

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:	Switching Power Supply, Built-In AC/DC
Model:	GTM9200P Series
Rating:	Input: Voltage: 100-240 Vac, Frequency: 50-60 Hz Rated Current for 350 W units: 5.0 A max (except for GTM9200P2313.3 which is rated at 4.0 A) Rated Current for 200 W units: 3.2 A max (except for Models GTM9200P1323.3 which is rated 2.5 A) Note: See the Model Differences section of report for Output ratings.
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.

Issue Date: 2013-11-20

Page 2 of 20

Report Reference #

E341350-A22-UL

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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 Model Series GTM9200 is a switch mode power supply series for building-in. The units are provided with an isolation transformer and associated circuitry mounted on a Printed Circuit Board. The units are provided with input and output connector headers, which mate to connectors within the end-use equipment.

Model Differences

Differences within the GTM9200 family are limited to minor component changes to determine specific output wattage, voltage and current parameters. The 9200 Series is the family model designation which is represented by the following generic nomenclature:

GT(M)9200P1853.3-X.X TO 35048-X.X where:

GT - designates GlobTek Series;

M - designates Medical Grade models with IEC 60601 safety approvals;

9200 - Family Designator

P - power factor correction;

1323.3 TO 20048 - 132W, 3.3V to 200W, 48V representing the range of Output power / Output Voltage respectively OR

1853.3 to 35048 - 185W, 3.3V to 350W, 48V representing the range of Output power / Output Voltage respectively;

X.X : Output Voltage deviation from standard model by subtracting X.X volts from standard output voltage in 0.1 volt increments;

May be followed by:

R - representing IEC input receptacle and output metal connector on board

S - representing input header and output metal connector on board

HIOXX - representing input and output wire harness. Where XXX may be between 000 and 999 (max. length for input is 100 mm and 200 mm for output)

HORXX - representing IEC input receptacle and output wire harness. Where XXX may be between 000 and 999 (max. length is 200 mm for output)

HOXXX - representing input header on board and output wire harness. Where XXX may be between 000 and 999 (max. length is 200 mm for output)

HIXXX - representing input wire harness and output metal terminal on board. Where XXX may be between 000 and 999 (max. length for input is 100 mm)

Standard Models:

	Vdc and A
GTM9200P1323.3-X.X-HIOXXX or -HORXXX or -HOXXX	3.3 40
GTM9200P2005-X.X-HIOXXX or -HORXXX or -HOXXX	5.0 40
GTM9200P2007.5-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX	7.5 26.67
GTM9200P2009-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	9.0 22.22
GTM9200P2012-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	12.0 16.67
GTM9200P2015-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	15.0 13.33
GTM9200P2018-X.X -S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	18.0 11.11
GTM9200P2024-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	24.0 8.33
GTM9200P20036-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	36.0 5.55
GTM9200P20048-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	48.0 4.17
GTM9200P1853.3-X.X- [HIOXXX or HORXXX or HOXXX]	3.3 56
GTM9200P2313.3-X.X--S or -R or -HIXXX	3.3 70
GTM9200P3505-X.X-S or -R or -HIXXX	5.0 70.
GTM9200P3507.5-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	7.5 46.67
GTM9200P3509-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	9.0 38.89
GTM9200P35012-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	12.0 29.17

GTM9200P35015-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	15.0	23.33
GTM9200P35018-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	18.0	19.44
GTM9200P35024-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	24.0	14.58
GTM9200P35036-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	36.0	9.72
GTM9200P35048-X.X-S or -R or -HIOXXX or -HORXXX or -HOXXX or -HIXXX	48.0	7.29

Note - This nomenclature only covers models employing output ratings equivalent to or less than those listed in Standard Models table.

Technical Considerations

- Classification of installation and use : For Building-In
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : None
- Mode of operation : Continuous
- Supply connection : To be determined in end product evaluation.
- Accessories and detachable parts included : None
- Other options include : (refer to Model Differences section)
- 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 60601-1-2), Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is:: Ordinary (IPX0)
- 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

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:

- This Power Supply was evaluated as 2MOOP between Primary and Secondary for a working voltage of 252 Vrms (564 Vpk); and 1MOOP between Primary and Protective Earth for a working voltage of 250 Vrms (364 Vpk).
- The Power Supply Transformer T1 incorporates a Class B (130°C) Insulation System. The temperature of the part must be verified in End Product Testing.
- When installed in an end product, consideration must be given to the following: 8.6.4 a - Impedance and Current Carrying Capability, 8.7 - Leakage Current Tests, 8.8.3 - Dielectric Voltage Withstand, 11 - Temperature
- ME Equipment is component for building-in. Applicability of the following is to be determined in End Product Evaluation: 5.9 - Accessibility, 7 - Identification marking and Documents, 8.4.2 - Accessible Parts Including Applied Parts, 8.6 - Protective Earthing, 8.8.4.1 - Ball Pressure Testing, 8.11.1 - Isolation from Supply Mains, 8.11.3 - Power Supply Cords, 9 - Protection against mechanical hazards, 11.3 - Fire Enclosure, 11.8 - Interruption of power supply, 15.3 - Mechanical Strength,

15.4.1 - Construction of Connectors, 15.4.4 - Indicators

- Temperature Test was conducted without Test Corner. End product to determine the acceptability of , risk in conjunction to temperature testing without test corner as part of the power supply.
- Clearance distance was evaluated for operating altitude up to 3000m above sea level.
- The series was submitted and evaluated for use at the maximum ambient temperature (Tma) permitted by , the manufacturer's specification of: 60°C for the 132W - 200 W Model GTM9200 Series at 100% load and 70°C for 185W - 350W Model GTM-9200 Series at 100% load. See Enclosure 7-01 and 7-02 for derating curves.
- The power supplies utilize both input/output connectors and output terminal blocks. The input/output connectors have not been evaluated for field connections and are only intended for connection to mating connectors of internal wiring inside the end-use product.
- ME Equipment has been evaluated as Class I. A reliable connection to Protective Earth complying with Clause 8.6 must be provided in the end installation.
- The maximum investigated branch circuit rating is: 20 A
- This component power supply employs micro type fuses which do not comply with the end product fuse requirement of Clause 8.11.5. The end product must provide acceptable fuses and be re-evaluated to Clause 8.11.5. Overcurrent releases of adequate breaking capacity must be employed in the end product.

Additional Information


This power supply has been previously evaluated in E341350-A14-UL to UL 60601-1: 1st ed, 2006-04-26 (includes National Differences for USA), and CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada).



The tests conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008) as stated under Summary of Testing above. Any testing which has been required to address items not covered in the previous CB evaluation have been identified as such in the Summary of Testing above.

Additional Standards

The product fulfills the requirements of: 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

Markings and instructions

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

Protective earth ground	
Operating Instructions	
Rated Output	Rated Output Voltage, Rated Output Current
Special Instructions to UL Representative N/A	

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
All Models	Not Exempt	Not Exempt	Exempt (No MOPP Provided)
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			
No Exemptions.			
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
Printed Circuit Board	Interchangeable	Interchangeable	Min V-0, rated 130°C min.	ZPMV2, ZPMV8	UL R/C, cUL or CSA
Layout of Main Power Board	--	--	Rev. D. Layout as per Enclosure 5-01.	--	--
Layout of Control Board	--	--	Rev. C. Layout as per Enclosure 5-02	--	--
Input Connector for -S and -HOXXX versions	Joint Tech Electronic Industrial Co Ltd	A3960WV05P	250V min, 5A min, V-2 min, 3.96mm. Second and fourth pins removed.	ECBT2, ECBT8 (E179987)	UL R/C, cUL or CSA
(Alternate) Input Connector for -S and -HOXXX versions	Interchangeable	Interchangeable	250V min, 5A min, V-2 min, 3.96mm. Second and fourth pins removed.	ECBT2, ECBT8	UL R/C, cUL or CSA
Input Connector for -HIXXX and -HIOXXX versions [Optional]	Joint Tech Electronic Industrial Co Ltd	A3960H-5P	250V min, 5A min, V-2 min, 3.96mm. Second and fourth pins removed.	ECBT2, ECBT8 (E179987)	UL R/C, cUL or CSA
(Alternate) Input Connector for -HIXXX and -HIOXXX versions [Optional]	Interchangeable	Interchangeable	250V min, 5A min, V-2 min, 3.96mm. Second and fourth pins removed.	ECBT2, ECBT8	UL R/C, cUL or CSA
Appliance Inlet for -R and -HORXXX versions	Inalways	0707-1	250V min, 10A min, 60 degree C min, V-0.	AXUT2, AXUT8 (E94191)	UL R/C, cUL R/C
(Alternate) Appliance Inlet for -R and -HORXXX versions	Rich Bay Co Ltd	R-30190	250V min, 10A min, 60 degree C min, V-0.	AXUT2, AXUT8 (E184638)	UL R/C, cUL R/C
(Alternate) Appliance Inlet for -R and -HORXXX versions	Zhejiang Leci Electronics Co Ltd	DB-14	250V min, 10A min, 60 degree C min, V-0.	AXUT2, AXUT8 (E302229)	UL R/C, cUL R/C
(Alternate) Appliance Inlet for -R and -HORXXX versions	Tecx-Unions Technology Corp	TU-301	250V min, 10A min, 60 degree C min, V-0.	AXUT2, AXUT8 (E220004)	UL R/C, cUL R/C
Output Connector for -HIXXX, HOXXX and HIOXXX versions	Joint Tech Electronic Industrial Co Ltd	C4255HF-2X8P	250V min, 7A min, V-2 min, 4.20mm.	ECBT2, ECBT8 (E179987)	UL R/C, cUL or CSA

