and high-intensity outputs for different treatments addressed in RISK MANAGEMENT PROCESS, confirmed in RISK MANAGEMENT FILE ..... :		N/A
12.4.4	When applicable, RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE ..... :		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 emitted by ME EQUIPMENT designed to produce radiation for diagnostic/therapeutic purposes	No Diagnostic or therapeutic radiation function	N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	RISKS associated with diagnostic X-rays addressed in RISK MANAGEMENT PROCESS as		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	confirmed in RISK MANAGEMENT FILE ..... :		
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE ..... :		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 confirmed by examination of RISK MANAGEMENT FILE ..... :		N/A
12.4.6	When applicable, RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
13	**HAZARDOUS SITUATIONS AND FAULT CONDITIONS**		Pass
13.1	Specific HAZARDOUS SITUATIONS		Pass
13.1.1	None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2	Refer to report E341350 -A4, identified models that evaluated in 2nd edition	Pass
13.1.2	Emissions, deformation of ENCLOSURE or exceeding maximum temperature		Pass
	- Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur	Refer to report E341350 -A4, identified models that evaluated in 2nd edition	Pass
	- Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		Pass
	- Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3 ..... :	No applied part	N/A
	- Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3 ..... :	See table 13.2 for detail	Pass
	-Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded		Pass
	Limits for windings in Tables 26, 27, and 31 not exceeded		Pass
	Table 22 not exceeded in all other cases		Pass
	Temperatures measured according to 11.1.3		Pass
	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:	No such construction	N/A
	- Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit, or		N/A
	- Parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation		N/A
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		N/A
13.1.3	- limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed ..... :	See appended Table 8.7	Pass
	- voltage limits for ACCESSIBLE PARTS including	Complywith 8.4.2 b)	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	APPLIED PARTS in 8.4.2 did not exceed ..... :		
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS		Pass
13. 2	SINGLE FAULT CONDITIONS		Pass
13.2.1	During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) applied in least favourable combination ..... :	See appended Table 13.2	Pass
13.2.2 - 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12... :	See appended Table 13.2	Pass
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to room temperature	Refer to report E341350 -A4, identified models that evaluated in 2nd edition	Pass
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted		Pass
	For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).		Pass
13.2.13.2	ME EQUIPMENT with heating elements		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, or for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests of 13.2.13.2 b) & 13.2.13.2 c)	No heating elements	N/A
	a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests of 13.2.13.2 b) and 13.2.13.2 c)		N/A
	a 3) other ME EQUIPMENT with heating elements met test of 13.2.13.2 b)		N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively		N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration		N/A
	Test repeated on a second sample when interruption was due to rupture of a heating		N/A

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

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Clause	Requirement + Test	Result - Remark	Verdict
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT	No motors used	N/A
	b) Motor met running overload protection test of this clause when:	No motors used	N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or	No motors used	N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended	No motors used	N/A
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured C)..... :	No motors used	N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps	No motors used	N/A
	Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload	No motors used	N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current	No motors used	N/A
	Test not conducted based on other justifications (justification)..... :	No motors used	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	Not connected to a multiphase AC input source	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	Not non-continuous operation	N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle	Not non-continuous operation	N/A
	Motor winding temperatures did not exceed values in 13.2.10..... :	Not non-continuous operation	N/A
	Insulation Class ..... :	Not non-continuous operation	-
	Maximum temperature measured (C) ..... :	Not non-continuous operation	-