Object/part or Description	Manufacturer/trademark	type/model	technical data	CCN	Marks of Conformity
[Optional]					
(Alternate) Output Connector for -HIXXX, HOXXX and HIOXXX versions [Optional]	Interchangeable	Interchangeable	250V min, 7A min, V-2 min, 4.20mm.	ECBT2, ECBT8	UL R/C, cUL or CSA
Input Wiring Harness for HIOXX and HIXXX versions	Interchangeable	Interchangeable	Rated 85 degree C min, 18 AWG min. Protective Earth Conductor coloured Gree/Yellow.	AVLV2, AVLV8	UL R/C, cUL R/C or CSA
Fuse (F1, F2)	Littelfuse Wickmann Werke	372 (TR5) Series	250 V, Time Lag, Micro-type, Low breaking current. For 132W units: 3.15 A For 200W & 185W units: 4 A For 231W units: 5A For 350W & 280W units: 6.3 A	JDYX2, JDYX8 (E67006)	UL R/C, cUL R/C
(Alternate) Fuse (F1, F2)	Bel Fuse Inc	MRT Series	250 V, Time Lag, Micro-type, Low breaking current. For 132W units: 3.15 A For 200W & 185W units: 4 A For 231W units: 5A For 350W & 280W units: 6.3 A [Fuse deemed an acceptable alternate based upon I-t curve found in Enclosure 7]	JDYX2, JDYX8 (E20624)	UL R/C, cUL R/C
(Alternate) Fuse (F1, F2)	Conquer Electronics Co Ltd	MET Series	250 V, Time Lag, Micro-type, Low breaking current. For 132W units: 3.2 A For 200W & 185W units: 4 A For 231W units: 5A For 350W & 280W units: 6.3 A [Fuse deemed an acceptable alternate based upon I-t curve found in Enclosure 7]	JDYX2, (E82636)	UL R/C, CSA
(Alternate) Fuse (F1, F2)	Walter Electronic Co Ltd	2000 Series	250 V, Time Lag, Micro-type, Low breaking current. For 132W units: 3.2 A For 200W & 185W units: 4 A For 231W units: 5A For 350W & 280W units: 6.3 A [Fuse deemed an acceptable alternate based upon	JDYX2, JDYX8 (E56092)	UL R/C, cUL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
			I-t curve found in Enclosure 7]		
MOV (VDR1) [Optional]	Thinking Electronic Industrial Co Ltd	TVR07471, TVR10471, TVR14471	300 Vac, 125 degree C	VZCA2, VZCA8 (E314979)	UL R/C, cUL R/C
(Alternate) MOV (VDR1) [Optional]	Littelfuse Inc	V07E300	300 Vac, 85 degree C	VZCA2, VZCA8 (E320116)	UL R/C, cUL R/C
(Alternate) MOV (VDR1) [Optional]	Panasonic Corporation Of North America	V7 Series V7471U (ERZV-07D471)	300 Vac, 85 degree C	VZCA2, VZCA8 (E321499)	UL R/C, cUL R/C
(Alternate) MOV (VDR1) [Optional]	Joyin Co Ltd	7N471K, 10N471K, 14N471K	300 Vac, 85 degree C	VZCA2, VZCA8 (E325508)	UL R/C, cUL R/C
(Alternate) MOV (VDR1) [Optional]	Centra Science Corp	CNR 07D 471 K, CNR 10D 471 K, CNR 14D 471 K	300 Vac, 85 degree C	VZCA2, VZCA8 (E316325)	UL R/C, cUL R/C
(Alternate) MOV (VDR1) [Optional]	Success Electronics Co Ltd	SVR07D 471K, SVR10D 471K, SVR14D 471K	300 Vac, 85 degree C	VZCA2, VZCA8 (E330256)	UL R/C, cUL R/C
(Alternate) MOV (VDR1) [Optional]	Ceramate Technical Co Ltd	GNR07D471K, GNR10D471K, GNR14D471K	300 Vac, 85 degree C	VZCA2, VZCA8 (E315429)	UL R/C, cUL R/C
(Alternate) MOV (VDR1) [Optional]	Brightking (Shenzhen) Co Ltd	471KD07, 471KD10, 471KD14	300 Vac, 85 degree C	VZCA2, VZCA8 (E327997)	UL R/C, cUL R/C
(Alternate) MOV (VDR1) [Optional]	Walsin Technology Corp	VZ07D471K, VZ10D471K, VZ14D471K	300 Vac, 85 degree C	VZCA2, VZCA8 (E309297)	UL R/C, cUL R/C
(Alternate) MOV (VDR1) [Optional]	Lien Shun Electronics Co Ltd	07D471K, 10D471K, 14D471K	300 Vac, 85 degree C	VZCA2, VZCA8 (E315524)	UL R/C, cUL R/C
(Alternate) MOV (VDR1) [Optional]	Hongzhi Enterprises Ltd	HEL07D471K, HEL10D471K,	300 Vac, 85 degree C	VZCA2, VZCA8 (E324904)	UL R/C, cUL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
		HEL14D471K			
(Alternate) MOV (VDR1) [Optional]	Guangxi New Future Information Industry Co Ltd	07D471K, 10D471K, 14D471K	300 Vac, 85 degree C	VZCA2, VZCA8 (E323753)	UL R/C, cUL R/C
Line to Line Capacitor (CX1) [Optional]	Cheng Tung Industrial Co Ltd	CTX	250V min, 0.33uF maximum, Class X1 or X2, 110 degree C.	FOWX2, FOWX8 (E193049)	UL R/C, cUL R/C
Line to Line Capacitor (CX1) [Optional]	Ultra Tech Xiphi Enterprise Co Ltd	HQX	250V min, 0.33uF maximum, Class X1 or X2, 110 degree C.	FOWX2, FOWX8 (E183780)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX1) [Optional]	Okaya Electric Industries Co Ltd	LE	250V min, 0.33uF maximum, Class X1 or X2, 100 degree C.	FOWX2, FOWX8 (E47474)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX1) [Optional]	Dain	MPX, MEX, NPX	250V min, 0.33uF maximum, Class X1 or X2, 100 degree C.	FOWX2, FOWX8 (E147776)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX1) [Optional]	Jiangsu Xinghua Huayu Electronics Co Ltd	MPX	250V min, 0.33uF maximum, X2, 100 degree C.	FOKY2, FOKY8 (E311166)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX1) [Optional]	Hongzhi Enterprises Ltd	X2	250V min, 0.33uF maximum, X2, 100 degree C.	FOWX2, FOWX8 (E192572)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX1) [Optional]	Sinhua Electronics (Huzhou) Co Ltd	MPX	250V min, 0.33uF maximum, Class X1 or X2, 110 degree C.	FOWX2, FOWX8 (E237560)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX1) [Optional]	Shantou High-New Technology Developmnt Zone Songtian Enterprise Co Ltd	MPX	250V min, 0.33uF maximum, Class X1 or X2, 110 degree C.	FOWX2, FOWX8 (E208107)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX1) [Optional]	Tenta Electric Industrial Co Ltd	MEX, MEY, MEX/Y	250V min, 0.33uF maximum, Class X1 or X2, 100 degree C.	FOWX2, FOWX8 (E222911)	UL R/C, cUL R/C
(Alternate) Line to Line	Carli Electronics Co	MPX	250V min, 0.33uF maximum, Class X1 or X2, 100	FOWX2, FOWX8	UL R/C, cUL

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
Capacitor (CX1) [Optional]	Ltd		degree C.	(E120045)	R/C
(Alternate) Line to Line Capacitor (CX1) [Optional]	Interchangeable	Interchangeable	250V min, 0.33uF maximum, Class X1 or X2, 85 degree C min. Must be evaluated to UL60384-14, CSA E60384-1, CSA E60384-14, IEC 60384-14.	FOWX2, FOWX8	UL R/C, cUL R/C or CSA
Line to Line Capacitor (CX2, CX3) [Optional]	Cheng Tung Industrial Co Ltd	CTX	250V min, 0.47uF maximum, Class X1 or X2, 110 degree C.	FOWX2, FOWX8 (E193049)	UL R/C, cUL R/C
Line to Line Capacitor (CX2, CX3) [Optional]	Ultra Tech Xiphi Enterprise Co Ltd	HQX	250V min, 0.47uF maximum, Class X1 or X2, 110 degree C.	FOWX2, FOWX8 (E183780)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX2, CX3) [Optional]	Okaya Electric Industries Co Ltd	LE, RE	250V min, 0.47uF maximum, Class X1 or X2, 100 degree C.	FOWX2, FOWX8 (E47474)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX2, CX3) [Optional]	Dain Electronics Co Ltd	MPX, MEX, NPX	250V min, 0.47uF maximum, Class X1 or X2, 100 degree C.	FOWX2, FOWX8 (E147776)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX2, CX3) [Optional]	Jiangsu Xinghua Huayu Electronics Co Ltd	MPX	250V min, 0.47uF maximum, Class X1 or X2, 90 degree C.	FOKY2, FOKY8 (E311166)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX2, CX3) [Optional]	Hongzhi Enterprises Ltd	X2	250V min, 0.47uF maximum, Class X1 or X2, 85 degree C.	FOWX2, FOWX8 (E192572)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX2, CX3) [Optional]	Sinhua Electronics (Huzhou) Co Ltd	MPX	250V min, 0.47uF maximum, Class X1 or X2, 110 degree C.	FOWX2, FOWX8 (E237560)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX2, CX3) [Optional]	Shantou High-New Technology Developmnt Zone Songtian Enterprise Co Ltd	MPX	250V min, 0.47uF maximum, Class X1 or X2, 110 degree C.	FOWX2, FOWX8 (E208107)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX2, CX3) [Optional]	Tenta Electric Industrial Co Ltd	MEX, MEY, MEX/Y	250V min, 0.47uF maximum, Class X1 or X2, 100 degree C.	FOWX2, FOWX8 (E222911)	UL R/C, cUL R/C

Object/part or Description	Manufacturer/trademark	type/model	technical data	CCN	Marks of Conformity
(Alternate) Line to Line Capacitor (CX2, CX3) [Optional]	Carli Electronics Co Ltd	MPX	250V min, 0.47uF maximum, Class X1 or X2, 100 degree C.	FOWX2, FOWX8 (E120045)	UL R/C, cUL R/C
(Alternate) Line to Line Capacitor (CX2, CX3) [Optional]	Interchangeable	Interchangeable	250V min, 0.47uF maximum, Class X1 or X2, 85 degree C min.	FOWX2, FOWX8	UL R/C, cUL R/C or CSA
Line to Earth Capacitor (CY1, CY2) [Optional]	Walsin Technology Corp	AC, AH	250V min, 1.5 nF maximum, Class Y1 or Y2, 125 degree C.	FOWX2, FOWX8 (E146544)	UL R/C, cUL R/C
(Alternate) Line to Earth Capacitor (CY1, CY2) [Optional]	Murata Mfg Co Ltd	KH, KX	250V min, 1.5 nF maximum, Class Y1 or Y2, 125 degree C.	FOWX2 (E37921)	UL R/C, CSA
(Alternate) Line to Earth Capacitor (CY1, CY2) [Optional]	TDK-EPC Corporation	CD, CS	250V min, 1.5 nF maximum, Class Y1 or Y2, 85 degree C min.	FOWX2 (E37861)	UL R/C, CSA
(Alternate) Line to Earth Capacitor (CY1, CY2) [Optional]	Success Electronics Co Ltd	SE, SB, SF	250V min, 1.5 nF maximum, Class Y1 or Y2, 125 degree C.	FOWX2 (E114280)	UL R/C, CSA
(Alternate) Line to Earth Capacitor (CY1, CY2) [Optional]	Jya-Nay Co. Ltd	JY, JN	250V min, 1.5 nF maximum, Class Y1 or Y2, 125 degree C.	FOWX2, FOWX8 (E201384)	UL R/C, cUL R/C
(Alternate) Line to Earth Capacitor (CY1, CY2) [Optional]	Haohua Electronic Co	CT 7	250V min, 1.5 nF maximum, Class Y1 or Y2, 125 degree C.	FOWX2, FOWX8 (E233106)	UL R/C, cUL R/C
(Alternate) Line to Earth Capacitor (CY1, CY2) [Optional]	Kunshan Wansheng Electronics Co Ltd	CT7	250V min, 1.5 nF maximum, Class Y1 or Y2, 125 degree C.	FOWX2, FOWX8 (E249006)	UL R/C, cUL R/C
(Alternate) Line to Earth Capacitor (CY1, CY2) [Optional]	Shantou High-New Technology Developmnt Zone Songtian Enterprise Co Ltd	CD	250V min, 1.5 nF maximum, Class Y1 or Y2, 125 degree C.	FOWX2, FOWX8 (E208107)	UL R/C, cUL R/C
(Alternate) Line to Earth Capacitor (CY1, CY2)	Zhi Wei Electronics Co Ltd	DJ, DY	250V min, 1.5 nF maximum, Class Y1 or Y2, 105 degree C.	FOWX2, (E330260)	UL R/C, cUL R/C