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Clause	Requirement + Test	Result - Remark	Verdict
14	**PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)**		N/A
14.1	Requirements of this clause not applied to PESS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or	Product is switching power adapter, and software is provided within control IC. RM report had evaluated the risks and hazards of IC lose effectiveness during normal and single fault situation, and inspected with single fault conditions identified in ANSI/AAMI ES60601-1 Clause 13.2, and there was no unacceptable risk directly to hazardous situations described in 13.1. According to above, there was no risk for loss effectiveness of software, and the evaluation of clause14 should be evaluated in end application, and these clauses are non applicable in this report.	N/A
	- when application of ISO 14971 showed that failure of PESS does not lead to unacceptable RISK ..... :		N/A
	Every PROCESS has been followed throughout the PEMS DEVELOPMENT LIFE-CYCLE and a RECORD of PROCESS has been made available as confirmed by RISK MANAGEMENT FILE REVIEW and assessment of PROCESSES cited in this Clause		N/A
	MANUFACTURER considered the need for additional RISK CONTROL measures when unable to follow all PROCESSES identified in Clause 14 for each constituent component of PEMS as confirmed by RISK MANAGEMENT FILE review and assessment of PROCESSES cited in this Clause		N/A
	Assessment of PROCESSES cited in this Clause made by internal audits		N/A
14.2	Documents produced from application of Clause 14 are maintained and form a part of RISK MANAGEMENT FILE in addition to RECORDS and documents required by ISO 14971..... :		N/A
14.3	RISK MANAGEMENT plan required by 3.5 of ISO 14971 includes reference to PEMS VALIDATION		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	plan		
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented		N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined		N/A
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone		N/A
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules		N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements		N/A
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained where appropriate		N/A
	Problem resolution system meets the prescribed criteria depending on type of product:		N/A
	- it is documented as a PART of PEMS DEVELOPMENT LIFE-CYCLE		N/A
	- it allows reporting of POTENTIAL or existing problems affecting BASIC SAFETY or ESSENTIAL performance		N/A
	- it includes an Assessment of each problem for associated RISKS		N/A
	- it identifies criteria that must be met for the issue to be closed		N/A
	- it identifies the action to be taken to resolve each problem		N/A
14.6	RISK MANAGEMENT PROCESS		N/A
14.6.1	MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including NETWORK/DATA COUPLING, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS		N/A
	In addition to the material in ISO 14971, Annex D, list of possible sources for HAZARDS associated with PEMS includes specified causes		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- failure of NETWORK/DATA COUPLING to provide characteristics necessary for PEMS to achieve its BASIC SAFETY or ESSENTIAL performance		N/A
	- undesired feedback [physical and data] (such as unsolicited/ out of range/ inconsistent input or input from electromagnetic interference)		N/A
	- unavailable DATA		N/A
	- lack of integrity of DATA		N/A
	- incorrect DATA		N/A
	- incorrect timing of DATA		N/A
	- unintended interactions within & among PESS		N/A
	- unknown aspects or quality of third-party software		N/A
	- unknown aspects or quality of third-party PESS		N/A
	- lack of DATA security, particularly vulnerability to tampering, unintended interaction with other programs and viruses		N/A
14.6.2	Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 6.1 of ISO 14971:		N/A
14.7	A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem ..... :		N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems ..... :		N/A
	The architecture specification makes use of considers the specified items to reduce RISK to an acceptable level, where appropriate:		N/A
	a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS		N/A
	b) fail-safe functions		N/A
	c) redundancy		N/A
	d) diversity;		N/A
	e) partitioning of functionality		N/A
	f) defensive design potentially limiting hazardous effects by restricting available output power or by introducing means to limit travel of actuators		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	g) allocation of RISK CONTROL measures to subsystems and components of PEMS		N/A
	h) failure modes of components and their effects;		N/A
	i) common cause failures		N/A
	j) systematic failures		N/A
	k) test interval duration and diagnostic coverage		N/A
	l) maintainability		N/A
	m) protection from reasonably foreseeable misuse		N/A
	n) NETWORK/DATA COUPLING specification, when applicable		N/A
14.9	Design is broken up into subsystems, each with a design and test specification where appropriate, and descriptive data on design environment included in RISK MANAGEMENT FILE ..... :		N/A
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures :		N/A
	- milestone(s) when VERIFICATION is to be performed for each function		N/A
	- selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the PERSONNEL performing the VERIFICATION		N/A
	- selection and utilization of VERIFICATION tools		N/A
	- coverage criteria for VERIFICATION		N/A
14.11	A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE and requiring checks for unintended functioning of PEMS to perform and document PEMS VALIDATION		N/A
	The person with overall responsibility for PEMS VALIDATION is independent of design team, and no member of a design team is responsible for PEMS VALIDATION of their own design		N/A
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE providing methods & results of PEMS VALIDATION		N/A
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
14.13	Technical description includes the following information when PEMS is to be connected to other equipment outside control of PEMS MANUFACTURER by NETWORK/DATA COUPLING ..... :		N/A
	a) characteristics of NETWORK/DATA COUPLING necessary for PEMS to achieve its INTENDED USE		N/A
	b) list of HAZARDOUS SITUATIONS resulting from a failure of NETWORK/DATA COUPLING to provide the specified characteristics		N/A
	c) instructions to RESPONSIBLE ORGANIZATION containing required information and warnings		N/A
	- connection of PEMS to a NETWORK/DATA COUPLING that includes other EQUIPMENT could result in previously unidentified RISKS and RESPONSIBLE ORGANIZATION shall identify, analyze, and control such RISKS		N/A
	- subsequent changes to NETWORK/DATA COUPLING introducing new RISKS and requiring new analysis; and changes to NETWORK/DATA COUPLING include:		N/A
	- NETWORK/DATA COUPLING configuration change		N/A
	- connection of additional items to NETWORK/DATA COUPLING		N/A
	- disconnecting items from NETWORK/DATA COUPLING		N/A
	- update of EQUIPMENT connected to NETWORK/DATA COUPLING		N/A
	- upgrade of EQUIPMENT connected to NETWORK/DATA COUPLING		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15	**CONSTRUCTION OF ME EQUIPMENT**		Pass
15.1	RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS, as confirmed by examination of RISK MANAGEMENT FILE ..... :	See Appended RM Results Table 15.1	N/A
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance	Recognized component, to be evaluated in end product	N/A
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		N/A
15.3	Mechanical strength		Pass
15.3.1	Mold stress relief, push, impact, drop, and rough handling tests did not result in unacceptable RISK and ME EQUIPMENT displayed adequate mechanical strength	For 1089 family. Refer to report E341350 -A4, identified models that evaluated in 2nd edition	Pass
15.3.2	Push test conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular (30mm) plane surface, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable test tool ... :	See Appended Table 15.3 and RM Results Table 15.3.2	Pass
	No damage resulting in an unacceptable RISK sustained as determined by examination of RISK MANAGEMENT FILE		Pass
15.3.3	Impact test conducted by subjecting a complete ENCLOSURE or its largest non-reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m..... :	See Appended Table 15.3 and RM Results Table 15.3.3. For 1089 family. Refer to report E341350 -A4, identified models that evaluated in 2nd edition	Pass
	Test not applied to flat panel displays, platen glass of ME EQUIPMENT, or cathode ray tubes		Pass
	No damage resulting in an unacceptable RISK sustained as shown in RISK MANAGEMENT FILE		Pass
15.3.4	Drop test		Pass
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT and HAND-HELD part with SAFE WORKING LOAD allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm ± 5 mm thick hardwood board lying	The equipment complied with this clause which is worse. See Appended Table 15.3.4.1. For 1089 family. Refer to report E341350 -A4, identified models that evaluated in 2nd	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	flat on a concrete or rigid base ..... :	edition	
	No unacceptable RISK resulted		Pass
15.3.4.2	Sample of PORTABLE ME EQUIPMENT and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 ± 5 mm thick hardwood board lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE (cm)..... :		N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		N/A
15.3.5	Each sample of MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests ..... :	Not mobile equipment	N/A
	a) Ascending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s against an ascending hardwood step obstruction without the sample going over the obstruction	Not mobile equipment	N/A
	b) Descending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s in order to fall over a vertical step affixed flat on a rigid base with direction of movement perpendicular to face of the step until full descent achieved	Not mobile equipment	N/A
	c) Door frame shock test conducted on the sample by moving it 3 times in its normal direction of travel at 0.4 m/s ± 0.1 m/s, or for motor driven EQUIPMENT, at maximum possible speed against a hardwood vertical obstacle higher than EQUIPMENT contact point(s)	Not mobile equipment	N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE	Not mobile equipment	N/A
15.3.6	Examination of ENCLOSURE made from molded or formed thermoplastic material indicated that material distortion due to release of internal stresses by molding or forming operations will not result in an unacceptable RISK		Pass
	Mold-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	See Appended Table 15.3	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
	in 11.1.3, but no less than 70 °C ..... :		
	No damage resulting in an unacceptable RISK		Pass
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT		N/A
	Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK		N/A
15.4	ME EQUIPMENT components and general assembly		N/A
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular..... :	No any outlet is provided on the power adapter except for dc output connector itself.	N/A
	a) Plugs for connection of PATIENT leads cannot be connected to other outlets on same ME EQUIPMENT intended for other functions, except when RISK MANAGEMENT FILE provides proof that no unacceptable RISK could result ..... :	No patient connections	N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable as verified by review of RISK MANAGEMENT FILE..... :	No Medical gas connections	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 result in a HAZARDOUS SITUATION by resetting action as verified by review of RISK MANAGEMENT FILE . :	No such component is incorporated.	N/A
	b) THERMAL CUT-OUTS with a safety function to be reset by a soldering operation affecting operating value not fitted in ME EQUIPMENT as verified by examination of design and RISK MANAGEMENT FILE ..... :	No thermal cut-outs used	N/A
	c) An independent non-SELF-RESETTING THERMAL CUT-OUT is, additionally, provided where a failure of a THERMOSTAT could constitute a HAZARD as verified by examination of design and RISK MANAGEMENT FILE ..... :	No thermostats used	N/A
	d) Based on design and RISK MANAGEMENT FILE review, loss of function of ME EQUIPMENT		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	due to operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION		
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS	No thermal cut-outs used	N/A
	f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following tests:		N/A
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 1999, clauses 15, 17, J.15, and J.17 as applicable		N/A
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13..... :		N/A
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified according to appropriate standards		N/A
	In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) operated 200 times		N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards		N/A
	When certification based on IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety-related function is not available, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times		N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted		N/A
	g) Protective device, provided on ME EQUIPMENT incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating	Does not use liquids in normal use	N/A
	h) ME EQUIPMENT with tubular heating elements provided with protection against overheating in both leads where a conductive connection to earth		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	could result in overheating as verified by review of design and RISK MANAGEMENT FILE ..... :		
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS	No thermostats used	N/A
15.4.3	Batteries		N/A
15.4.3.1	Battery housings from which gases can escape during charging or discharging likely to result in a HAZARD ventilated to minimize RISK of accumulation and ignition as verified by review of design and RISK MANAGEMENT FILE ..... :	No batteries used	N/A
	Battery compartments prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as verified by examination of design and RISK MANAGEMENT FILE	No batteries used	N/A
15.4.3.2	Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery..... :	No batteries used	N/A
15.4.3.3	Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design ..... :	No batteries used	N/A
15.4.3.4	Lithium batteries that could become a HAZARD complied with appropriate tests of IEC 60086-4	No batteries used	N/A
	Tests of IEC 60086-4 waived on the lithium battery based on examination of design	No batteries used	N/A
15.4.3.5	A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire caused by excessive currents when (in case of a short circuit) layout of internal wiring, cross-sectional area, rating of connected components can result in a fire ..... :	No batteries used	N/A
	Protective device has adequate breaking capacity to interrupt the maximum fault current	No batteries used	N/A
	Justification for OVER-CURRENT RELEASES or FUSE exclusion is included in RISK MANAGEMENT FILE	No batteries used	N/A
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for NORMAL USE, except when apparent to OPERATOR from normal operating position, and marking of 7.4.1 are insufficient for this purpose..... :	Recognized component should be considered in the end product.	N/A
	An additional indicator light provided on ME	No stand-by or warm-up state	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s, except when apparent to OPERATOR from normal operating position		
	Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational when a HAZARDOUS SITUATION could exist, except when apparent to OPERATOR from normal operating position		N/A
	Requirement not applied to heated stylus-pens for recording purposes		N/A
	Indicator lights provided on ME EQUIPMENT to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION		N/A
	Colours of indicator lights complied with 7.8.1		N/A
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE		N/A
15.4.5	RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS when applicable as verified by review of RISK MANAGEMENT FILE ..... :	No pre-set controls function	N/A
15.4.6	Actuating parts of controls of ME EQUIPMENT		N/A
15.4.6.1	a) Actuating parts cannot be pulled off or loosened up during NORMAL USE	No Actuating parts	N/A
	b) Indication of scales (e.g., "on" "off" positions, etc.) always corresponds to position of controls with adjustment that can result in a HAZARDOUS SITUATION for PATIENT or OPERATOR while ME EQUIPMENT is in use		N/A
	c) Incorrect connection of indicating device to relevant component prevented by adequate construction when it could be separated without use of a TOOL		N/A
	When torque values per Table 30 applied between control knob and shaft of rotating controls for not less than 2 s, 10 times in each direction, knobs did not rotate ..... :		N/A
	Tests conducted by applying an axial force of 60 N for electrical components and 100 N for other components for 1 min when an axial pull was required in NORMAL USE with no unacceptable RISK ..... :		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
15.4.6.2	Stops of adequate mechanical strength provided on rotating/ movable parts of controls of ME EQUIPMENT where necessary to prevent an unexpected change from max to min, or vice-versa, of the controlled parameter when this could cause a HAZARDOUS SITUATION..... :		N/A
	Torque values in Table 30 applied 10 times in each direction to rotating controls for 2 sec ..... :		N/A
	Application of an axial force of 60 N for electrical components and 100 N for other components to rotating or movable parts of controls for 1 min when an axial pull was required in NORMAL USE ..... :		N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N/A
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1		N/A
	b) Foot-operated control device supported an actuating force of 1350 N for 1 min applied over an area of 30 mm diameter in its position of NORMAL USE with no damage to device causing an unacceptable RISK..... :		N/A
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :		N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position		N/A
15.4.7.3	a) Foot-operated control device is at least IPX1 & complies with tests of IEC 60529 (IP Code)..... :		N/A
	b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6 and complies with IEC 60529 if in NORMAL USE liquids are likely to be found (IP Code)..... :		N/A
	Probability of occurrence estimated as part of RISK MANAGEMENT PROCESS	No Aluminum wires	N/A
15.4.8	Aluminum wires less than 16 mm2 in cross-sectional area are not used		N/A
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed to prevent loss of oil in any position	No Oil container	N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	Not mobile equipment	N/A
	A pressure-release device operating during NORMAL USE is, optionally, provided	Not mobile equipment	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage		N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements		N/A
15.5	MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5		Pass
15.5.1	Overheating		Pass
15.5.1.1	Transformers of ME EQUIPMENT are protected against overheating in the event of short circuit or overload of output windings and comply with this Clause and tests of 15.5.1.2 - 3 ..... :	See appended Tables 15.5.1.2 and 15.5.1.3. Refer to report E341350 -A4, identified models that evaluated in 2nd edition	Pass
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		Pass
	Dielectric strength test of 8.8.3 conducted on transformer after short circuit and overload tests . :	See appended table 15.5.1	Pass
15.5.1.2	Transformer output winding short circuited, and test continued until protective device operated or THERMAL STABILITY achieved ..... :	See appended Table 15.5.1.2. Refer to report E341350 -A4, identified models that evaluated in 2nd edition	Pass
	Short circuit applied directly across output windings for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2		N/A
15.5.1.3	Multiple overload tests conducted on windings with more than one protective device to evaluate worst-case NORMAL USE loading and protection..... :		N/A
15.5.2	Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION	Product is switching power adapter, and the transformer was stressed at high frequency during normal and single fault operation. Evaluation of clause 15.5.2 was considered unnecessary.	N/A
	Dielectric strength tests were conducted in accordance with requirements of this clause with no breakdown of insulation system and no detectable deterioration of transformer ..... :		N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with IEC 61558-1:1997, Clause 5.12..... :	See appended Table 8.10	Pass

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Clause	Requirement + Test	Result - Remark	Verdict
16	**ME SYSTEMS**		N/A
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- ME SYSTEM provides the level of SAFETY within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- ME SYSTEM provides the level of SAFETY outside PATIENT ENVIRONMENT equivalent to EQUIPMENT complying with their respective IEC or ISO SAFETY standards	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- tests performed in NORMAL CONDITION, except as specified	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	RISK MANAGEMENT methods, optionally, used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR to determine configurations with highest RISKS and measures to ensure any configuration of ME SYSTEM will not present unacceptable RISKS	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	The ME Equipment is not part of an ME System as defined by the manufacturer	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	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM	The ME Equipment is not part of an ME System as defined	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
		by the manufacturer	
	ACCOMPANYING DOCUMENTS are, optionally, provided in electronic format (e.g. electronic file format or CD ROM) and ME SYSTEM is capable of displaying or printing these documents	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	c) the required information is provided:	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- instructions for cleaning and, when applicable, disinfecting and sterilizing each item of EQUIPMENT or EQUIPMENT PART forming PART of the ME SYSTEM	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- additional SAFETY measures to be APPLIED during installation of ME SYSTEM	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- additional measures to be APPLIED during preventive maintenance	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- a warning forbidding placement of MULTIPLE socket-OUTLET, when provided and it is a separate item, on the floor	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- a warning indicating an additional MULTIPLE socket-OUTLET or extension CORD not to be connected to ME SYSTEM	The ME Equipment is not part of an ME System as defined by the manufacturer	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	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- MAXIMUM permissible LOAD for any MULTIPLE	The ME Equipment is not part	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	socket-OUTLET(s) used with ME SYSTEM	of an ME System as defined by the manufacturer	
	- 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	The ME Equipment is not part of an ME System as defined by the manufacturer	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	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- an explanation indicating RISKS of connecting any EQUIPMENT supplied as a PART of ME SYSTEM to MULTIPLE socket-OUTLET	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- adjustment, cleaning, sterilization, and disinfection PROCEDURES	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- assembly of ME systems and modifications during actual SERVICE LIFE shall be evaluated based on the requirements of this standard	The ME Equipment is not part of an ME System as defined by the manufacturer	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	The ME Equipment is not part of an ME System as defined by the manufacturer	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, etc., without use of a TOOL operated at a voltage ≤ voltage in 8.4.2 c) supplied from a source separated from SUPPLY MAINS by two MEANS OF OPERATOR PROTECTION	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and	No input/ouput ports used	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed		
	SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION appropriate for highest voltage occurring across SEPARATION DEVICE during a fault condition	No input/ouput ports used	N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V) ... :	No input/ouput ports used	N/A
16.6	LEAKAGE CURRENTS		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION, from or between parts of ME SYSTEM within the PATIENT ENVIRONMENT, did not exceed 100 uA ..... :	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	TOUCH CURRENT did not exceed 500 uA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, from or between parts of ME SYSTEM within PATIENT ENVIRONMENT ..... :	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET did not exceed 5 mA ..... :	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.6.3	PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values specified for ME EQUIPMENT in Tables 3 and 4 :	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	Measurements made using a device as in clause 8.7.4.4	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.7	ME SYSTEM complied with applicable requirements of Clause 9 when a MECHANICAL HAZARD existed ..... :	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.8	Interruption and restoration of relevant power connections of ME SYSTEM one at a time and all connections simultaneously did not result in a HAZARDOUS SITUATION other than interruption of its intended function	The ME Equipment is not part of an ME System as defined by the manufacturer	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 a HAZARDOUS SITUATION could otherwise exist . :	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- Connectors complied with Clause 15.4.1	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	- plugs for connection of PATIENT leads 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 hazardous SITUATION could result	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.9.2	MAINS PARTS, components and layout	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.9.2.1	a) - MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or	No multiple socket outlets used	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	No multiple socket outlets used	N/A
	- MULTIPLE socket-OUTLET is supplied via a separating transformer	No multiple socket outlets used	N/A
	b) - MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 (i.e., safety sign ISO 7010-W001) visible in NORMAL USE, and	No multiple socket outlets used	N/A
	- marked either individually or in combinations, with the MAXIMUM allowed Continuous output in amperes or volt-amperes, or	No multiple socket outlets used	N/A
	- marked to indicate the EQUIPMENT or EQUIPMENT parts it may safely be attached to	No multiple socket outlets used	N/A
	- MULTIPLE socket-OUTLET is a separate item or an integral PART of ME EQUIPMENT or non-ME EQUIPMENT	No multiple socket outlets used	N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:	No multiple socket outlets used	N/A
	- CREEPAGE and CLEARANCES complied with 8.9	No multiple socket outlets used	N/A
	- it is CLASS I, and PROTECTIVE EARTH conductor is connected to earthing contacts in socket-outlets	No multiple socket outlets used	N/A
	- PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6, except total impedance for ME SYSTEM was up to 400 m , or higher when conditions of 8.6.4 b) met (m) ..... :	No multiple socket outlets used	N/A
	- ENCLOSURE complied with 8.4.2 d)	No multiple socket outlets	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
		used	
	- MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable	No multiple socket outlets used	N/A
	- RATINGS of components are not in conflict with conditions of use	No multiple socket outlets used	N/A
	- electrical TERMINALS and connectors of MULTIPLE socket-outlets prevent incorrect connection of accessible connectors removable without a TOOL	No multiple socket outlets used	N/A
	- POWER SUPPLY CORD complied with 8.11.3	No multiple socket outlets used	N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:	No multiple socket outlets used	N/A
	- Separating transformer complied with IEC 61558-2-1, except requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 were not applied ..... :	No multiple socket outlets used	N/A
	- separating transformer is CLASS I	No multiple socket outlets used	N/A
	- Degree of protection against ingress of water specified as in IEC 60529	No multiple socket outlets used	N/A
	- Separating transformer assembly marked according to 7.2 and 7.3	No multiple socket outlets used	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	No multiple socket outlets used	N/A
16.9.2.2	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	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
17	**ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS**		N/A
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review ..... :	It not evaluated by Underwriters Laboratories Inc.	N/A
	- electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ..... :		N/A
	- introduction of electromagnetic phenomena into ENVIRONMENT by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical EQUIPMENT, and systems		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
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 ANESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	Not rated AP or APG	N/A
G.2.2	FLAMMABLE AESTHETIC MIXTURE WITH AIR occurring due to a leakage or discharge of a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE from an ENCLOSURE considered 5 to 25 cm from point of occurrence	Not rated AP or APG	N/A
G.2.3	A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE contained in a completely / partly enclosed ME EQUIPMENT part and in PATIENT'S respiratory tract 5 cm from an ENCLOSURE part where leakage or discharge occurs	Not rated AP or APG	N/A
G.2.4	ME EQUIPMENT or parts thereof specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR (in a location as in G.2.2) are CATEGORY AP or APG ME EQUIPMENT and complied with G.4 and G.5	Not rated AP or APG	N/A
G.2.5	ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE (location per G.2.2) are CATEGORY APG ME EQUIPMENT and comply with G.4 and G.6	Not rated AP or APG	N/A
	ME EQUIPMENT in G.2.3 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7	Not rated AP or APG	N/A
G.3	Marking, ACCOMPANYING DOCUMENTS		N/A
G.3.1	CATEGORY APG ME EQUIPMENT prominently marked. with a green-coloured band 2 cm wide with letters "APG" according to symbol 23 in Table D.1 ..... :	Not rated AP or APG	N/A
	Length of green-coloured band is 4 cm, and size of marking is as large as possible for particular case	Not rated AP or APG	N/A
	When above marking not possible, relevant information included in instructions for use ..... :	Not rated AP or APG	N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	Not rated AP or APG	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle 2 cm in diameter, with characters "AP" according to symbol 22 in Table D.1 ..... :	Not rated AP or APG	N/A
	Marking is as large as possible for the particular case	Not rated AP or APG	N/A
	When above marking not possible, the relevant information included in instructions for use ..... :	Not rated AP or APG	N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	Not rated AP or APG	N/A
G.3.3	The marking according to G.3.2 and G.3.3 placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts, and not repeated on detachable parts that can only be used with the marked EQUIPMENT	Not rated AP or APG	N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts	Not rated AP or APG	N/A
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG	Not rated AP or APG	N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N/A
G.4.1	a) CREEPAGE and CLEARANCES between points of POWER SUPPLY CORD connection are according to Table 12 for one MEANS OF PATIENT PROTECTION	Not rated AP or APG	N/A
	b) Connections, except those in circuits described in G.5.3 and G.6.3, protected against accidental disconnection in NORMAL USE or connection and disconnection can be performed only with a TOOL	Not rated AP or APG	N/A
	c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD, except when circuit complied with G.5.3 and G.6.3	Not rated AP or APG	N/A
G.4.2	Construction details		N/A
	a) Opening of an ENCLOSURE providing protection against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL	Not rated AP or APG	N/A
	b) ENCLOSURE complies with requirements to minimize arcing and sparking due to penetration of foreign objects ..... :	Not rated AP or APG	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- no openings on top covers of ENCLOSURE, except for openings for controls covered by control knobs	Not rated AP or APG	N/A
	- openings in side-covers prevented penetration of a solid cylindrical test rod of 4 mm in diameter applied in all possible directions without appreciable force	Not rated AP or APG	N/A
	- openings in base plates prevented penetration of a solid cylindrical test rod of 12 mm in diameter applied in all directions without appreciable force	Not rated AP or APG	N/A
	c) Short circuiting conductor(s) to a conductive part without presence of explosive gasses where insulation may contact a part containing a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE, ignitable gases alone, or oxygen, did not result in loss of integrity of the part, an unacceptable temperature, or other HAZARD	Not rated AP or APG	N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures	Not rated AP or APG	N/A
	- Use of antistatic materials with a limited electrical resistance as specified in G.4.3 b) ..... :	Not rated AP or APG	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 of medical room	Not rated AP or APG	N/A
	b) Electrical resistance limits of aesthetic tubing, mattresses and pads, castor tires, and other antistatic material complied with ISO 2882 based on measurements according to ISO 1853, ISO 2878 and ISO 23529 ..... :	Not rated AP or APG	N/A
G.4.4	Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5	Not rated AP or APG	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 (inclusive)	Not rated AP or APG	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 ..... :	Not rated AP or APG	N/A
G.5.2	ME EQUIPMENT, its parts, and components in contact with gas mixtures in NORMAL USE and CONDITIONS not producing sparks and not resulting in surface temperatures above 150 °C in case of restricted or 200 °C in case of unrestricted vertical air circulation measured at 25 °C comply with G.5.1..... :	Not rated AP or APG	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 Umax and Imax occurring in their circuits, and complied as follows:	Not rated AP or APG	N/A
	Measured Umax ≤ UzR with IzR as in Fig. G.1..... :	Not rated AP or APG	N/A
	Measured Umax ≤ Uc with Cmax as in Fig. G.2 .. :	Not rated AP or APG	N/A
	Measured Imax ≤ IzR with UzR as in Fig G.1 ..... :	Not rated AP or APG	N/A
	Measured Imax ≤ IzL with Lmax and a Umax ≤ 24 V as in Fig G.3..... :	Not rated AP or APG	N/A
	- Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1	Not rated AP or APG	N/A
	No extrapolation made for voltages above 42 V	Not rated AP or APG	N/A
	- Combinations of capacitances and corresponding voltages within limitations of C/2U2 1.2 mJ extrapolated from Fig G.2	Not rated AP or APG	N/A
	No extrapolation made for voltages above 242V	Not rated AP or APG	N/A
	Umax, additionally, determined using actual resistance R when the equivalent resistance R was less than 8000	Not rated AP or APG	N/A
	- Combinations of currents and corresponding inductances within limitations L/2I2 0.3 mJ extrapolated from Fig G.3	Not rated AP or APG	N/A
	No extrapolation made for inductances larger than 900 mH	Not rated AP or APG	N/A
	- Umax was the highest supply voltage occurring in circuit under investigation with sparking contact open, taking into consideration MAINS VOLTAGE	Not rated AP or APG	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	variations in 4.10		
	- Imax was the highest current flowing in circuit under investigation with sparking contact closed, taking into consideration MAINS VOLTAGE variations required in 4.10	Not rated AP or APG	N/A
	- Cmax and Lmax taken as values occurring at the component under investigation producing sparks	Not rated AP or APG	N/A
	- peak value considered when a.c. supplied	Not rated AP or APG	N/A
	- an equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent Umax and Imax, either as d.c. or a.c. peak values in case of a complicated circuit	Not rated AP or APG	N/A
	Temperature measurements made according to 11.1, and Umax, Imax, R, Lmax , and Cmax determined with application of Figs G.1-G.3	Not rated AP or APG	N/A
	Alternatively, compliance was verified by examination of design data..... :	Not rated AP or APG	N/A
G.5.4	External ventilation with internal overpressure		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:	Not rated AP or APG	N/A
	a) FLAMMABLE AESTHETIC MIXTURES WITH AIR that might have penetrated into ENCLOSURE of ME EQUIPMENT or part removed by ventilation before EQUIPMENT energized, and penetration of such mixtures during operation was prevented by maintenance of overpressure by means of air without flammable gases, or by physiologically acceptable inert gas (e.g., nitrogen)	Not rated AP or APG	N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa) ..... :	Not rated AP or APG	N/A
	Overpressure maintained at the site of potential ignition even when air or inert gas could escape through openings in ENCLOSURE necessary for normal operation of ME EQUIPMENT or its parts	Not rated AP or APG	N/A
	ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE so that the displaced volume of air or inert gas was at least five times the volume of ENCLOSURE	Not rated AP or APG	N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present	Not rated AP or APG	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	c) Ignition sources de-energized automatically by means used where G.4 does not apply, or complied with G.5 when during operation overpressure dropped below 50 Pa (Pa)..... :	Not rated AP or APG	N/A
	d) External surface of ENCLOSURE in which internal overpressure was maintained did not exceed 150 °C in 25 °C ambient under NORMAL USE and CONDITION (°C)..... :	Not rated AP or APG	N/A
G.5.5	ENCLOSURES with restricted breathing		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:	Not rated AP or APG	N/A
	a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing when it was surrounded by a FLAMMABLE AESTHETIC MIXTURE WITH AIR of a high concentration for at least 30 min without any pressure difference inside ENCLOSURE	Not rated AP or APG	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... :	Not rated AP or APG	N/A
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained when the cords were stressed by bending or pulling	Not rated AP or APG	N/A
	Cords are fitted with adequate anchorages to limit stresses	Not rated AP or APG	N/A
	After the test in G.5.4 b), an internal overpressure of 400 Pa was created and 30 pulls of the value in Table G.1 applied to each flexible cord in axial direction of cord inlet and in the least favourable direction for 1 s	Not rated AP or APG	N/A
	Overpressure not reduced below 200 Pa	Not rated AP or APG	N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)	Not rated AP or APG	N/A
	Operating temperature of external surface of ENCLOSURE was 150 °C in 25 °C (°C) ..... :	Not rated AP or APG	N/A
	Steady state operating temperature of ENCLOSURE also measured (°C)..... :	Not rated AP or APG	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	Not rated AP or APG	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	NORMAL USE and SINGLE FAULT CONDITION		
	ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test after attaining thermal steady state (max. 3 h) over a period of 10 min in a 12.2 % ± 0.4 ether by volume/oxygen mixture	Not rated AP or APG	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 ..... :	Not rated AP or APG	N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS ..... :	Not rated AP or APG	N/A
	a) no sparks produced and temperatures did not exceed 90 °C, or	Not rated AP or APG	N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except Umax and Imax occurring in their circuits complied with requirements, taking Cmax and Lmax into consideration:	Not rated AP or APG	N/A
	Measured Umax ≤ UzR with IzR as in Fig. G.4 .... :	Not rated AP or APG	N/A
	Measured Umax ≤ UzC with Cmax as in Fig. G.5. :	Not rated AP or APG	N/A
	Measured Imax ≤ IzR with UzR as in Fig G.4 ..... :	Not rated AP or APG	N/A
	Measured Imax ≤ IzL with Lmax and a Umax ≤ 24 V as in Fig G.6 ..... :	Not rated AP or APG	N/A
	- Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated	Not rated AP or APG	N/A
	- Umax was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10	Not rated AP or APG	N/A
	- Imax was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10	Not rated AP or APG	N/A
	- Cmax and Lmax are values occurring in relevant circuit	Not rated AP or APG	N/A
	- Umax additionally determined with actual resistance R when equivalent resistance R in Fig	Not rated AP or APG	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	G.5 was less than 8000		
	- peak value taken into consideration when a.c. supplied	Not rated AP or APG	N/A
	- an equivalent circuit calculated to determine max capacitance, inductance, and Umax and Imax, either as d.c. or a.c. peak values in case of a complicated circuit	Not rated AP or APG	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	Not rated AP or APG	N/A
	Above requirement not applied to transformers complying with this standard	Not rated AP or APG	N/A
	Above requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture	Not rated AP or APG	N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or	Not rated AP or APG	N/A
	Temperature measurements made in accordance with 11.1, or	Not rated AP or APG	N/A
	Umax, Imax, R, Lmax and Cmax determined together with application of Figs G.4-G.6 ..... :	Not rated AP or APG	N/A
	Alternatively, compliance verified by comparison with design data..... :	Not rated AP or APG	N/A
G.6.4	ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1 ..... :	Not rated AP or APG	N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	Not rated AP or APG	N/A
G.7	Test apparatus for flammable mixtures		N/A
	Test apparatus used was in accordance with this Clause and Fig G.7	Not rated AP or APG	N/A