Object/part or Description	Manufacturer/trademark	type/model	technical data	CCN	Marks of Conformity
[Optional]					
(Alternate) Line to Earth Capacitor (CY1, CY2) [Optional]	Jerro Electronics Corp	JX, JL	250V min, 1.5 nF maximum, Class Y1 or Y2, 125 degree C.	FOWX2, FOWX8 (E333001)	UL R/C, cUL R/C
(Alternate) Line to Earth Capacitor (CY1, CY2) [Optional]	Hongzhi Enterprises Ltd	Y	250V min, 1.5 nF maximum, Class Y1 or Y2, 85 degree C.	FOWX2, FOWX8 (E192572)	UL R/C, cUL R/C
Capacitor, bridging (CY6)	Walsin Technology Corp	AH	250V min, 1nF maximum, Class Y1, 125 degree C.	FOWX2, FOWX8 (E146544)	UL R/C, cUL R/C
(Alternate) Capacitor, bridging (CY6)	Murata Mfg Co Ltd	KX	250V min, 1nF maximum, Class Y1, 125 degree C.	FOWX2 (E37921)	UL R/C, CSA
(Alternate) Capacitor, bridging (CY6)	TDK-EPC Corporation	CD	250V min, 1nF maximum, Class Y1, 85 degree C.	FOWX2 (E37861)	UL R/C, CSA
(Alternate) Capacitor, bridging (CY6)	Jya-Nay Co. Ltd	JN	250V min, 1nF maximum, Class Y1, 125 degree C.	FOWX2, FOWX8 (E201384)	UL R/C, cUL R/C
(Alternate) Capacitor, bridging (CY6)	Success Electronics Co Ltd	SE, SB	250V min, 1nF maximum, Class Y1, 125 degree C.	FOWX2 (E114280)	UL R/C, CSA
(Alternate) Capacitor, bridging (CY6)	Haohua Electronic Co	CT 7	250V min, 1nF maximum, Class Y1, 125 degree C.	FOWX2, FOWX8 (E233106)	UL R/C, cUL R/C
(Alternate) Capacitor, bridging (CY6)	Kunshan Wansheng Electronics Co Ltd	CT7	250V min, 1nF maximum, Class Y1, 125 degree C.	FOWX2, FOWX8 (E249006)	UL R/C, cUL R/C
(Alternate) Capacitor, bridging (CY6)	Shantou High-New Technology Developmnt Zone Songtian Enterprise Co Ltd	CD	250V min, 1nF maximum, Class Y1, 125 degree C.	FOWX2, FOWX8 (E208107)	UL R/C, cUL R/C
(Alternate) Capacitor, bridging (CY6)	Zhi Wei Electronics Co Ltd	DJ	250V min, 1nF maximum, Class Y1, 105 degree C.	FOWX2, (E330260)	UL R/C, cUL R/C
(Alternate) Capacitor, bridging (CY6)	Jerro Electronics Corp	JX	250V min, 1nF maximum, Class Y1, 125 degree C.	FOWX2, FOWX8 (E333001)	UL R/C, cUL R/C
(Alternate) Capacitor, bridging (CY6)	Hongzhi Enterprises Ltd	Y	250V min, 1nF maximum, Class Y1, 85 degree C.	FOWX2, FOWX8 (E192572)	UL R/C, cUL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
NTC Thermistor (THR1) [Optional]	Interchangeable	Interchangeable	240 Vac min, 16 Ohm, 4A min, 200 degree C max.	XGPU2, XGPU8	UL R/C, cUL R/C or CSA
Diode Bridge (BD1)	Interchangeable	Interchangeable	600V min 10A minimum.	--	--
Capacitor (C8)	Rubycon	MXG Series	400V min, min 220uF, max 390uF, 105 degree C	--	--
(Alternate) Capacitor (C8)	Interchangeable	Interchangeable	400V min, min 220uF, max 390uF, 105 degree C	--	--
(Alternate) MOSFET (Q1)	Interchangeable	Interchangeable	500V min, 40A min	--	--
(Alternate) MOSFET (Q2, Q3)	Interchangeable	Interchangeable	500V min, 15A min	--	--
(Alternate) Diode (D3)	Interchangeable	Interchangeable	600V min, 6A min	--	--
Transformer (T1) for 3.3 - 5.0 Vdc models	Interchangeable	400-0093	Provides 2MOOP. Class B (130°C). See Enclosure 4-01 for details.	--	--
Transformer (T1) for 5.1 - 9 Vdc models	Interchangeable	400-0094	Provides 2MOOP. Class B (130°C). See Enclosure 4-02 for details.	--	--
Transformer (T1) for 9.1 - 12 Vdc models	Interchangeable	400-0095	Provides 2MOOP. Class B (130°C). See Enclosure 4-03 for details.	--	--
Transformer (T1) for 12.1 - 15 Vdc models	Interchangeable	400-0096	Provides 2MOOP. Class B (130°C). See Enclosure 4-04 for details.	--	--
Transformer (T1) for 15.1 - 19 Vdc models	Interchangeable	400-0097	Provides 2MOOP. Class B (130°C). See Enclosure 4-05 for details.	--	--
Transformer (T1) for 19.1 -29.9 Vdc models	Interchangeable	400-0098	Provides 2MOOP. Class B (130°C). See Enclosure 4-06 for details.	--	--
Transformer (T1) for 30 - 48 Vdc models	Interchangeable	400-0099	Provides 2MOOP. Class B (130°C). See Enclosure 4-07 for details.	--	--
PFC Choke (L6) – Reinforced Insulation	Interchangeable	405-0004	Provides 2MOOP. Class B (130°C). See Enclosure 4-08 for details.	--	--
Insulation System (employed in T1 and L6)	Globtek Inc	GTX-130-TM (Table II, Table IV, Table VII Only).	Class B (130°C). Insulation Components Provided in Enclosure 4-09.	OBJY2 (E243347)	UL R/C
(Alternate) Insulation System (employed in T1	Wuxi Zhongtong Electronics Co Ltd	ZT-130 (Table II, Table IV, Table	Class B (130°C). Insulation Components Provided in Enclosure 4-09.	OBJY2, OBJY8 (E315275)	UL R/C, cUL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
and L6)		VII Only)			
(Alternate) Insulation System (employed in T1 and L6)	Shan Dong Boam Electric Co Ltd	BOAM-01 (Table III Only)	Class B (130°C). Insulation Components Provided in Enclosure 4-09.	OBJY2, OBJY8 (E252329)	UL R/C, cUL R/C
Differential Choke L3	Interchangeable	403-0040	130 deg. C min. wire on a core, 337uH. Constructed as per Enclosure 4-10	Tested in the power supply.	--
Common Mode Choke L4	Interchangeable	404-0013	130 deg. C min. wire on a core, 4.3uH. Constructed as per Enclosure 4-11	Tested in the power supply.	--
Common Mode Choke L5	Interchangeable	404-0011	130 deg. C min. wire on a core, 21mH. Constructed as per Enclosure 4-12	Tested in the power supply.	--
Optical Isolator (U203, U204)	Lite-On Technology Corp	LTV817, LTV817C	Double protection, 5300 Vrms, 115 degree C max.	FPQU2, FPQU9 (E113898)	UL R/C, cUL R/C
(Alternate) Optical Isolator (U203, U204)	Sharp Corp Electronic Components And Devices Div	PC817C	Double protection, 5300 Vrms, 115 degree C max.	FPQU2 (E64380)	UL R/C, CSA
(Alternate) Optical Isolator (U203, U204)	Fairchild	FOD817C	Double protection, 5000 Vrms, 105 degree C max.	FPQU2, FPQU8 (E90700)	UL R/C, cUL R/C
(Alternate) Optical Isolator (U203, U204)	Vishay Infrared Components Inc	SFH615ABM	Double protection, 5300 Vrms, 115 degree C max.	FPQU2, FPQU8 (E52744)	UL R/C, cUL R/C
(Alternate) Optical Isolator (U203, U204)	Cosmo Electronics Co.	KP1010C	Double protection, 5000 Vrms, 115 degree C max.	FPQU2, FPQU8 (E169586)	UL R/C, cUL R/C
(Alternate) Optical Isolator (U203, U204)	Everlight Electronics Co Ltd	EL817C	Double protection, 5000 Vrms, 110 degree C max.	FPQU2, FPQU8 (E214129)	UL R/C, cUL R/C
(Alternate) Optical Isolator (U203, U204)	Bright Led Electronics Corp	BPC-817, BPC-817M, BPC-817S	Double protection, 5000 Vrms, 100 degree C max.	FPQU2, FPQU8 (E236324)	UL R/C, cUL R/C
Light Emitting Diode (LED1) [Optional]	Interchangeable	Interchangeable	400 - 700 nm wavelength. (Visible light range only). Green.	--	--
Glue on Termination Points	Interchangeable	Interchangeable	Glue or potting compound provided on T1, L6, FAN, and flying lead terminations on PCB.	--	--
Insulator between PCB and Chassis	Interchangeable	Interchangeable	Rated min V-0, min thickness of 0.43mm. Rated 85 degree C minimum.	QMFZ2	UL R/C

Object/part or Description	Manufacturer/trademark	type/model	technical data	CCN	Marks of Conformity
(Alternate) Insulator between PCB and Chassis	Interchangeable	Interchangeable	Rated min V-0, min thickness of 0.43mm. Rated 85 degree C minimum.	QMFZ2	UL R/C
Insulator between Metal Cover and PCB (for 350W Version)	Interchangeable	Interchangeable	Rated min V-0, min thickness of 0.25mm. Rated 85 degree C minimum.	QMFZ2	UL R/C
Insulator on metal top of C8 (for 350W Version)	Interchangeable	Interchangeable	Rated min V-0, min thickness of 0.25mm. Rated 85 degree C minimum.	QMFZ2	UL R/C
U-Channel Chassis	Interchangeable	Interchangeable	Aluminium or Steel, Dimensions: minimum 107.2mm by 198.4mm by 45.6mm; max 3mm thick.	-	-
Metal Cover for 350W version	Interchangeable	Interchangeable	Aluminum or Steel, Dimensions: minimum 107.2mm by 198.4mm; max 1.5mm thick. Provided with holes for FAN	-	-
Nylon Bushing for secondary side heat sinks	Interchangeable	Interchangeable	Rated V-2, 85 degree C minimum.	QMFZ2	UL R/C
Fan for 231W and 350W version	ADDA Corp	AD0812MB-A70GL	Brushless 12VDC, 0.15 A (max), 80x80x25mm, 34.4 CFM, V-0, Class A (105). Tubing provided on wiring.	GPWV2, GPWV8 (E132139)	UL R/C, cUL R/C
(Alternate) Fan for 231W and 350W version	Sunonwealth Electric Machine Industry Co Ltd	KD1208PTB3, KD1208PT	Brushless 12VDC, 0.15 A (max), 80x80x25mm, 33.1 CFM, V-0, Class A (105). Tubing provided on wiring.	GPWV2, GPWV8 (E77551)	UL R/C, cUL R/C
(Alternate) Fan for 231W and 350W version	Minebea Co Ltd	3110KL-04W-B30-P00	Brushless 12VDC, 0.22 A (max) 80x80x25mm, 31.8 CFM, V-2, Class A (105). Tubing provided on wiring.	GPWV2, GPWV8 (E89936)	UL R/C, cUL R/C
(Alternate) Fan for 231W and 350W version	EBM-Papst St Georgen Gmbh & Co Kg	8412NME	Brushless 12VDC, 2.0 W (max), 80x80x25mm, 34.1 CFM, V-0, Class A (105). Tubing provided on wiring.	GPWV2 (E38324)	UL R/C, CSA
Marking Label [Optional]	Avery (China) Co Ltd	2M WH PET TC3/S333	150 deg C on Aluminum or steel.	PGJI2 (MH20558)	UL R/C
(Alternate) Marking Label [Optional]	Dongguan Xiangquan Printing	XQ03	150 deg C on Aluminum or steel.	PGDQ2 (MH27594)	UL R/C