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Clause	Requirement + Test	Result - Remark	Verdict
L	**INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION**		Pass
L.1	BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters	Triple insulation wire provided as reinforced insulation between primary and secondary in transformer, T1	Pass
L.2	Wire construction		Pass
	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		Pass
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap		Pass
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	Used with certified triple insulation wire, the test was conducted during certification process of insulation wire.	N/A
	Temperature (°C)..... :	--	-
	Humidity (%)..... :	--	-
L.3.1	Dielectric strength		N/A
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with test voltages at least twice Tables 6 & 7, but not less than below with no breakdown:	Used with certified triple insulation wire, the test was conducted during certification process of insulation wire.	N/A
	- 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :		N/A
	- 6000 V for REINFORCED INSULATION (V)..... :		N/A
L.3.2	Flexibility and adherence		N/A
	Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1	Used with certified triple insulation wire, the test was conducted during certification process of insulation wire.	N/A
	Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown		N/A
	Test voltage was at least the voltage in Tables 6 and 7but not less than the following:		N/A

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Clause	Requirement + Test	Result - Remark	Verdict
	- 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	- 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... :		N/A
L.3.3	Heat Shock		N/A
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3, except test voltage applied between the wire and mandrel	Used with certified triple insulation wire, the test was conducted during certification process of insulation wire.	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	- 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	- 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Oven temperature based on Table L.2 (C)..... :	-	-
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm2) ..... :		N/A
	Dielectric strength test conducted at room temperature after removal from the oven		N/A
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	Used with certified triple insulation wire, the test was conducted during certification process of insulation wire.	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:		N/A
	- 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... :		N/A
	- 3000 V for REINFORCED INSULATION (V) ..... :		N/A
	Test voltage applied between the shot and conductor.		N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm2) ..... :		N/A
L.4	Tests during manufacture		N/A
L.4.1	Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3.. :	The requirement is provided in UL SPECIFIC INSPECTION CRITERIA.	N/A
L.4.2	Test voltage for routine testing (100 % testing) is at		N/A

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

Enclosure

National Differences

Canada
USA

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict

Canada - Differences to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)			
1	Scope, object and related documents	Noted.	Pass
1.1	Scope	Noted	Pass
1.1	This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32.	Noted	Pass
1.1	NOTE 1A: In the IEC 60601 standards series adopted for use in Canada, the Canadian-particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.	Noted	Pass
1.3	Collateral standards	Not evaluated with Collateral standards	N/A
1.3	Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard.	Not evaluated with Collateral standards	N/A
1.3	NOTE 1: When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards.	Not evaluated with Collateral standards	N/A
1.4	Particular standards	Not evaluated with Particular standards	N/A
1.4	A requirement of a Canadian-particular safety standard takes precedence over this standard.	Not evaluated with Collateral standards.	N/A
3	Terminology and definitions	Comply.	Pass
3.41	HIGH VOLTAGE	The secondary output circuit of the product is SELV.	N/A
3.41	any voltage above 750 V, 1 050 V peak, as defined in the Canadian Electrical Code (CEC), Part I	Rated voltage: 100-240Vac	N/A
4.8	a) the applicable safety requirements of a relevant CSA, IEC, or ISO standard; or		N/A
4.8	NOTE 1: For the components, it is not necessary to carry out identical or equivalent tests already		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
	performed to check compliance with the component standard.		
4.8	b) where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied		N/A
4.8	NOTE 2: If there are neither requirements in this standard nor in a CSA, IEC, or ISO standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.		N/A
4.10.2	and shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1:	CSA C22.2 No.60601-1-08 was applied for this device.	N/A
7.7.1	and shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1		N/A
7.7.1	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49	Class II with functional earth wire, provided by green and yellow insulation	N/A
7.7.2	and shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1		N/A
7.7.2	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49	Class II with functional earth wire, provided by green and yellow insulation	N/A
7.7.3	and shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1		Pass
7.7.3	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49		N/A
7.7.4	and shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1	Power supply cord is optional, to be considered in end application	N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
7.7.4	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49		N/A
7.7.5	and shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1	Power supply cord is optional, to be considered in end application	N/A
7.7.5	A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49	Power supply cord is optional, to be considered in end application	N/A
8.7.3	Allowable values shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1.		Pass
8.11.3.2	a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be		N/A
8.11.3.2	i) if molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21;...:		N/A
8.11.3.2	ii) hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or		N/A
8.11.3.2	iii) Class II equipment having fuses on the line side/sides and neutral and may use a non-polarized attachment plug or a polarized attachment plug - CSA configuration type 1-15P shall be required and shall meet all applicable requirements in CSA C22.2 No. 21 and CSA C22.2 No. 42. Where a polarized attachment plug is used, the POWER SUPPLY CORD shall be connected to the wiring of the EQUIPMENT on the ungrounded side of the line when any of the following devices are used in the primary circuit:.....:		N/A
8.11.3.2	1- the centre contact of an Edison base lampholder;		N/A
8.11.3.2	2- a single pole switch;		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
8.11.3.2	3- an automatic control with a marked off position;		N/A
8.11.3.2	4- a solitary fuse/fuse holder; or		N/A
8.11.3.2	5- any other single pole overcurrent protective device		N/A
8.11.3.2	b) Detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type that		N/A
8.11.3.2	i) can be shown to be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety HAZARD to a PATIENT or OPERATOR;		N/A
8.11.3.2	ii) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and		N/A
8.11.3.2	iii) has a terminal configuration or other constructional feature that will minimize the possibility of its replacement by a detachable POWER SUPPLY CORD which could create a HAZARDOUS SITUATION		N/A
8.11.3.2	c) A detachable POWER SUPPLY CORD shall		N/A
8.11.3.2	i) comply with the applicable requirements of CSA C22.2 No. 21; and.....:		N/A
8.11.3.2	ii) not be smaller than No. 18 AWG, and the mechanical serviceability shall be not less than		N/A
8.11.3.2	1) Type SJ or equivalent for mobile or exposed to abuse ME EQUIPMENT; and		N/A
8.11.3.2	2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature)		N/A
8.11.3.2	NOTE 1A: See CSA C22.2 No. 49 for requirements on the cord types mentioned in Sub-item 2).		N/A
8.11.3.2	d) Power supply cords shall meet the requirements of the Canadian Electrical Code, Part I, as applicable		N/A
8.11.3.2	Connecting cords between equipment parts shall meet the requirements of the Canadian Electrical Code, Part I, as applicable		N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the Canadian Electrical Code (CEC), Part I,	Fuses meet the requirements of CSA requirement	Pass

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
	CSA C22.1 .....:		
9.7.5	Pressure vessels shall comply with the requirements of CSA B51, as applicable		N/A
9.7.7	A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements .....:		N/A
15.4.1	bA) The point of connection of gas cylinders to EQUIPMENT shall be gas specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on EQUIPMENT shall be		N/A
15.4.1	i) gas specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1 380 kPa (200 psi); or .....:		N/A
15.4.1	ii) DISS type complying with CGA V-5 for pressures 1 380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359		N/A
15.4.1	NOTE 1A: Users of this standard should consult the CSA Z305 series of standards, CAN/CSA-Z9170-1, CAN/CSA-Z9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke-type valve connections; and ISO 32 for colour coding.		N/A
15.4.8	Internal wiring of ME EQUIPMENT shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1 .....:		N/A
16.1	General requirements for the ME SYSTEMS	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.1	An ME SYSTEM shall provide	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.1	- within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A

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SubClause	Difference + Test	Result - Remark	Verdict
16.1	- outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA, IEC, or ISO safety standards	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.1	Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with CSA, IEC, or ISO safety standards that are relevant to that equipment.	The ME Equipment is not part of an ME System as defined by the manufacturer	N/A
16.9.2.1	c) The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements .....:	No multiple socket outlets used	N/A
16.9.2.1	- The separating transformer shall comply with the requirements of CAN/CSA-E61558-2-1 with a rated output not exceeding	No multiple socket outlets used	N/A
16.9.2.1	- 1 kVA for single-phase transformers; and	No multiple socket outlets used	N/A
16.9.2.1	- 5 kVA for polyphase transformers	No multiple socket outlets used	N/A
16.9.2.1	The separating transformer shall also have a degree of protection not exceeding IPX4.	No multiple socket outlets used	N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict

USA - Differences to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)			
4.8	Replacement: where there was no relevant IEC/ISO standard, the relevant US ANSI standard applied		N/A
4.8	- when no relevant US ANSI standard existed, the requirements of this standard applied		N/A
4.10.2	Replacement: Rated voltage not exceeding 250V dc or single phase ac. or 600V poly-phase ac for me equipment and me systems up to 4kVA	100-240Vac	N/A
4.10.2	Rated voltage not exceeding 600 V for all other me equipment and me systems	100-240Vac	N/A
6.6	Addition: To comply with NFPA 70, X-Ray systems are classified as long time operation (> 5 min) or momentary operation (< 5 sec)	No X-ray	N/A
7.2.11	Addition: To comply with NFPA 70, X-Ray systems are marked as long time operation or momentary operation		N/A
7.2.21	New Sub-clause: Colors of medical gas cylinders		N/A
7.2.21	To comply with NFPA 99: Cylinders containing medical gases and their connection points are colored in accordance with the requirements of NFPA 99		N/A
8.2	Addition: All fixed me equipment & permanently installed me equipment are class I me equipment	Not fixed or permanently installed equipment	N/A
8.6.1	Addition: To comply with NFPA 99, the enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850Vdc MAINS VOLTAGE, or containing voltages up to 50 V peak and enclosed in protectively earthed enclosure as well as connections to X-ray tubes and other high voltage components that include high voltage shielded cables are PROTECTIVELY EARTHED		N/A
8.6.1	To comply with NFPA 99, non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized are PROTECTIVELY EARTHED		N/A
8.7.3	Earth leakage current values are not higher than the stated values	Leakage current of functional earth terminal was measured for reference. See appeded table 8.7	N/A
8.7.3	5 mA in normal condition		N/A
8.7.3	10 mA in single fault condition		N/A

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SubClause	Difference + Test	Result - Remark	Verdict
8.11	Addition: permanently connected me equipment provided with field wiring provision in accordance with NEC	Not Permanently connected equipment	N/A
8.11	Addition prior to the first paragraph:a) To comply with the NEC, add the following requirements to this clause:		N/A
8.11	Addition at the end of the clause:b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked	Power supply cord is optional, to be determined in end application	N/A
8.11	Installation of connecting cords between equipment parts comply with NEC		N/A
8.11	Cable used as external interconnection between units		N/A
8.11	1) Exposed to abuse: Type SJT, SJTO, SJO, ST, SO, STO, or equivalent, or similar multiple-conductor appliance-wiring material,	Product is switching power adapter, no power supply cord provided, to be evaluated in end product	N/A
8.11	2) Not exposed to abuse: The cable was as in item 1) above, or		N/A
8.11	i) Type SPT-2, SP-2, or SPE-2, or equivalent		N/A
8.11	ii) Type SVr, SVRO, SVE, or equivalent or similar multiple-conductor appliance wiring material,		N/A
8.11	iii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more,		N/A
8.11	- enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more		N/A
8.11	Receptacles provided as part of me equipment and me systems for use in the patient care areas of pediatric wards, rooms, or areas are Listed tamper resistant		N/A
8.11	- or employ a Listed tamper resistant cover in accordance with NEC		N/A
8.11.3.2	Addition: The flexible cord is a type acceptable for the particular application,		N/A
8.11.3.2	- and it is acceptable for use at a voltage not less than the rated voltage of the appliance		N/A

IEC 60601			
SubClause	Difference + Test	Result - Remark	Verdict
8.11.3.2	- and has an ampacity as in NEC, not less than the current rating of the appliance		N/A
8.11.3.3	Addition: To comply with NFPA 99, for X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug is 2X the maximum input current of the equipment		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

4.2	**RM TABLE: Risk Management Process for ME Equipment or ME Systems**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
3.3 a	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for determining acceptable risk, and relevant international standards clearly defined.	Pass
3.5 e	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Procedure for creation of risk management plan, including criteria for risk acceptability provided.	Pass
4.1	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for application of Risk analysis as per 4.2-4.4 provided. Description of ME Equipment, identification of personnel, and date of analysis required to be provided.	Pass
4.2	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for description of MEE, intended use, and reasonably foreseeable use provided.	Pass
4.3	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for compilation and documentation of known or foreseeable hazards under normal and SFC provided.	Pass
4.4	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for estimation and documentation of risk and the system used to categorise risk provided.	Pass
5	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for risk evaluation, documentation, and policy for acceptable risk provided.	Pass
6.1	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for application of risk reduction (As specified in 6.2 - 6.7) provided.	Pass
6.2	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for implementation and documentation of risk control measures provided.	Pass
6.3	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for implementation and documentation of risk control measures and analysis of effectiveness provided.	Pass
6.4	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for assessment and documentation of residual risk provided.	Pass
6.5	Risk Management Procedure	Policy for conduct and documentation of	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	risk/benefit analysis provided.	
6.6	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for assessment and documentation of changed or other generated hazards provided.	Pass
6.7	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy to evaluate the risk for all hazards provided and document the result.	Pass
7	Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for evaluating and documenting the overall risk provided.	Pass

4.3	**TABLE: Essential Performance**		N/A
List of Essential Performance functions	Manufacturer's document number reference or reference from this standard or collateral or particular standard(s)	Remarks	
Supplementary Information: Essential Performance is performance, the absence or degradation of which, would result in an unacceptable risk.			

4.3	**RM TABLE: Essential Performance**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No Essential Performance.	N/A
4.3	NA	NA	N/A
4.4	NA	NA	N/A
5	NA	NA	N/A

4.5	**RM TABLE: Equivalent Safety for ME Equipment of ME System**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No alternative means used.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

4.6	**RM TABLE: ME Equipment or system parts contacting the patient**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No such parts.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

4.7	**RM TABLE: Single Fault Condition for ME Equipment**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0) (Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment. Fault conditions considered: Failure of Optocoupler or Operation of Mains Fuses (Which are tested as part of the mandatory evaluation to Clause 13.2.)	Pass
4.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 5 (EL5))	Hazard due to single fault conditions identified.	Pass
4.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 5 (EL5))	Estimation of risk associated with single fault conditions provided. Intention to address SFC tests in type test evaluation provided.	Pass

4.8	**RM TABLE: Components of ME Equipment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	v	All components used within their ratings. See Appended Table 8.10.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

4.9	**RM TABLE: Use of components with high-integrity characteristics**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No such components.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

4.11	**TABLE: Power Input**				Pass
Operating Conditions / Ratings	Voltage (V)	Frequency (Hz)	Current (A)	Power (W or VA)	Power factor (cos φ)
-	-	-	-	-	-
Supplementary information:					
Refer to report E341350 -A4, identified models that evaluated in 2nd edition					

5.1	**RM TABLE: Type Tests**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	All required tests performed	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

5.4 a)	**RM TABLE: Other Conditions**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); (Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment. Least favourable working conditions provided and identified as maximum normal load, in the most onerous environmental condition.	Pass
4.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 10 (OP1))	Hazard of usage outside of specified conditions identified.	Pass
4.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 10 (OP1))	Estimation of risk associated with usage outside of specified conditions provided.	NA

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Clause	Requirement + Test	Result - Remark	Verdict

5.7	**RM TABLE: Humidity preconditioning treatment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	Risk management process does not indicate equipment can be exposed to high humidity for extended periods.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

5.9.2	**TABLE: Determination of ACCESSIBLE parts**		N/A
Location	Determination method (NOTE1)	Comments	
Supplementary information: NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.			