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN	Marks of Conformity
	Co Ltd				
(Alternate) Marking Label [Optional]	Fan Ja Paper Printing Co Ltd	FJ-03-1	125 deg C on Steel.	PGDQ2 (MH19546)	UL R/C
(Alternate) Marking Label [Optional]	Fan Ja Paper Printing Co Ltd	FJ-03-3	150 deg C on Aluminum or steel.	PGDQ2 (MH19546)	UL R/C
(Alternate) Marking Label [Optional]	Fan Ja Paper Printing Co Ltd	FJ07	150 deg C on Aluminum or steel.	PGDQ2 (MH19546)	UL R/C
(Alternate) Marking Label [Optional]	Dongguan Xiangquan Printing Co Ltd	XQ004-B	125 deg C on steel.	PGJI2 (MH47303)	UL R/C
(Alternate) Marking Label [Optional]	E-Lin Adhesive Label Co Ltd	EL-15	80 deg C on all metals.	PGDQ2, PGDQ8 (MH19546)	UL R/C, cUL R/C
(Alternate) Marking Label [Optional]	Suzhou Hairong Packing Production Co Ltd	HR-01	150 deg C on Aluminum or steel.	PGDQ2 (MH48692)	UL R/C
(Alternate) Marking Label [Optional]	Suzhou Hairong Packing Production Co Ltd	HR-04	100 deg C on Aluminum or steel.	PGDQ2 (MH48692)	UL R/C
(Alternate) Marking Label [Optional]	Yuen Chang Special Printing (Shenzhen) Co Ltd	JL-02	100 deg C on Aluminum or steel.	PGDQ2 (MH29752)	UL R/C
(Alternate) Marking Label [Optional]	Yuen Chang Special Printing (Shenzhen) Co Ltd	JL-08	80 deg C on Aluminum or steel.	PGDQ2 (MH29752)	UL R/C
(Alternate) Marking Label [Optional]	Shenzhen Corwin Printing Co Ltd	CW-01	100 deg C on Aluminum or steel.	PGDQ2 (MH47077)	UL R/C
(Alternate) Marking Label [Optional]	Dongguan Shangmao Printing Co Ltd	C-019	80 deg C on Aluminum or steel.	PGDQ2 (MH17427)	UL R/C
(Alternate) Marking Label [Optional]	Dongguan Shangmao Printing Co Ltd	C-004	100 deg C on Aluminum or steel.	PGDQ2 (MH17427)	UL R/C

Issue Date: 2013-11-20

Page 19 of 20

Report Reference #

E341350-A22-UL

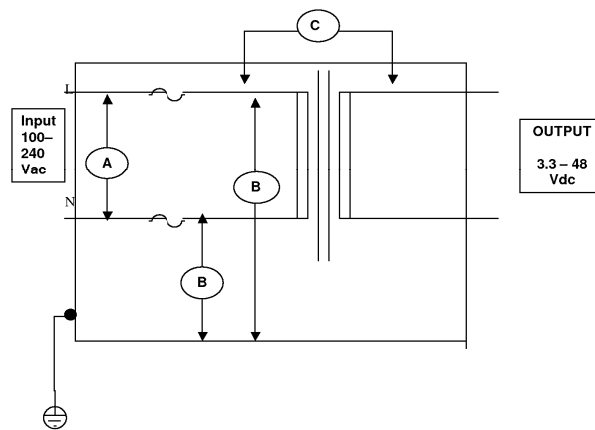
Enclosures

<u>Type</u>	<u>Supplement Id</u>	<u>Description</u>
Collateral		
Particular		
Photographs	3-01	External View
Photographs	3-02	External View - Input Connectors
Photographs	3-03	External View - Output Connectors
Photographs	3-04	Internal View (Upper Enclosure Removed)
Photographs	3-05	Internal View (Lower Enclosure Removed)
Photographs	3-06	Printed Circuit Board View - Component View
Photographs	3-07	Printed Circuit Board View - Trace View
Photographs	3-08	Printed Circuit Board View - Heatsink View
Photographs	3-09	Printed Circuit Board View - Heatsink View
Photographs	3-10	Internal View - Insulator (Positioned Underneath Printed Circuit Board)
Diagrams	4-01	Transformer (T1) for 3.3 - 5.0 Vdc models (Part 400-0093)
Diagrams	4-02	Transformer (T1) for 5.1 - 9 Vdc models (Part 400-0094)
Diagrams	4-03	Transformer (T1) for 9.1 - 12 Vdc models (Part 400-0095)
Diagrams	4-04	Transformer (T1) for 12.1 - 15 Vdc models (Part 400-0096)
Diagrams	4-05	Transformer (T1) for 15.1 - 19 Vdc models (Part 400-0097)
Diagrams	4-06	Transformer (T1) for 19.1 -29.9 Vdc models (Part 400-0098)
Diagrams	4-07	Transformer (T1) for 30 - 48 Vdc models (Part 400-0099)
Diagrams	4-08	PFC Choke (L6) (Part 405-0004)
Diagrams	4-09	Insulation System (employed in T1 and L6) - Comparison Table
Diagrams	4-10	Differential Choke L3 (Part 403-0040)
Diagrams	4-11	Common Mode Choke L4 (Part 404-0013)
Diagrams	4-12	Common Mode Choke L5 (Part 404-0011)
Schematics + PWB	5-01	PCB (PWB) Layout / Artwork - Main Power Board
Schematics + PWB	5-02	PCB (PWB) Layout / Artwork - GTM9200P Control Board
Manuals		
Miscellaneous	7-01	350 W Unit Specification
Miscellaneous	7-02	200 W Unit Specification

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

Insulation Diagram for Power Supply



IEC 60601			
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	3000		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
A	BOP	IIIb	250	354	3.0	1.9	4.5	3.0	Complies.
B	1MOOP	IIIb	250	354	2.5	2.3	4.5	3.0	Complies.
C	2MOOP	IIIb	252	564	--	--	--	--	Triple Insulated Wire employed in T1 and L6.
C	--	IIIb	252	564	5.1	5.0	9.0	5.5	--
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.

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
4	GENERAL REQUIREMENTS		Pass
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse		Pass
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.	N/A
	ESSENTIAL PERFORMANCE functions maintained following particular tests as applicable	No Essential Performance.	N/A
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE	Risk Management Report (GTM9200P), 2013-08-19; Section 6.2.7. ESL: 10 years.	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 used.	N/A
4.6	RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10	No such parts.	N/A
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	Pass
	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.	Pass
	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		Pass
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 :	All components used within their ratings. See Appended Table 8.10.	Pass
	Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following:		Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Applicable safety requirements of a relevant IEC or ISO standard		Pass
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard		Pass
4.9	A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK..... :	No such components.	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 :	No such components.	N/A
4.10	Power supply		Pass
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 :	Connection to: Supply Mains.	Pass
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 \leq 4 kVA (V) :	Refer to Models and Ratings area of Report.	Pass
	- 500 V for all other ME EQUIPMENT and ME SYSTEMS		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-A14-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-A14-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 relevant voltage range		N/A
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	product of steady state current (measured as described above) and supply voltage..... :		

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		Pass
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods	All required tests performed	N/A
	Results of RISK ANALYSIS used to determine combination(s) of simultaneous faults to be tested		N/A
5.2	TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected	Refer to testing results	Pass
5.3	a) Tests conducted within the environmental conditions specified in technical description		Pass
	Temperature (°C), Relative Humidity (%)	0 - 40°C; 0 - 93 % RH	-
	Atmospheric Pressure (kPa).....	700 - 1060 hPa	-
	b) ME EQUIPMENT shielded from other influences that might affect the validity of tests		Pass
	c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained	Refer to testing results	Pass
5.4	a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use and identified during RISK ANALYSIS, except as noted.....	Equipment operated under maximum normal load. 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	No such parts.	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	No such parts.	N/A
	d) Potable water used for cooling	No such parts.	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)	Refer to testing results	Pass
	ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)	Refer to testing results	Pass
	ME EQUIPMENT with more than one RATED voltage, or both a.c./ d.c. tested in conditions (see	Refer to testing results	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	5.4) related to the least favourable voltage, nature of supply, and type of current		
	ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions		N/A
	ME EQUIPMENT connected to a separate power supply as specified in instructions for use		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.....	No indication of equipment being exposed to high humidity in RM.	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		Pass
	When RISK MANAGEMENT PROCESS indicated ME EQUIPMENT can be exposed to high humidity for extended periods (i.e., out-door use), test time extended proportionally (h).....		N/A
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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	All additional parts that became accessible checked using standard test finger and by inspection	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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		Pass
	CLASS II ME EQUIPMENT, externally powered	Not class II equipment	N/A
	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	Not internally powered	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		N/A
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use		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..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/E
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6 :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	N/A
	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..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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 parts.	N/A
7.2.2	MANUFACTURER's name or trademark marked on ME EQUIPMENT and detachable components :	See attached copy of Marking Plate	Pass
	Misidentification does not present an unacceptable risk	Marking provided.	N/A
	MODEL OR TYPE REFERENCE also marked,	See attached copy of Marking	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	except when misidentification would not present an unacceptable RISK..... :	Plate	
	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 PEMS	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
7.2.4	ACCESSORIES marked with name or trademark of MANUFACTURER or supplier, and with a MODEL or TYPE REFERENCE..... :	No accessories provided.	N/A
	Markings applied to individual packaging when not practical to apply to ACCESSORIES	No accessories provided.	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..... :		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		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)..... :	Refer to Models and Ratings area of Report.	Pass
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)..... :	Single voltage range provided.	N/A
	- Nature of supply (e.g., No. of phases, except single-phase) and type of current..... :	Refer to Models and Ratings area of Report.	Pass
	Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all DB:	Symbol not used.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	2002-10) used, optionally, for same parameters... :		
	- RATED supply frequency or RATED frequency range in hertz..... :	Refer to Models and Ratings area of Report.	Pass
	- Symbol 9 of Table D.1 (symbol IEC 60417-5172, DB: 2003-02) used for CLASS II ME EQUIPMENT:	Not class II equipment	N/A
7.2.7	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)..... :	Refer to Models and Ratings area of Report.	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 $\pm 10\%$ of the mean value of specified range (A, VA,W)..... :	Max value for entire range provided.	N/A
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)..... :		N/A
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)..... :	Rating provided in Amperes.	N/A
	Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W)..... :	No such connections.	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)..... :	Refer to Models and Ratings area of Report.	-
	Rated Power (W), Output Frequency (Hz)..... :	Refer to Models and Ratings area of Report.	-
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 (IP0X or 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
	TYPE B APPLIED PARTS with symbol 19 of Table	No applied parts used	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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..... :		
	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.	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 accessible fuse-holders provided. ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	No such outputs.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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 OPERATOR		
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use	No such outputs.	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)	No high voltage used or present	N/A
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air).....		N/A
7.2.16	ME EQUIPMENT with limited mechanical stability	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Permissible environmental conditions for transport and storage marked on outside of packaging	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK	No such hazard.	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	No functional earth terminals used	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.....		N/A
	No marking applied when an interlock provided		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
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)		N/A
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL		N/A
7.3.2	Symbol 24 of Table D.1 (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 voltage used or present	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		Pass
	Type	Time-Lag, Micro-Type	-
	Voltage (V) and Current (A) rating.....	3.15 A (132 W) 4 A (185, 200 W) 5 A (231 W) 6.3 A (350 W) Voltage: 250 V	-
	Operating speed (s) and Breaking capacity	Time-Lag, Low breaking capacity.	-
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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
7.3.6	Symbol 7 of Table D.1 (IEC 60417-5017, DB: 2002-10) marked on FUNCTIONAL EARTH TERMINALS	No functional earth terminals used	N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals, except when no HAZARD would result when interchanging connections	Marking provided adjacent to terminals.	Pass
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	Marking provided.	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)	Not permanently installed	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		Pass
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	Not permanently installed	N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made	Not permanently installed	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	No controls provided.	N/A
	- indicated by an adjacent indicator light, or	No controls provided.	N/A
	- indicated by other unambiguous means	No controls provided.	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	No controls provided.	N/A
	- status indicated by adjacent indicator light	No controls provided.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	- status indicated by other unambiguous means	No controls provided.	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	No controls provided.	N/A
	- status indicated by adjacent indicator light	No controls provided.	N/A
	- status indicated by other unambiguous means	No controls provided.	N/A
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	No controls provided.	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	No controls provided.	N/A
	- an indication of direction in which magnitude of the function changes	No controls provided.	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	No controls provided.	N/A
	ISO 1000 applied for application of SI units, their multiples, and certain other units	No controls provided.	N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3	No controls provided.	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 markings.	N/A
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT	No such markings.	N/A
	Specified colours in ISO 3864-1 used for safety signs	No such markings.	N/A
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	No such markings.	N/A
	Safety signs including any supplementary text or symbols described in instructions for use	No such markings.	N/A
7.6	Symbols		Pass
7.6.1	Meanings of symbols used for marking described in instructions for use	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
7.6.2	Symbols required by this standard conform to IEC		Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	or ISO publication referenced		
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable	No controls provided.	N/A
7.7	Colours of the insulation of conductors		Pass
7.7.1	PROTECTIVE EARTH CONDUCTOR identified 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	For models with flying leads.	Pass
7.7.3	Green and yellow insulation identify only following conductors:		Pass
	- PROTECTIVE EARTH CONDUCTORS		Pass
	- conductors specified in 7.7.2		N/A
	- POTENTIAL EQUALIZATION CONDUCTORS	No potential equalization terminals used	N/A
	- FUNCTIONAL EARTH CONDUCTORS	No functional earth terminals used	N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are "light blue" specified in IEC 60227-1 or IEC 60245-1	Component only, to be determined in the end product	N/A
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	Component only, to be determined in the end product	N/A
7.8	Indicator lights and controls		Pass
7.8.1	Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required)	No such indicators.	N/A
	Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required)	No such indicators.	N/A
	Green indicator lights mean: Ready for use	Ready for operation.	Pass
	Other colours, if used: Meaning other than red, yellow, or green (colour, meaning)..... :	No such indicators.	N/A
7.8.2	Red used only for emergency control	No such controls.	N/A
7.9	ACCOMPANYING DOCUMENTS		N/A
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	ACCOMPANYING DOCUMENTS identify ME	ME Equipment is component	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	EQUIPMENT by the following, as applicable:	for building-in. To be determined in End Product Evaluation.	
	- Name or trade-Name of MANUFACTURER and an address the RESPONSIBLE ORGANIZATION can be referred to	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- MODEL or TYPE REFERENCE.....	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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)	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
7.9.2	Instructions for use include the required information		N/A
7.9.2.1	- intended use of ME EQUIPMENT,	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- frequently used functions, and	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- known contraindication(s) to use of ME EQUIPMENT	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Instructions for use are in a language acceptable to the intended operator	ME Equipment is component for building-in. To be determined in End Product	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
		Evaluation.	
7.9.2.2	Instructions for use include all warning and safety notices	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Warning statement for CLASS I ME EQUIPMENT indicating: "WARNING: To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth"	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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"	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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"	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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 used	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided. :	Not internally powered	N/A
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an	ME Equipment is component for building-in. To be determined in End Product	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	unacceptable RISK..... :	Evaluation.	
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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to when such exposure can constitute an unacceptable RISK	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected	No input/output ports used	N/A
	APPLIED PARTS specified	No applied parts used	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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)	No supply cords provided	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	No batteries used	N/A
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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)	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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)	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
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:	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- information as in clause 7.2	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- permissible environmental conditions of use including conditions for transport and storage	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- special installation requirements such as max. permissible apparent impedance of supply MAINS	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- a description of means of isolating ME EQUIPMENT from supply MAINS, when such means not in ME EQUIPMENT	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	WARNING: No modification of this equipment is allowed	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	WARNING: Do not modify this equipment without authorization of the manufacturer	ME Equipment is component for building-in. To be determined in End Product	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
		Evaluation.	
	WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	- information as in clause 7.2	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- a brief description of ME EQUIPMENT, how it functions, and its significant physical and performance characteristics	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	Not permanently installed	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	No supply cords provided	N/A
	- instructions for correct replacement of interchangeable or DETACHABLE parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- warnings identifying Nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
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		Pass
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 for connection to separate power source.	N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified	Not for connection to separate power source.	N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	Not for connection to separate power source.	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