5.9.2.3	**RM TABLE: Actuating mechanisms**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No such parts.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

7.1.2	**TABLE: Legibility of Marking**		N/A
Markings tested	Ambient illuminance (lx)	Remarks	
Supplementary information: Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20), 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 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.			

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Clause	Requirement + Test	Result - Remark	Verdict

7.1.3	**TABLE: Durability of marking test**		Pass
Characteristics of the Marking Label tested:			Remarks
Material of Marking Label :		See below	-
Ink/other printing material or process :		-	-
Material (composition) of Warning Label :		-	-
Ink/other printing material or process :		-	-
Other:		-	-
FAN JA PAPER PRINTING CO LTD (PGDQ2.MH19546) Type FJ-03-3		--	T-w = 15s ,T-m =15s, T-i =15s
FAN JA PAPER PRINTING CO LTD (PGDQ2.MH19546) Type FJ07		--	T-w = 15s ,T-m =15s, T-i =15s
FAN JA PAPER PRINTING CO LTD (PGDQ2.MH19546) Type FJ-03-1		--	T-w = 15s ,T-m =15s, T-i =15s
DONGGUAN XIANGQUAN PRINTING CO LTD (PGDQ2.MH27594) Type XQ03		--	T-w = 15s ,T-m =15s, T-i =15s
DONGGUAN XIANGQUAN PRINTING CO LTD (PGJI2.MH47303) Type XQ004-B		--	T-w = 15s ,T-m =15s, T-i =15s
E-LIN ADHESIVE LABEL CO LTD (PGDQ2.MH45549) Type EL-15		--	T-w = 15s ,T-m =15s, T-i =15s
SHENZHEN CORWIN PRINTING CO LTD (PGDQ2.MH47077) Type CW-01		--	T-w = 15s ,T-m =15s, T-i =15s
SUZHOU HAIRONG PACKING PRODUCTION CO LTD (PGDQ2.MH48692) Type HR-01		--	T-w = 15s ,T-m =15s, T-i =15s
SUZHOU HAIRONG PACKING PRODUCTION CO LTD (PGDQ2.MH48692) Type HR-04		--	T-w = 15s ,T-m =15s, T-i =15s
DONGGUAN SHANGMAO PRINTING CO LTD (PGDQ2.MH17427) Type C-019		--	T-w = 15s ,T-m =15s, T-i =15s
DONGGUAN SHANGMAO PRINTING CO LTD (PGDQ2.MH17427) Type C-004		--	T-w = 15s ,T-m =15s, T-i =15s
Supplementary information: Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with methylated spirit, and then for 15 s with a cloth rag soaked with isopropyl alcohol.			
T-w = Time with distilled water T-m =Time with methylated spirit T-i = Time with isopropyl alcohol The markngs did not work loose and did not curl at the edges. The markings were clearly readable			

7.2.2	**RM TABLE: Identification**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	Marking provided.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.4	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

7.2.5	**RM TABLE: ME EQUIPMENT powered from other equipment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No such risk.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.4	NA	NA	NA

7.2.13	**RM TABLE: Physiological effects (safety signs and warning)**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No such outputs.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.3	NA	NA	NA

7.2.17	**RM TABLE: Protective packaging**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No such hazard.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA

7.3.3	**RM TABLE: Batteries**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No batteries used	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.3	NA	NA	NA

7.3.7	**RM TABLE: Supply Terminals**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

7.4.2	**RM TABLE: Control devices**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No controls provided.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA

7.5	**RM TABLE: Safety signs**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No such markings.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.3	NA	NA	NA

7.9.1	**RM TABLE: General accompanying documents (See Table C.4)**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	Specification sheet provided in hard-copy.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA

7.9.2.4	**RM TABLE: Electrical power source**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No batteries used	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.3	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

7.9.3.2	**RM TABLE: Replacement of fuses, power supply cords, other parts**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	ME Equipment is component for building-in. To be determined in End Product Evaluation.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

8.1 b(1)	**RM TABLE: Fundamental rule of protection against electric shock - interruption of any one power-carrying conductor**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	Equipment not provided with separate enclosures.	NA
4.4	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

8.1 b(2)	**RM TABLE: Fundamental rule of protection against electric shock - unintended movement of a component**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); (Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment. Movement of components considered.	Pass
4.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 3 (EL3))	Hazard of component movement identified.	Pass
4.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 3 (EL3))	Estimation of risk associated with component movement provided.	Pass
5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 3 (EL3))	Risk of component movement evaluated.	Pass
6.2	NA	No risk reduction required.	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

8.1 b(3)	**RM TABLE: Fundamental rule of protection against electric shock - accidental detachment of conductors and connectors**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 6 (EL6))	Intended use and reasonably foreseeable misuse identified for the ME Equipment. Accidential detachment of conductors considered: PFC Flying Leads and DC Fan Wiring.	Pass

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Clause	Requirement + Test	Result - Remark	Verdict

8.2.2	**RM TABLE: Connection to an external d.c. power sources**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	Not connected to an external DC supply source	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

8.3 d	**RM TABLE: Requirements of Type BF or CF Applied Parts**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
6.2	NA	No parts that are not applied parts that need to be treated as applied parts used	NA

8.4.2	**TABLE: Working Voltage / Power Measurement**					Pass
Test supply voltage/frequency (V/Hz) (1) :						
-	Measured values					-
Location From/To	Vrms	Vpk or Vdc	Peak-to-peak ripple (2)	Power W/VA	Energy (J)	Remarks
Supplementary Information: 1. The input supply voltage to the ME EQUIPMENT shall be the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4. 2. If the d.c. peak-to-peak ripple > 10%, waveform considered as a.c. See clause 8.4.2.2						

8.4.2 c	**RM TABLE: Accessible parts including applied parts**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No such parts.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

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**									Pass
Maximum allowable voltage (V) :								60		
Voltage measured (V)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
-	-	-	-	-	-	-	-	-	-	-
Maximum allowable stored charge when measured voltage exceeded 60 v (µc):								45		
Calculated stored charge (µc)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Supplementary information:										
Refer to report E341350 -A4, identified models that evaluated in 2nd edition										

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Clause	Requirement + Test	Result - Remark	Verdict

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

8.5.2.2	**RM TABLE: Type B applied parts**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No type B applied parts or parts needed to be treated as type B applied parts	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

8.5.2.3	**RM TABLE: PATIENT Leads**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No patient connections.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

8.5.5.1a	**TABLE: Defibrillation-proof applied parts - measurement of hazardous electrical energies**				N/A
Test Condition: Figs. 9 and 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 ohm load**			N/A
Test Voltage applied to	Measured Energy E1 (mJ)	Measured Energy E2 (mJ)	Energy E1 as % of E2 (%)	
Supplementary information: For compliance: E1 must at least 90% of E2 E1= Measured energy delivered to 100 ohm with ME Equipment connected; E2= Measured energy delivered to 100 ohm without ME equipment connected.				

8.6.3	**RM TABLE: Protective earthing of moving parts**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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

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Clause	Requirement + Test	Result - Remark	Verdict

8.7	**TABLE: Leakage current**				Pass
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)		-	-	Calculated values: before / after humidty	Maximum allowed values: 5 mA NC; 10 mA SFC
Model GTM21089-0903-T3		-	-	-	-
ER, NC, S1 = 1, S5 = N		264	60	63 / 62	For reference
ER, NC, S1 = 1, S5 = R		264	60	64 / 62	For reference
ER, SFC (Neutral Open), S1 = 0, S5 = N		264	60	123 / 124	For reference
ER, SFC (Neutral Open), S1 = 0, S5 = R		264	60	123 / 125	For reference
Model GTM21089-1824-W3		-	-	-	-
ER, NC, S1 = 1, S5 = N		264	60	115 / 118	For reference
ER, NC, S1 = 1, S5 = R		264	60	114 / 117	For reference
ER, SFC (Neutral Open), S1 = 0, S5 = N		264	60	225 / 231	For reference
ER, SFC (Neutral Open), S1 = 0, S5 = R		264	60	225 / 230	For reference
Fig. 14 - Touch Current (TC)		-	-	-	Maximum allowed values: 100 µA NC; 500 µA SFC
Model GTM21089-0903-T3		-	-	Calculated Max. Value ((A): before / after humidity	-
TC, NC, S1 = 1, S5 = N, S7/S10 = 1		264	60	3 / 7	Pass
TC, NC, S1 = 1, S5 = R, S7/S10 = 1		264	60	3 / 7	Pass
TC, SFC (Neutral Open), S1 = 0, S5 = N, S7/S10 = 1		264	60	4 / 10	Pass
TC, SFC (Neutral Open), S1 = 0, S5 = R,		264	60	4 / 10	Pass

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Clause	Requirement + Test	Result - Remark	Verdict

S7/S10 = 1				
TC, SFC (Ground Open), S1 = 1, S5 = N, S7/S10 = 0	264	60	7 / 11	Pass
TC, SFC (Ground Open), S1 = 1, S5 = R, S7/S10 = 0	264	60	7 / 11	Pass
TC, SFC (Neutral Open and Ground Open), S1 = 0, S5 = N, S7/S10 = 0	264	60	9 / 14	Pass
Enclosure to PE / Model GTM21089-1824-W3	-	-	-	-
TC, NC, S1 = 1, S5 = N, S7/S10 = 1	264	60	1 / 9	Pass
TC, NC, S1 = 1, S5 = R, S7/S10 = 1	264	60	1 / 9	Pass
TC, SFC (Neutral Open), S1 = 0, S5 = N, S7/S10 = 1	264	60	2 / 19	Pass
TC, SFC (Neutral Open), S1 = 0, S5 = R, S7/S10 = 1	264	60	2 / 20	Pass
TC, SFC (Ground Open), S1 = 1, S5 = N, S7/S10 = 0	264	60	4 / 11	Pass
TC, SFC (Ground Open), S1 = 1, S5 = R, S7 = 0	264	60	4 / 11	Pass
TC, SFC (Neutral Open and Ground Open), S1 = 0, S5 = N, S7/S10 = 0	264	60	9 / 17	Pass
TC, SFC (Neutral Open and Ground Open), S1 = 0, S5 = R, S7/S10 = 0	264	60	9 / 17	Pass
Fig. 15 - Patient Leakage Current (P)	-	-	-	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM)	-	-	-	Maximum allowed values: Type B: N/A Type BF AP: 5000 µA Type CF AP: 50 µA
Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	-	-	-	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current)
Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed	-	-	-	Maximum allowed values: Type B or BF AP: 500 µA Type CF: N/A
Fig. 19 - Patient Auxiliary Current	-	-	-	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
Fig. 15 and 20 - Total Patient Leakage Current with all AP of same type connected	-	-	-	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC

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Clause	Requirement + Test	Result - Remark	Verdict

together				(d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
Fig. 17 and 20 - Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	-	-	-	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
Fig. 16 and 20 - Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	-	-	-	Maximum allowed values: Type B: NA Type BF: 5000µA 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

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 and disinfection, and sterilization).