IEC 60601			
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		N/A
	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..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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) :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- accessible contacts of connectors	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- contacts of fuseholders accessible during replacement of fuse	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- contacts of lampholders accessible after removal of lamp	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Voltage to earth or to other ACCESSIBLE PARTS	ME Equipment is component	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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.)..... :	for building-in. To be determined in End Product Evaluation.	
	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.). :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential up to 2 V (VA or J) :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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)..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	d) Voltage and energy limits specified in c) above also applied to the following:	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- internal parts touchable by a metal test rod with a diameter of 4 mm and a length 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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Test repeated with a TOOL specified in instructions for use	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	A TOOL is required when it is possible to prevent the devices from operating	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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. Test conducted in previous 2nd Edition evaluation (Ref.: E341350-A14-UL).	Pass
	A triggering circuit used to ensure disconnection occurred at peak of supply voltage waveform	Triggering circuit not used, test repeated 10 x (Ref.: E341350-A14-UL)	N/A
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 uC..... :		N/A
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 :	No such parts.	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	No such parts.	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 :	No such parts.	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		Pass
	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	2 MOOP provided from Primary (Mains) to Secondary Output.	Pass
	Varnishing, enameling, oxidation, and similar protective finishes and coatings with sealing compounds replasticizing at temperatures	Noted.	Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	expected during operation and sterilization disregarded as MEANS OF PROTECTION		
	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	No coatings used	N/A
	RISK MANAGEMENT PROCESS taken into consideration for MEANS OF PATIENT PROTECTION	No MOPP used.	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)	No MOPP used.	N/A
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6	No MOPP used.	N/A
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12	No MOPP used.	N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6	No MOPP used.	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	No MOPP used.	N/A
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	No MOPP used.	N/A
	Voltage Total Working (V) and C Nominal (uF)..... :		-
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)		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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	- requirements of IEC 60950-1 for INSULATION CO-ORDINATION	Insulation co-ordination not employed.	N/A
	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	Insulation co-ordination not employed.	N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6, or		Pass
	- requirements and tests of IEC 60950-1 for protective earthing	Insulation co-ordination not employed.	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... :	See Appended Tables 8.8.3 and 8.10	Pass
	A Y1 capacitor complying with IEC 60384-14 and having passed dielectric strength test for two MEANS OF OPERATOR PROTECTION considered equivalent to two MEANS OF OPERATOR PROTECTION..... :	See Appended Tables 8.8.3 and 8.10	Pass
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Single capacitor used.	N/A
	Voltage Total Working (V) and C Nominal (uF)..... :		-
	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		Pass
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION..... :	No MOPP used.	N/A
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION	2 MOOP provided from Primary (Mains) to Secondary Output and 1 MOOP from Primary to Ground	Pass
8.5.2	Separation of PATIENT CONNECTIONS		N/A
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED	No type F applied parts used	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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	or parts needed to be treated as type F applied parts	
	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
	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	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

		parts needed to be treated as type B applied parts	
	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	No patient connections.	N/A
	- conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter	No patient connections.	N/A
	- CLEARANCE between connector pins and a flat surface is at least 0.5 mm	No patient connections.	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	No patient connections.	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	No patient connections.	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)	Rated: 100 - 240 Vac.	Pass
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	- 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)	Rated: 100 - 240 Vac.	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	Pass
	- Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING voltage involving a PATIENT connection not connected to EARTH	No patient connections.	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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 Ohm load to at least 90% of energy delivered to this load with ME EQUIPMENT disconnected	No defibrillation-protected applied parts or parts needed to be treated as defibrillation-protected applied parts	N/A
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	Insulation co-ordination not employed.	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	Appliance inlet, Internal Wiring, or Wiring Header (For assembly in end installation) provided.	Pass
	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Earth pin of APPLIANCE INLET forming supply		Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL		
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop	ME Equipment is component for building-in. To be determined in End Product Evaluation. Test conducted from earthing tab (pin) of unit to the farthest point away on the chassis. (see Test Report Reference E341350-A14-UL)	Pass
	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.....	Limits of 8.6.4 a) met.	N/A
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	No such construction.	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	No supply cords provided	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	No potential equalization	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	NORMAL use	terminals used	
	- 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	No functional earth terminals used	N/A
8.6.9	Class II ME EQUIPMENT		N/A
	Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow	Not class II equipment	N/A
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring connected to them with a related explanation in technical description	Not class II equipment	N/A
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		Pass
	- where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)		Pass
	- the only single FAULT CONDITION for EARTH LEAKAGE current was interruption of one supply conductor at a time		Pass
	- LEAKAGE CURRENTS and PATIENT		Pass

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	AUXILIARY current not measured in single FAULT CONDITION of short circuiting of one constituent PART of DOUBLE insulation		
	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	No such construction.	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 patient connections.	N/A
	c) TOUCH CURRENT did not exceed 100 μ A in NORMAL CONDITION and 500 μ A in SINGLE FAULT CONDITION (ITNC, ITSFC):		N/A
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (IENC, IESFC)	See appended Table 8.7	Pass
	Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710:..... :	Not permanently installed	N/A
	e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device:	See appended Table 8.7	Pass
8.7.4	LEAKAGE and PATIENT AUXILIARY CURRENTS measurements:	See appended Table 8.7	Pass
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)		N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for	Insulation co-ordination not employed.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	INSULATION CO-ORDINATION not tested as in 8.8		
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		N/A
	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		N/A
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION		N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION		Pass
	BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when		Pass
	c) Wire with solid insulation, other than solvent based enamel, complying with a)		N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L		N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	See appended Table 8.10	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	Triple insulated wire provided in Transformer T1 (Secondary Winding).	Pass
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less	Triple insulated wire provided in Transformer T1 constructed	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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	with Extruded layers only.	
	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	Layer of insulating tape provided between primary (bare) and secondary (TIW) windings. Additionally, tubing provided at termination/exit points of TIW.	Pass
	Finished component complied with routine dielectric strength tests of 8.8.3..... :	Evaluated as part of R/C Triple Insulated Wire Inspection Process.	N/A
	Tests of Annex L not repeated since material data sheets confirm compliance..... :	See appended Table 8.10	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
	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 comment be below	Pass
	Tests conducted in absence of satisfactory evidence for resistance to heat	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	No non-metallic enclosure provided.	N/A
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 °C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C) :	Tests of Clause 8.8.4.1 (Ball pressure testing to address retention of live parts under heat) waived based on following justifications: - Input Connectors are separately UL R/C to ECBT2/8	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
		and as such, the plastic materials used for the body material must be UL R/C to QMFZ2/8 - The live pins of Input connectors are provided with multiple means of retention: Mating Female Connector, Body Material, Printed Circuit Board Materials - Appliance Inlets are separately UL R/C to AXUT2/8 and evaluated to IEC 60320-1, and as such the plastic materials used for the body material must be UL R/C to QMFZ2/8. - Transformer T1 Bobbin Materials are noted in Enclosure 4-09. Rationale for waiving the Ball Pressure Tests is provided in TRef Enclosure 9-04.	
	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	Noted.	N/A
8.8.4.2	Resistance to environmental stress		Pass
	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		Pass
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY or REINFORCED INSULATION	No such materials used.	N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No such materials used.	N/A
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples	No such materials used.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h	No such materials used.	N/A
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	Insulation co-ordination not employed.	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 materials used.	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	Noted.	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)..... :	Rated altitude: < 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	MOOP Clearance Multiplication Factor: 1.14	Pass
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE	Noted.	Pass
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	Working voltages do not exceed 2800 Vpk	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	higher 0.1 mm increment (mm)		
	- for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied		Pass
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group)	See Insulation Diagram/Table	Pass
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112.....	All material assumed to be IIIb	N/A
	Material of unknown group considered IIIb		Pass
8.9.1.8	- Pollution degree 1: Micro-environment sealed to exclude dust and moisture	PD2	N/A
	- Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation		Pass
	- Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation	PD2	N/A
	- Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions	PD2	N/A
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION	PD2	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	No such hazard.	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
	For ME EQUIPMENT intended for overvoltage	OVC II	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used		
	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	OVC II	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)		Pass
	Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT	No such construction.	N/A
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS		Pass
	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	No such construction.	N/A
	Table 15 column for circuits not subject to transient overvoltages applied to:	No such construction.	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	No such construction.	N/A
	- CIRCUITS in INTERNALLY powered ME EQUIPMENT	No such construction.	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:	Working voltages do not exceed 1400 Vpk	N/A
	- CLEARANCE was at least 5 mm	Working voltages do not exceed 1400 Vpk	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	Working voltages do not exceed 1400 Vpk	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	Working voltages do not exceed 1400 Vpk	N/A
	- CLEARANCE path was partly or entirely through	Working voltages do not	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	AIR or along the surface of an insulating material of material group I	exceed 1400 Vpk	
	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	Working voltages do not exceed 1400 Vpk	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 cemented joints.	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	No cemented joints.	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	No cemented joints.	N/A