Conduct for Non-frequency-weighted Leakage Current measurements.

ER - Earth leakage current TC - Touch current P - Patient leakage current PA - Patient auxiliary current TP - Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device	A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition

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Clause	Requirement + Test	Result - Remark	Verdict

8.8.3	**TABLE: Dielectric strength test of solid insulating materials with safety function - MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)**				Pass
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	PEAK WORKING VOLTAGE (U) V peak	PEAK WORKING VOLTAGE (U) V d.c.	A.C. test voltages in V r.m.s1	Dielectric breakdown after 1 minute Yes/No2
Test both before humidity and After humidity	-	-	-	-	-
A) Prim to Sec	2MOOP	496V	-	3000Vrms	No
C) Prim to Functional Earth	2MOOP	354V	-	3000Vrms	No
B) Prim to Enclosure	2MOOP	354V	-	4000Vrms*	No
Test both before humidity and After humidity / One layer for test	-	-	-	-	-
Insulating Tape (All models except WF)	2MOOP	496V	-	3000Vrms	No
Insulating Tape (Model WF, Sample# 1677421-15)	2MOOP	496V	-	5000Vrms*	No
TIW (All Models)	2MOOP*1.5	496V	-	7500Vrms*	No
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).					
Insulation tape and TIW tested can refer to table: TEST SAMPLE IDENTIFICATION for details. Triple insulated wire: GREAT LEOFLON /TRW(B), TOTOKU /TIW-2, FURUKAWA /TEX-E are certified to UL2353 with sufficient test voltage evaluation, no need to additional tested.. Tests are for reference only. * Higher test voltage was used.					

8.8.4.1	**TABLE: Resistance to heat - Ball pressure test of thermoplastic parts**		Pass
	Allowed impression diameter (mm) :	=<2 mm	-
	Force (N) :	20	-

Part/material	Test temperature (°C)	Impression diameter (mm)
-	-	-
Supplementary information:		
Refer to report E341350 -A4, identified models that evaluated in 2nd edition		

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Clause	Requirement + Test	Result - Remark	Verdict

8.8.4.1	**RM TABLE: Mechanical strength and resistance to heat**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); (Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment.	Pass
4.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 4 (EL4))	Hazard of insulation failure identified.	Pass
4.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 4 (EL4))	Estimation of risk associated with insulation failure provided.	Pass
5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 4 (EL4))	Risk of insulation failure evaluated.	Pass
6.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Column "Risk Reduction Plan" (Risk No 2 (EL4))	Risk control measure identified, selected, and recorded in RMF: Material specification or Ball Pressure test. (Note: See remark for Clause 8.8.4.1 in the report body)	Pass
6.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Columns "Evaluation"; "Verification" (Risk No 2 (EL4))	Risk control measure implemented and evaluated, effectiveness verified, and results provided in RMF.	Pass
6.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.2 Residual risk evaluation" (Risk No 2 (EL4))	Residual risk analysed using defined criteria. All residual risk judged to be acceptable.	Pass
6.5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.3 Risk/benefit analysis"	No risk / benefit analysis conducted.	NA

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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 CLEARANCE1	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks
Supplementary information: Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE			

8.9.3.2	**TABLE: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts**		N/A
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per Cl. 5.7 except for 48 h only, Breakdown: Yes/No
Supplementary information: 1 T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.			

8.9.3.4	**TABLE: Thermal cycling tests on one sample of cemented joint (see 8.9.3.3)**		N/A
Test Sequence No.	Each test duration and temperature	Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)	Dielectric strength test after humidity preconditioning per Cl. 5.7 except for 48 h only, Breakdown: Yes/No
Supplementary information: 1 T1 = 10 °C above the maximum temperature of relevant part determined per 11.1.1, or 85 °C, the higher of the two. 10 °C not added to T1 when temperature measured by an embedded thermocouple. Used gradual transition from one temperature to another.			

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Clause	Requirement + Test	Result - Remark	Verdict

8.10.1	**RM TABLE: Fixing of components**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); (Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment.	Pass
4.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 3 (EL3))	Hazard of component movement identified.	Pass
4.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 3 (EL3))	Estimation of risk associated with component movement provided.	Pass
5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 3 (EL3))	Risk of component movement evaluated.	Pass
6.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Column "Risk Reduction Plan"	No risk reduction required.	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

8.10.2	**RM TABLE: Fixing of wiring**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 6 (EL6))	Hazard of movement of wiring terminations identified: PFC Chole L6 Flying Leads, Fan Wiring	Pass
4.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 6 (EL6))	Estimation of risk associated with movement of wiring terminations provided.	Pass
5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 6 (EL6))	Risk of movement of wiring terminations evaluated.	Pass
6.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Column "Risk Reduction Plan" (Risk No 4 (EL6))	Risk control measure identified, selected, and recorded in RMF. Glue and tubing employed.	Pass
6.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Columns "Evaluation"; "Verification" (Risk No 4 (EL6))	Risk control measure implemented and evaluated, effectiveness verified, and results provided in RMF.	Pass
6.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.2 Residual risk evaluation" (Risk No 4 (EL6))	Residual risk analysed using defined criteria. All residual risk judged to be acceptable.	Pass
6.5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.3 Risk/benefit analysis"	No risk / benefit analysis conducted.	NA

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Clause	Requirement + Test	Result - Remark	Verdict

8.10.5	**RM TABLE: Mechanical protection of wiring**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 6 (EL6))	Hazard of movement of wiring terminations (and thus wiring touching moving parts) identified: PFC Choke L6 Flying Lead and Fan Wiring.	Pass
4.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 6 (EL6))	Estimation of risk associated with movement of wiring terminations (and thus wiring touching moving parts) provided.	Pass
5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 6 (EL6))	Risk of movement of wiring terminations (and thus wiring touching moving parts) evaluated.	Pass
6.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Column "Risk Reduction Plan" (Risk No 4 (EL6))	Risk control measure identified, selected, and recorded in RMF. Glue and Tubing provided.	Pass
6.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Columns "Evaluation"; "Verification" (Risk No 4 (EL6))	Risk control measure implemented and evaluated, effectiveness verified, and results provided in RMF.	Pass
6.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.2 Residual risk evaluation" (Risk No 4 (EL6))	Residual risk analysed using defined criteria. All residual risk judged to be acceptable.	Pass
6.5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.3 Risk/benefit analysis"	No risk / benefit analysis conducted.	NA

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

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Clause	Requirement + Test	Result - Remark	Verdict

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

8.11.5	**RM TABLE: Mains fuses and over-current releases**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	Not Omitted.	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.2.1	**RM TABLE: HAZARDS associated with moving parts - General**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.2.2.2	**TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996)**				N/A
Part of body	Allowable adult gap1, mm	Measured adult gap, mm	Allowable children gap1, mm	Measured children gap, mm	
Supplementary information: 1 In general, gaps for adults used, except when the device is specifically designed for use with children, values for children applied.					

9.2.2.4.3	**RM TABLE: Movable guards**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

9.2.2.4.4	**RM TABLE: Protective measures**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.2.2.5 c)	**RM TABLE: Continuous activation**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.2.2.6	**RM TABLE: Speed of movement(s)**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

9.2.3.2	**RM TABLE: Over travel**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.2.4	**RM TABLE: Emergency stopping devices**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA
6.6			

9.2.5	**RM TABLE: Release of patient**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

9.3	**RM TABLE: Hazards associated with surfaces, corners and edges**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	No sharp edges or points	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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

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

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

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

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

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Clause	Requirement + Test	Result - Remark	Verdict

9.4.2.4.3	**RM TABLE: Movement over a threshold**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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

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

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

9.5.1	**RM TABLE: Protective means**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

9.6.1	**RM TABLE: Acoustic energy - General**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.6.2.2	**RM TABLE: Infrasound and ultrasound energy**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.7.2	**RM TABLE: Pneumatic and hydraulic parts**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.7.4	**RM TABLE: Pressure rating of ME equipment parts**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

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

9.7.6	**RM TABLE: Pressure-control device**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.7.7	**RM TABLE: Pressure-relief device**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.8.1	**RM TABLE: Hazards associated with support systems - General**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

9.8.2	**RM TABLE: Tensile safety factor**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.8.3.1	**RM TABLE: Strength of patient or operator support or suspension systems - General**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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

9.8.3.2a, b	**RM TABLE: Static forces due to loading from persons**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

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

9.8.4.1	**RM TABLE: Systems with mechanical protective devices - General**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.8.4.3	**RM TABLE: Mechanical protective device for single activation**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

9.8.5	**RM TABLE: Systems without mechanical protective devices**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

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

10.1.2	**RM TABLE: ME equipment intended to produce diagnostic or therapeutic X-radiation**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

10.2	**RM TABLE: Alpha, beta, gamma, neutron & other particle radiation**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

10.3	**RM TABLE: Microwave radiation**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

10.5	**RM TABLE: Other visible electromagnetic radiation**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

10.6	**RM TABLE: RISK associated with infrared radiation other than emitted by lasers and LEDs**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

10.7	**RM TABLE: RISK associated with ultraviolet radiation other than emitted by lasers and LEDs**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

11.1.1	**TABLE: Excessive temperatures in ME EQUIPMENT**					Pass
Model No. :		-	-	-	-	-
Test ambient (°C) :		-	-	-	-	-
Test supply voltage/frequency (V/Hz)(4) :		-	-	-	-	-
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	
-	-	-	-	-	-	

Supplementary information:
1 Maximum allowable temperature on surfaces of test corner is 90 °C
2 Max temperature determined in accordance with 11.1.3e)
3 When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
4 Supply voltage:
- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of
the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.
- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum
RATED voltage and at 90 % of the minimum RATED voltage.
5 APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

Refer to report E341350 -A4, identified models that evaluated in 2nd edition

11.1.1	**RM TABLE: Maximum temperature during normal use (Table 23 or 24)**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	Table 23 limits apply for accessible part	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

11.1.2.1	**RM TABLE: Applied parts intended to supply heat to patient**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

11.1.2.2	**RM TABLE: Applied parts not intended to supply heat to patient**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

11.1.3	**TABLE: Temperature of windings by change-of-resistance method**						N/A
Temperature T of winding:	t1 (°C)	R1 (ohm)	t2 (°C)	R2 (ohm)	T (°C)	Allowed Tmax(°C)	Insulation class
Supplementary information: Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur.							