IEC 60601			
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	No cemented joints.	N/A
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint	No cemented joints.	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:	No cemented joints.	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	No cemented joints.	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	No cemented joints.	N/A
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times	No cemented joints.	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		N/A
	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

IEC 60601			
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	No hand-held parts	N/A
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple	No hand-held parts	N/A
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit	No hand-held parts	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	No hand-held parts	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	Applies to Transformer T1 Output Wiring.	Pass

IEC 60601			
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 :		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 :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	N/A
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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 :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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) :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	g) A fuse or a semiconductor device not used as an isolating means	No such parts.	N/A
	h) ME EQUIPMENT not provided with a device	No such parts.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device		
	i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering	No such parts.	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)	No such parts.	N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause	No such parts.	N/A
	Standard test finger of Fig 6 applied	No such parts.	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 parts.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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)..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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 (mm ² Cu)	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
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	No supply cords provided	N/A
	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:	No supply cords provided	N/A
	- insulating material, or	No supply cords provided	N/A
	- metal, insulated from conductive accessible parts non-PROTECTIVELY EARTHED by a means of PROTECTION, or	No supply cords provided	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	No supply cords provided	N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	No supply cords provided	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	No supply cords provided	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	No supply cords provided	N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	No supply cords provided	N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18	No supply cords provided	N/A
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests	No supply cords provided	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	No supply cords provided	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	than 1 mm from their connected position		
	CREEPAGE and CLEARANCES not reduced below limits in 8.9	No supply cords provided	N/A
	It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged	No supply cords provided	N/A
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	No supply cords provided	N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or	No supply cords provided	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)..... :	No supply cords provided	N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance	No supply cords provided	N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D..... :	No supply cords provided	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	Component only, to be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	No such construction.	N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	ords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection		
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6		N/A
	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	No such terminals.	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	No such terminals.	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	No such construction.	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 :	Fusing provided in both L, N.	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	No such omission.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	components		
	Effect of short-circuit fault conditions in other circuits taken into consideration before eliminating fuses or OVER-CURRENT RELEASES	No such omission.	N/A
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Justification for omission of fuses or OVER-CURRENT RELEASES is in RISK MANAGEMENT FILE	Not omitted.	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 (mm ² Cu) :	See appended Table 8.10	Pass
	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 and Table 13	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
9	PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS		N/A
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)		N/A
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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)	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its function	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Warnings marked on ME EQUIPMENT or included in instructions for use when HAZARDS persisted after implementing all reasonable protective measures..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	No trapping zones.	N/A
	- Gaps in Clause 9.2.2.2, or	No trapping zones.	N/A
	- Safe distances in Clause 9.2.2.3, or	No trapping zones.	N/A
	- GUARDS and protective measures in 9.2.2.4, or	No trapping zones.	N/A
	- Continuous activation in Clause 9.2.2.5	No trapping zones.	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	No trapping zones.	N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20..... :	No trapping zones.	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	No trapping zones.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	13852		
	Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse	No trapping zones.	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	No trapping zones.	N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that cannot be dismantled without a TOOL	No trapping zones.	N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open	No trapping zones.	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,	No trapping zones.	N/A
	- absence or failure of one of their components prevents starting, and stops moving parts	No trapping zones.	N/A
	Movable GUARDS complied with all applicable tests as confirmed by review of RISK MANAGEMENT FILE	No trapping zones.	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	No trapping zones.	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	No trapping zones.	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	No trapping zones.	N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed	No trapping zones.	N/A
9.2.2.5	Continuous activation		N/A
	TRAPPING ZONE not considered to present a MECHANICAL HAZARD where impractical to	No trapping zones.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	make TRAPPING ZONE inaccessible when:		
	a) movement was in OPERATOR'S field of view	No trapping zones.	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	No trapping zones.	N/A
	Manually operated movements complied with this clause since mass and velocity allowed adequate control of positioning without causing an unacceptable RISK	No trapping zones.	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	No trapping zones.	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	No trapping zones.	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	No trapping zones.	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	No such moving parts.	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	No such moving parts.	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	No emergency stopping devices.	N/A
	a) Emergency stopping device reduced RISK to an acceptable level	No emergency stopping devices.	N/A
	b) Proximity and response of OPERATOR to	No emergency stopping	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	actuate emergency stopping device could be relied upon to prevent HARM	devices.	
	c) Emergency stopping device actuator was readily accessible to OPERATOR	No emergency stopping devices.	N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT	No emergency stopping devices.	N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original HAZARD	No emergency stopping devices.	N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like	No emergency stopping devices.	N/A
	g) Means for stopping of movements operate as a result of one single action	No emergency stopping devices.	N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls	No emergency stopping devices.	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"	No emergency stopping devices.	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	No emergency stopping devices.	N/A
	k) Emergency stopping device is suitable for its application	No emergency stopping devices.	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	No emergency stopping devices.	N/A
	- Uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented	No emergency stopping devices.	N/A
	- Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of NORMAL exit routes, or other HAZARDS prevented	No emergency stopping devices.	N/A
	- measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME	No emergency stopping devices.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	EQUIPMENT can move in a hazardous way		
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK avoided or covered	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
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		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) . :	ME Equipment is component for building-in.	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)	ME Equipment is component for building-in.	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	ME Equipment is component for building-in.	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	No facility for pushing, resting, or sitting.	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)	No facility for pushing, resting, or sitting.	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	No facility for pushing, resting, or sitting.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	upward component		
	b) ME EQUIPMENT, other than FIXED ME EQUIPMENT, for use on the floor or on a table, did 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)	No facility for pushing, resting, or sitting.	N/A
	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	No facility for pushing, resting, or sitting.	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	- CREEPAGE DISTANCES and AIR CLEARANCES measured compared favourably with min distances in clause 8.9	Not mobile equipment	N/A
	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	Not transportable or stationary equipment	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	Not transportable or stationary equipment	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	N, applied in different directions, except a direction with an upwards component, at highest point of ME EQUIPMENT but 1.5 m from floor..... :		
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT	Not transportable or stationary 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	No grips or handling devices provided.	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	No grips or handling devices provided.	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	Not portable equipment	N/A
	c) Carrying handles and grips and their means of attachment withstood loading test..... :	Not portable equipment	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..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965..... :	No such parts.	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..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- 80 dBA for a cumulative exposure of 24 h over a		-

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	24 h period (dBA)		
	- 83 dBA (when halving the cumulative exposure time) (dBA)		-
	- 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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	Not hand-held equipment.	N/A
	- 2.5 m/s ² for a cumulative time of 8 h during a 24 h period (m/s ²)	Not hand-held equipment.	N/A
	- Accelerations for different times, inversely proportional to square root of time (m/s ²)	Not hand-held equipment.	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.	N/A
	Parts of a pneumatic or hydraulic system used as a support system, comply with 9.8	No pressure vessels.	N/A
9.7.2	Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met following requirements based on examination of RISK MANAGEMENT FILE	No pressure vessels.	N/A
	- no unacceptable RISK resulted from loss of pressure or loss of vacuum	No pressure vessels.	N/A
	- no unacceptable RISK resulted from a fluid jet caused by LEAKAGE or a component failure	No pressure vessels.	N/A
	- Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects	No pressure vessels.	N/A
	- Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its POWER supply	No pressure vessels.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible	No pressure vessels.	N/A
	- all Elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its POWER supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these Elements before setting or maintenance activity	No pressure vessels.	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:	No pressure vessels.	N/A
	a) RATED maximum supply pressure from an external source	No pressure vessels.	N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly	No pressure vessels.	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	No pressure vessels.	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	No pressure vessels.	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 kPa.....	No pressure vessels.	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	No pressure vessels.	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.....	No pressure vessels.	N/A
	a) Connected as close as possible to pressure	No pressure vessels.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	vessel or parts of system it is to protect		
	b) Installed to be readily accessible for inspection, maintenance, and repair	No pressure vessels.	N/A
	c) Could be adjusted or rendered inoperative without a TOOL	No pressure vessels.	N/A
	d) With discharge opening located and directed as to not to release material towards any person	No pressure vessels.	N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK	No pressure vessels.	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	No pressure vessels.	N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect	No pressure vessels.	N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)	No pressure vessels.	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	No support systems used	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	quality of materials used to make the connection and list the required materials		
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to	No support systems used	N/A
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest	No 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	No support systems used	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	ACCOMPANYING DOCUMENTS		
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance	No support systems used	N/A
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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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 parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE did not result in an unacceptable RISK as confirmed by following test:	No support systems used	N/A
	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	- ACCOMPANYING DOCUMENTS instruct once MECHANICAL PROTECTIVE device is Activated, SERVICE PERSONNEL shall be called, and MECHANICAL PROTECTIVE device must be replaced before ME EQUIPMENT can be used	No support systems used	N/A
	- 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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
10	PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS		Pass
10.1	X-Radiation		N/A
10.1.1	X-radiation dose-rate was ≤ 36 pA/kg (5 μ Sv/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	Equipment does not produce such radiation.	N/A
	Amount of radiation measured by means of an ionizing chamber radiation monitor with an effective area of 10 cm ² or by other instruments producing equal results	Equipment does not produce such radiation.	N/A
	ME EQUIPMENT operated as in NORMAL USE at most unfavourable RATED MAINS VOLTAGE and controls adjusted to emit maximum radiation	Equipment does not produce such radiation.	N/A
	Internal pre-set controls not intended for adjustment during EXPECTED SERVICE LIFE of ME EQUIPMENT not taken into consideration	Equipment does not produce such radiation.	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) :	Not X-ray equipment	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	Equipment does not produce such radiation.	N/A
10.3	RISK associated with microwave radiation, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE	Equipment does not produce such 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	This product contains only visible indicator LEDs (Class 1) operating in the range of 400 - 700 nm wavelength. No IEC60825-1 evaluation was deemed necessary.	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	Equipment does not produce such radiation.	N/A
10.6	RISK associated with infrared radiation other than emitted by lasers and LEDs, as applicable, addressed in RISK MANAGEMENT PROCESS as	Equipment does not produce such radiation.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	indicated in RISK MANAGEMENT FILE :		
10.7	RISK associated with ultraviolet radiation other than emitted by lasers and LEDS, as applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE :	Equipment does not produce such radiation.	N/A

IEC 60601			
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. Test conducted in previous 2nd Edition evaluation (Ref.: E341350-A14-UL).	Pass
	Surfaces of test corner did not exceed 90 °C	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	No applied parts.	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	No applied parts.	N/A
	Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS	No applied parts.	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	All measurements made.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	ME Equipment is component for building-in. To be determined in End Product	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
		Evaluation.	
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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of 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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three	Not used with oxygen or oxygen enriched environments	N/A
	b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
11.2.2.3	Electrical connections within a compartment 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)	Not used with oxygen or oxygen enriched environments	N/A
	- 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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Justification, when requirement not met:	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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 materials data:	See appended Table 8.10	Pass
	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	Flammability data reviewed.	N/A
	b) Fire ENCLOSURE met following:	No fire enclosure provided.	N/A
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh 2 x 2 mm centre to centre and wire diameter of at least 0.45 mm	No fire enclosure provided.	N/A
	2) No openings on the sides within the area included within the inclined line C in Fig 39	No fire enclosure provided.	N/A
	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)..... :	No fire enclosure provided.	N/A
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable 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..... :	Not intended for use with flammable agents.	N/A
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME		N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	EQUIPMENT		
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT..... :	Does not use liquids in normal use	N/A
11.6.2	Overflow in ME EQUIPMENT	Does not use liquids in normal use	N/A
	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..... :	Does not use liquids in 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..... :	Does not use liquids in normal use	N/A
11.6.3	Spillage on ME EQUIPMENT and ME SYSTEM	Does not use liquids in normal use	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..... :	Does not use liquids in 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..... :	Does not use liquids in normal use	N/A
11.6.4	Leakage	Does not use liquids in normal use	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)..... :	Rated with no ingress protection (IP0X or IPX0)	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	Rated with no ingress protection (IP0X or IPX0)	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	CONDITION		
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	Equipment not intended to be cleaned, disinfected, or sterilised.	N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests, with no deterioration resulting in an unacceptable RISK present	Equipment not intended to be cleaned, disinfected, or sterilised.	N/A
	Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER and assurance that no unacceptable RISK will occur verified by RISK MANAGEMENT FILE review	Equipment not intended to be cleaned, disinfected, or sterilised.	N/A
11.6.7	Sterilization of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented according to ISO 11134, ISO 11135, or ISO 11137 as appropriate	Equipment not intended to be cleaned, disinfected, or sterilised.	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	Equipment not intended to be cleaned, disinfected, or sterilised.	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	Equipment not intended to be cleaned, disinfected, or sterilised.	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	Not investigated by Underwriters Laboratories.	N/E
11.8	Interruption and restoration of power supply did not result in a HAZARDOUS SITUATION, except interruption of its intended function	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
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 controls or instruments.	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..... :	No controls or instruments.	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	No controls or instruments.	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	No controls or instruments.	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..... :	No controls or instruments.	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	No controls or instruments.	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	No controls or instruments.	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	Equipment does not produce such radiation.	N/A
	Radiation safety ensured by compliance with requirements of appropriate standards	Equipment does not produce such radiation.	N/A
12.4.5.2	RISKS associated with diagnostic X-rays addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE	Equipment does not produce such radiation.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE :	Equipment does not produce such radiation.	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 :	Equipment does not produce such radiation.	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 :	Equipment does not produce such radiation.	N/A

IEC 60601			
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		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		Pass
	- Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur		N/A
	- Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3..... :	No applied parts.	N/A
	- Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3..... :		N/A
	-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:		N/A
	- Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit, or	No such circuits	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	No thermal cut-outs used	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	See appended Table 8.7	Pass

IEC 60601			
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		N/A
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 and RM Results Table 13.2.6	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	No AC motors.	N/A
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted	No AC motors.	N/A
	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).	No AC motors.	N/A
13.2.13.2	ME EQUIPMENT with heating elements		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, 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)	No heating elements.	N/A
	a 3) other ME EQUIPMENT with heating elements met test of 13.2.13.2 b)	No heating elements.	N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively	No heating elements.	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	No heating elements.	N/A
	Test repeated on a second sample when interruption was due to rupture of a heating	No heating elements.	N/A

IEC 60601			
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	No heating elements.	N/A
	b) ME EQUIPMENT with heating elements tested per 11.1 without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V)..... :	No heating elements.	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	No heating elements.	N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted	No heating elements.	N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION	No heating elements.	N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and	No heating elements.	N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS	No heating elements.	N/A
	2) When more than one control provided, they were disabled in turn	No heating elements.	N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time	No heating elements.	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

IEC 60601			
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	-

IEC 60601			
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	No PEMS or PESS.	N/A
	- when application of ISO 14971 showed that failure of PESS does not lead to unacceptable RISK	No PEMS or PESS.	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	No PEMS or PESS.	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	No PEMS or PESS.	N/A
	Assessment of PROCESSES cited in this Clause made by internal audits	No PEMS or PESS.	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.....	No PEMS or PESS.	N/A
14.3	RISK MANAGEMENT plan required by 3.5 of ISO 14971 includes reference to PEMS VALIDATION plan	No PEMS or PESS.	N/A
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	No PEMS or PESS.	N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	No PEMS or PESS.	N/A
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	No PEMS or PESS.	N/A
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	No PEMS or PESS.	N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	No PEMS or PESS.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained where appropriate	No PEMS or PESS.	N/A
	Problem resolution system meets the prescribed criteria depending on type of product:	No PEMS or PESS.	N/A
	- it is documented as a PART of PEMS DEVELOPMENT LIFE-CYCLE	No PEMS or PESS.	N/A
	- it allows reporting of POTENTIAL or existing problems affecting BASIC SAFETY or ESSENTIAL performance	No PEMS or PESS.	N/A
	- it includes an Assessment of each problem for associated RISKS	No PEMS or PESS.	N/A
	- it identifies criteria that must be met for the issue to be closed	No PEMS or PESS.	N/A
	- it identifies the action to be taken to resolve each problem	No PEMS or PESS.	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	No PEMS or PESS.	N/A
	In addition to the material in ISO 14971, Annex D, list of possible sources for HAZARDS associated with PEMS includes specified causes	No PEMS or PESS.	N/A
	- failure of NETWORK/DATA COUPLING to provide characteristics necessary for PEMS to achieve its BASIC SAFETY or ESSENTIAL performance	No PEMS or PESS.	N/A
	- undesired feedback [physical and data] (such as unsolicited/ out of range/ inconsistent input or input from electromagnetic interference)	No PEMS or PESS.	N/A
	- unavailable DATA	No PEMS or PESS.	N/A
	- lack of integrity of DATA	No PEMS or PESS.	N/A
	- incorrect DATA	No PEMS or PESS.	N/A
	- incorrect timing of DATA	No PEMS or PESS.	N/A
	- unintended interactions within & among PESS	No PEMS or PESS.	N/A
	- unknown aspects or quality of third-party software	No PEMS or PESS.	N/A
	- unknown aspects or quality of third-party PESS	No PEMS or PESS.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	- lack of DATA security, particularly vulnerability to tampering, unintended interaction with other programs and viruses	No PEMS or PESS.	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:	No PEMS or PESS.	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	No PEMS or PESS.	N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems	No PEMS or PESS.	N/A
	The architecture specification makes use of considers the specified items to reduce RISK to an acceptable level, where appropriate:	No PEMS or PESS.	N/A
	a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS	No PEMS or PESS.	N/A
	b) fail-safe functions	No PEMS or PESS.	N/A
	c) redundancy	No PEMS or PESS.	N/A
	d) diversity;	No PEMS or PESS.	N/A
	e) partitioning of functionality	No PEMS or PESS.	N/A
	f) defensive design potentially limiting hazardous effects by restricting available output power or by introducing means to limit travel of actuators	No PEMS or PESS.	N/A
	g) allocation of RISK CONTROL measures to subsystems and components of PEMS	No PEMS or PESS.	N/A
	h) failure modes of components and their effects;	No PEMS or PESS.	N/A
	i) common cause failures	No PEMS or PESS.	N/A
	j) systematic failures	No PEMS or PESS.	N/A
	k) test interval duration and diagnostic coverage	No PEMS or PESS.	N/A
	l) maintainability	No PEMS or PESS.	N/A
	m) protection from reasonably foreseeable misuse	No PEMS or PESS.	N/A
	n) NETWORK/DATA COUPLING specification, when applicable	No PEMS or PESS.	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	No PEMS or PESS.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures :	No PEMS or PESS.	N/A
	- milestone(s) when VERIFICATION is to be performed for each function	No PEMS or PESS.	N/A
	- selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the PERSONNEL performing the VERIFICATION	No PEMS or PESS.	N/A
	- selection and utilization of VERIFICATION tools	No PEMS or PESS.	N/A
	- coverage criteria for VERIFICATION	No PEMS or PESS.	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	No PEMS or PESS.	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	No PEMS or PESS.	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	No PEMS or PESS.	N/A
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	No PEMS or PESS.	N/A
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	No PEMS or PESS.	N/A
	a) characteristics of NETWORK/DATA COUPLING necessary for PEMS to achieve its INTENDED USE	No PEMS or PESS.	N/A
	b) list of HAZARDOUS SITUATIONS resulting from a failure of NETWORK/DATA COUPLING to provide the specified characteristics	No PEMS or PESS.	N/A
	c) instructions to RESPONSIBLE ORGANIZATION containing required information and warnings	No PEMS or PESS.	N/A
	- connection of PEMS to a NETWORK/DATA COUPLING that includes other EQUIPMENT could	No PEMS or PESS.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	result in previously unidentified RISKS and RESPONSIBLE ORGANIZATION shall identify, analyze, and control such RISKS		
	- subsequent changes to NETWORK/DATA COUPLING introducing new RISKS and requiring new analysis; and changes to NETWORK/DATA COUPLING include:	No PEMS or PESS.	N/A
	- NETWORK/DATA COUPLING configuration change	No PEMS or PESS.	N/A
	- connection of additional items to NETWORK/DATA COUPLING	No PEMS or PESS.	N/A
	- disconnecting items from NETWORK/DATA COUPLING	No PEMS or PESS.	N/A
	- update of EQUIPMENT connected to NETWORK/DATA COUPLING	No PEMS or PESS.	N/A
	- upgrade of EQUIPMENT connected to NETWORK/DATA COUPLING	No PEMS or PESS.	N/A

IEC 60601			
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	No such controls.	N/A
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
15.3	Mechanical strength		N/A
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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
15.3.2	Push test conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N \pm 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 ... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of RISK MANAGEMENT FILE	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
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 \pm 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Test not applied to flat panel displays, platen glass of ME EQUIPMENT, or cathode ray tubes	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	No damage resulting in an unacceptable RISK sustained as shown in RISK MANAGEMENT FILE	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
15.3.4	Drop test		N/A
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT and	No hand-held parts	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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 \pm 5 mm thick hardwood board lying flat on a concrete or rigid base		
	No unacceptable RISK resulted	No hand-held parts	N/A
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 \pm 5 mm thick hardwood board lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE (cm).....	Not portable or mobile	N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE	Not portable or mobile	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 \pm 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 \pm 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 \pm 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	No plastic enclosures used	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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 in 11.1.3, but no less than 70 °C	No plastic enclosures used	N/A
	No damage resulting in an unacceptable RISK	No plastic enclosures used	N/A
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/E
	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/E
15.4	ME EQUIPMENT components and general assembly		Pass
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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 leads	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 gas.	N/A
15.4.2	Temperature and overload control devices		Pass
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 automatically resetting thermal cut-outs.	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	No thermostats used	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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		
	d) Based on design and RISK MANAGEMENT FILE review, loss of function of ME EQUIPMENT due to operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION	See Appended RM Results Table 15.4.2.1 d)	Pass
	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:	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 1999, clauses 15, 17, J.15, and J.17 as applicable	No such parts.	N/A
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13..... :	See appended Table 13.2. Test conducted in previous 2nd Edition evaluation (Ref.: E341350-A14-UL).	Pass
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified according to appropriate standards	No resettable over-current releases.	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	No resettable over-current releases.	N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards	No resettable over-current releases.	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	No resettable over-current releases.	N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted	No resettable over-current releases.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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 could result in overheating as verified by review of design and RISK MANAGEMENT FILE	No heating elements.	N/A
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	No batteries used	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	MANAGEMENT FILE		
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..... :	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s, except when apparent to OPERATOR from normal operating position	No such state.	N/A
	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	No non-luminous heaters.	N/A
	Requirement not applied to heated stylus-pens for recording purposes	No such parts.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A
	Colours of indicator lights complied with 7.8.1		Pass
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE	(Ref.: E341350-A14-UL)	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 such parts.	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	No actuating parts.	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	No actuating parts.	N/A
	When torque values per Table 30 applied between control knob and shaft of rotating controls for not	No actuating parts.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	less than 2 s, 10 times in each direction, knobs did not rotate		
	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	No actuating parts.	N/A
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.....	No actuating parts.	N/A
	Torque values in Table 30 applied 10 times in each direction to rotating controls for 2 sec	No actuating parts.	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	No actuating parts.	N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N/A
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	No hand-held or foot-operated parts.	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.....	No hand-held or foot-operated parts.	N/A
15.4.7.2	Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface	No hand-held or foot-operated parts.	N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position	No hand-held or foot-operated parts.	N/A
15.4.7.3	a) Foot-operated control device is at least IPX1 & complies with tests of IEC 60529 (IP Code).....	No hand-held or foot-operated parts.	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).....	No hand-held or foot-operated parts.	N/A
	Probability of occurrence estimated as part of RISK MANAGEMENT PROCESS	No hand-held or foot-operated parts.	N/A
15.4.8	Aluminum wires less than 16 mm ² in cross-sectional area are not used	No such parts.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed to prevent loss of oil in any position	No oil.	N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	No oil.	N/A
	A pressure-release device operating during NORMAL USE is, optionally, provided	No oil.	N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage	No oil.	N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements	No oil.	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. Test conducted in previous 2nd Edition evaluation (Ref.: E341350-A14-UL).	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 Tables 15.5.2. Test conducted in previous 2nd Edition evaluation (Ref.: E341350-A14-UL).	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. Test conducted in previous 2nd Edition evaluation (Ref.: E341350-A14-UL).	Pass
	Short circuit applied directly across output windings for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2		Pass
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.....	Single output winding.	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	Non-linear Transformer T1. Tests of 15.5.1.2 applied.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	Dielectric strength tests were conducted in accordance with requirements of this clause with no breakdown of insulation system and no detectable deterioration of transformer	Non-linear Transformer T1. Tests of 15.5.1.2 applied.	N/A
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with IEC 61558-1:1997, Clause 5.12	Non-linear Transformer T1 evaluated to the requirements of 60601-1.	N/A