11.1.3	**RM TABLE: Measurements**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

11.2.2.1	**RM TABLE: Risk of fire in an oxygen rich environment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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

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Clause	Requirement + Test	Result - Remark	Verdict

11.3	**RM TABLE: Constructional requirements for fire enclosures of ME equipment**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0);(Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment.	Pass
4.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 5 (H2))	Hazard of fire enclosure failure identified.	Pass
4.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 5 (H2))	Estimation of risk associated with fire enclosure failure provided.	Pass
5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 5 (H2))	Risk of fire enclosure failure evaluated.	Pass
6.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Column "Risk Reduction Plan" (Risk No 5 (H2))	Risk control measure identified, selected, and recorded in RMF.	Pass
6.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Columns "Evaluation"; "Verification" (Risk No 5 (H2))	Risk control measure implemented and evaluated, effectiveness verified, and results provided in RMF.	Pass
6.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0);Sections "8.2 Residual risk evaluation" (Risk No 5 (H2))	Residual risk analysed using defined criteria. All residual risk judged to be acceptable.	Pass
6.5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0);Sections "8.3 Risk/benefit analysis"	No risk / benefit analysis conducted.	NA

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Clause	Requirement + Test	Result - Remark	Verdict

11.5	**RM TABLE: ME equipment and ME systems intended for use in conjunction with flammable agents**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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:				

11.6.2	**RM TABLE: Overflow in ME equipment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

11.6.3	**RM TABLE: Spillage on ME equipment and ME system**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

11.6.5	**RM TABLE: Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

11.6.6	**RM TABLE: Cleaning and disinfection of ME equipment and ME systems**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

11.6.7	**RM TABLE: Sterilization of ME equipment and ME systems**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

11.6.8	**RM TABLE: Compatibility with substances used**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

12.1	**RM TABLE: Accuracy of controls and equipment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

12.3	**RM TABLE: Alarm systems**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

12.4.1	**RM TABLE: Intentional exceeding of safety limits**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

12.4.2	**RM TABLE: Indication of parameters relevant to safety**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

12.4.3	**RM TABLE: Accidental selection of excessive output values**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

12.4.4	**RM TABLE: Incorrect output**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

12.4.5.2	**RM TABLE: Diagnostic X-ray equipment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

12.4.5.3	**RM TABLE: Radiotherapy equipment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

12.4.5.4	**RM TABLE: Other ME equipment producing diagnostic or therapeutic radiation**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

12.4.6	**RM TABLE: Diagnostic or therapeutic acoustic pressure**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

13.1.2	**TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances**			N/A
Power dissipated less than (W)		15		
Energy dissipated less than (J)		900		
Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks
Supplementary information:				

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Clause	Requirement + Test	Result - Remark	Verdict

13.2	**TABLE: Single Fault Conditions in accordance with 13.2.2 to 13.2.13, inclusive**		Pass
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	Hazardous Situation (Yes/No)
-	Electrical SINGLE FAULT CONDITIONS per Clause 8.1:	-	-
-	Refer to report E341350 -A4, identified models that evaluated in 2nd edition	-	-
13.2.3	Overheating of transformers per Clause 15.5:	-	-
-	Refer to report E341350 -A4, identified models that evaluated in 2nd edition	-	-
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	-	-
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	-	-
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	-	-
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	-	-
13.2.8	Locking of moving parts - Only one part locked at a time - Also see 13.2.10 below:	-	-
13.2.9	Interruption and short circuiting of motor capacitors - Motor capacitors short & open circuited 1 - Also see 13.10	-	-
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:	-	-
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	-	-
-	Refer to report E341350 -A4, identified models that evaluated in 2nd edition	-	-
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	-	-
	See 9 and 15.3		
Supplementary information: 1 Test with short-circuited capacitor not performed when motor provided with a capacitor complying with			

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Clause	Requirement + Test	Result - Remark	Verdict

IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.
Refer to report E341350 -A4, identified models that evaluated in 2nd edition

13.2.6	**RM TABLE: Leakage of liquid**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

14.1	**RM TABLE: Programmable electrical medical systems - General**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No PEMS or PESS	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

14.6.1	**RM TABLE: Identification of known and foreseeable hazards**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.3	NA	NA	NA

14.6.2	**RM TABLE: Risk control**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
6.1	NA	NA	NA

14.7	**RM TABLE: Requirement specification**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
6.3	NA	NA	NA

14.8	**RM TABLE: Architecture**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
6.3	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

14.9	**RM TABLE: Design and Implementation**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
6.2	NA	NA	NA
6.3	NA	NA	NA

14.10	**RM TABLE: Verification**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
6.3	NA	NA	NA

14.11	**RM TABLE: PEMS validation**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
6.3	NA	NA	NA

14.13	**RM TABLE: Connection of PEMS by NETWORK/DATA COUPLING to other equipment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA

15.1	**RM TABLE: Construction of ME equipment - Arrangements of controls and indicators of ME equipment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

15.3	**TABLE: Mechanical Strength tests 1)**			Pass
Clause	Name of Test	Test conditions	Observed results/Remarks	
15.3.2	Force test	Force 15.3.2: 250N+/-10N, 5s	Enclosure top / bottom / side: no cracking , no live parts become accessible	
Supplementary information: 1)As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).				
Test on all enclosure sources				

15.3.2	**RM TABLE: Push test**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	Test applies with no damage	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

15.3.3	**RM TABLE: Impact test**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	Test applies with no damage	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

15.3.4.2	**RM TABLE: Portable ME equipment**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	Test applies with no damage	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

15.3.5	**RM TABLE: Rough handling test**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

15.4.1	**RM TABLE: Construction of connectors**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	1089 family provides standard appliance inlet for connection; 1096 familiy is component for building-in. To be determined in End Product Evaluation.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

15.4.2.1 a	**RM TABLE: THERMAL CUT-OUTS and OVER-CURRENT RELEASES**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

15.4.2.1 b	**RM TABLE: THERMAL CUT-OUTS with a safety function**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

15.4.2.1 c	**RM TABLE: Independent non-SELF-RESETTING THERMAL CUT-OUT**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

15.4.2.1 d	**RM TABLE: Loss of function of ME EQUIPMENT**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

15.4.2.1 h	**RM TABLE: ME EQUIPMENT with tubular heating elements**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

15.4.3.1	**RM TABLE: Housing**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

15.4.3.2	**RM TABLE: Connection**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

15.4.3.3	**RM TABLE: Protection against overcharging**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

15.4.3.4	**RM TABLE: Lithium batteries**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

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Clause	Requirement + Test	Result - Remark	Verdict

15.4.3.5	**RM TABLE: Excessive current and voltage protection**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

15.4.4	**RM TABLE: Indicators**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

15.4.5	**RM TABLE: Pre-set controls**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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)					

15.4.7.3 b	**RM TABLE: Entry of liquids**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

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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**						Pass
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: 1 Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION							
Refer to report E341350 -A4, identified models that evaluated in 2nd edition							

15.5.1.3	**TABLE: transformer overload test - conducted only when protective device under short-circuit test operated**					Pass
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 & 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.						
Refer to report E341350 -A4, identified models that evaluated in 2nd edition						

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15.5.2	**TABLE: Transformer dielectric strength after humidity preconditioning of 5.7**				N/A
Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
Supplementary information: Tests conducted under the conditions of 11.1, in ME EQUIPMENT or under simulated conditions on the bench. See Clause 15.5.2 for test parameters & other details					

16.1	**RM TABLE: General requirements for ME Systems**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

16.6.1	**TABLE: Leakage Currents in ME System _ Touch Current Measurements**				N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (µA)	Measured TOUCH CURRENT in NORMAL CONDITION (µA)	Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)	Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)	
Supplementary information:					

16.9.1	**RM TABLE: Connection terminals and connectors**		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	NA	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA
6.2	NA	NA	NA
6.3	NA	NA	NA
6.4	NA	NA	NA
6.5	NA	NA	NA

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17	**RM TABLE: Electromagnetic compatibility of ME equipment and ME systems**		Pass
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); (Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment.	Pass
4.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0);Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 9 (M1))	Hazard of EMI identified.	Pass
4.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 9 (M1))	Estimation of risk associated with EMI provided.	Pass
5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0);Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 9 (M1))	Risk of EMI evaluated.	Pass
6.2	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Column "Risk Reduction Plan" (Risk No 6 (M1))	Risk control measure identified, selected, and recorded in RMF.	Pass
6.3	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0); Sections "8.1 Risk reduction analysis" - Columns "Evaluation"; "Verification" (Risk No 6 (M1))	Risk control measure implemented and evaluated, effectiveness verified, and results provided in RMF.	Pass
6.4	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0);Sections "8.2 Residual risk evaluation" (Risk No 6 (M1))	Residual risk analysed using defined criteria. All residual risk judged to be acceptable.	Pass
6.5	Risk Management Report (GT-RM2013-009, Issued: 2013-11-11, Rev A.0);Sections "8.3 Risk/benefit analysis"	No risk / benefit analysis conducted.	NA
SP	**TABLE: Additional or special tests conducted**		Pass
Clause and Name of Test	Test type and condition	Observed results	

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HUMIDITY PRECONDITIONING TREATMENT (Clause 5.7)	Humidity preconditioning treatment: 95%RH, 25 deg. C, 48 hours Complete Unit, Model GTM21089-1824-W3	Pre-chamber: 25°C Chamber: 25°, 95% RH, 48 h Duration. There was no dielectric breakdown. See table 8.8.3 for detail.
HUMIDITY PRECONDITIONING TREATMENT (Clause 5.7)	Humidity preconditioning treatment: 95%RH, 25 deg. C, 48 hours Complete Unit, Model GTM21089-0903-T3	Pre-chamber: 25°C Chamber: 25°, 95% RH, 48 h Duration. There was no dielectric breakdown. See table 8.8.3 for detail.
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	Model GTM21089-1824-W3 as representative	Vrms / Vpk / Vpk-pk
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 1 to Pin 6	211 / 340 / 364
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 1 to Pin 8	214 / 416 / 464
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 2 to Pin 6	221 / 352 / 368
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 2 to Pin 8	223 / 380 / 468
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 3 to Pin 6	280 / 496 / 836
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 3 to Pin 8	256 / 464 / 752
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 4 to Pin 6	220 / 360 / 384
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 4 to Pin 8	226 / 388 / 492
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	CY1 Pri Pin to Sec Pin	221 / 356 / 368
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U1 Pin 1 to Pin 3	239 / 380 / 368
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U1 Pin 1 to Pin 4	232 / 372 / 376
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U1 Pin 2 to Pin 3	238 / 376 / 368
WORKING VOLTAGE	U1 Pin 2 to Pin 4	231 / 368 / 376

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MEASUREMENT (Clause 8.5.4)		
Supplementary information:		
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