IEC 60601			
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

IEC 60601			
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

IEC 60601			
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 \leq 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/output ports used	N/A

IEC 60601			
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/output 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/output 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

IEC 60601			
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

IEC 60601			
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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

17	ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS		Pass
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review	See Appended RM Results Table 17	Pass
	- electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	N/A

IEC 60601			
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

IEC 60601			
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

IEC 60601			
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

IEC 60601			
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 U_{max} and I_{max} occurring in their circuits, and complied as follows:	Not rated AP or APG	N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.1..... :	Not rated AP or APG	N/A
	Measured $U_{max} \leq U_c$ with C_{max} as in Fig. G.2 .. :	Not rated AP or APG	N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.1	Not rated AP or APG	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ V as in Fig G.3..... :	Not rated AP or APG	N/A
	- Combinations of currents and corresponding voltages within the limitations $I_{zR}.U_{zR} \leq 50$ 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 $C/2U^2 \leq 1.2$ 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
	U_{max} , 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 $L/2I^2 \leq 0.3$ 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
	- U_{max} 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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	variations in 4.10		
	- I _{max} 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
	- C _{max} and L _{max} 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 U _{max} and I _{max} , 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 U _{max} , I _{max} , R, L _{max} , and C _{max} 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

IEC 60601			
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

IEC 60601			
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 % \pm 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 U_{max} and I_{max} occurring in their circuits complied with requirements, taking C_{max} and L_{max} into consideration:	Not rated AP or APG	N/A
	Measured $U_{max} \leq U_{zR}$ with I_{zR} as in Fig. G.4	Not rated AP or APG	N/A
	Measured $U_{max} \leq U_{zC}$ with C_{max} as in Fig. G.5. :	Not rated AP or APG	N/A
	Measured $I_{max} \leq I_{zR}$ with U_{zR} as in Fig G.4	Not rated AP or APG	N/A
	Measured $I_{max} \leq I_{zL}$ with L_{max} and a $U_{max} \leq 24$ 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
	- U_{max} 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
	- I_{max} 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
	- C_{max} and L_{max} are values occurring in relevant circuit	Not rated AP or APG	N/A
	- U_{max} additionally determined with actual resistance R when equivalent resistance R in Fig	Not rated AP or APG	N/A

IEC 60601			
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

IEC 60601			
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	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	Pass
L.2	Wire construction		N/A
	Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
L.3	Type Test		N/A
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	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:	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 6000 V for REINFORCED INSULATION (V)..... :	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	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	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
	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	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 3000 V for REINFORCED INSULATION (V)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa \pm 11.8 MPa	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	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	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 3000 V for REINFORCED INSULATION (V)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	Oven temperature based on Table L.2 (C).....		-
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm ²)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	Dielectric strength test conducted at room temperature after removal from the oven	Compliance with Annex L determined based on	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
		component evaluation. Refer to appended Table 8.10.	
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	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 3000 V for REINFORCED INSULATION (V)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	Test voltage applied between the shot and conductor.	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm ²)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	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.. :	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
L.4.2	Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	N/A
	- 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION	Compliance with Annex L determined based on component evaluation. Refer to appended Table 8.10.	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	Design and Development Management Procedure GTQPR01000 (Issued 2011-05-13, Ver A.1) 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.	P
3.5 e	Design and Development Management Procedure GTQPR01000 (Issued 2011-05-13, Ver A.1) 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.	P
4.1	Design and Development Management Procedure GTQPR01000 (Issued 2011-05-13, Ver A.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.	P
4.2	Design and Development Management Procedure GTQPR01000 (Issued 2011-05-13, Ver A.1) 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.	P
4.3	Design and Development Management Procedure GTQPR01000 (Issued 2011-05-13, Ver A.1) 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.	P
4.4	Design and Development Management Procedure GTQPR01000 (Issued 2011-05-13, Ver A.1) 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.	P
5	Design and Development Management Procedure GTQPR01000 (Issued 2011-05-13, Ver A.1) Risk Management	Policy for risk evaluation, documentation, and policy for acceptable risk provided.	P

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9		
6.1	Design and Development Management Procedure GTQPR01000 (Issued 2011-05- 13, Ver A.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.	P
6.2	Design and Development Management Procedure GTQPR01000 (Issued 2011-05- 13, Ver A.1) 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.	P
6.3	Design and Development Management Procedure GTQPR01000 (Issued 2011-05- 13, Ver A.1) 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.	P
6.4	Design and Development Management Procedure GTQPR01000 (Issued 2011-05- 13, Ver A.1) 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.	P
6.5	Design and Development Management Procedure GTQPR01000 (Issued 2011-05- 13, Ver A.1) Risk Management Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9	Policy for conduct and documentation of risk/benefit analysis provided.	P
6.6	Design and Development Management Procedure GTQPR01000 (Issued 2011-05- 13, Ver A.1) 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.	P
6.7	Design and Development Management Procedure GTQPR01000 (Issued 2011-05- 13, Ver A.1) Risk Management	Policy to evaluate the risk for all hazards provided and document the result.	P

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

	Procedure GTQPR05000 (Issued: 2013-08-10, Ver A.1); Sections 1; 2; 3; 5; 9		
7	Design and Development Management Procedure GTQPR01000 (Issued 2011-05-13, Ver A.1) 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.	P

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.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

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-RM2013-003, Issued: 2013-10-24, 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.)	P
4.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, 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.	P
4.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, 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.	P

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	NA	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

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:						
Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).						

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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-RM2013-003, Issued: 2013-10-24, 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.	P
4.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, 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.	P
4.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, 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

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.			

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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.			

IEC 60601			
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 :	Ink	--	
Material (composition) of Warning Label :	--	--	
Ink/other printing material or process :	--	--	
Other:	--	--	
YUEN CHANG SPECIAL PRINTING (SHENZHEN) CO LTD (PGDQ2.MH29752) Type JL-02	--	T-w = 15s ,T-m =15s, T-i =15s	
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 markings did not work loose and did not curl at the edges. The markings were clearly readable			

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	Marking provided adjacent to terminals.	NA

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

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

IEC 60601			
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-RM2013-003, Issued: 2013-10-24, 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.	P
4.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 3 (EL3))	Hazard of component movement identified.	P
4.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 3 (EL3))	Estimation of risk associated with component movement provided.	P
5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 3 (EL3))	Risk of component movement evaluated.	P
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-RM2013-003, Issued: 2013-10-24, 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. Accidental detachment of conductors considered: PFC Flying Leads and DC Fan Wiring.	P

IEC 60601			
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					N/A
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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

8.4.3	TABLE: ME Equipment for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply									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:											
Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).											

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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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:					

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	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS			Pass
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:				
Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).				

IEC 60601			
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 (μ A)	Remarks	
Fig. 13 - Earth Leakage (ER)	-	-	Before /After Humidity (μ A)	Maximum allowed values: 5 mA NC; 10 mA SFC	
--	--	--	--	Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).	
Test on Model GTM9200P35048-X.X-S [Output: 48 V dc, 350 W]	--	--	--	--	
AA, ER, NC, S1 = 1, S5 = N	264	60	189 / -	5mA / After Abnormal ONLY.	
AA, ER, NC, S1 = 1, S5 = R	264	60	182 / -	5mA / After Abnormal ONLY.	
AA, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	356 / -	10mA / After Abnormal ONLY.	
AA, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	357 / -	10mA / After Abnormal ONLY.	
Non Frequency-Weighted, ER, NC, S1 = 1, S5 = N	264	60	203 / 208	5mA	
Non Frequency-Weighted, ER, NC, S1 = 1, S5 = R	264	60	195 / 217	5mA	
Non Frequency-Weighted, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	380 / 408	10mA	
Non Frequency-Weighted, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	381 / 408	10mA	
Non Frequency-Weighted, AA, ER, NC, S1 = 1, S5 = N	264	60	215 / -	5mA / After Abnormal ONLY.	
Non Frequency-Weighted, AA, ER, NC, S1 = 1, S5 = R	264	60	214 / -	5mA / After Abnormal ONLY.	
Non Frequency-Weighted, AA, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	389 / -	10mA / After Abnormal ONLY.	
Non Frequency-Weighted, AA, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	388 / -	10mA / After Abnormal ONLY.	

IEC 60601					
Clause	Requirement + Test	Result - Remark		Verdict	
	Test on Model GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W]	--	--	--	--
	AA, ER, NC, S1 = 1, S5 = N	264	60	211 / - -	5mA / After Abnormal ONLY.
	AA, ER, NC, S1 = 1, S5 = R	264	60	190 / - -	5mA / After Abnormal ONLY.
	AA, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	407 / - -	10mA / After Abnormal ONLY.
	AA, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	407 / - -	10mA / After Abnormal ONLY.
	Non Frequency-Weighted, ER, NC, S1 = 1, S5 = N	264	60	189 / 215	5mA
	Non Frequency-Weighted, ER, NC, S1 = 1, S5 = R	264	60	209 / 238	5mA
	Non Frequency-Weighted, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	398 / 435	10mA
	Non Frequency-Weighted, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	398 / 435	10mA
	Non Frequency-Weighted, AA, ER, NC, S1 = 1, S5 = N	264	60	221 / - -	5mA / After Abnormal ONLY.
	Non Frequency-Weighted, AA, ER, NC, S1 = 1, S5 = R	264	60	220 / - -	5mA / After Abnormal ONLY.
	Non Frequency-Weighted, AA, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	412 / - -	10mA / After Abnormal ONLY.
	Non Frequency-Weighted, AA, ER, SFC (Neutral Open), S1 = 0, S5 = N, S7 = 1	264	60	411 / - -	10mA / After Abnormal ONLY.
	Fig. 14 - Touch Current (TC)	-	-	-	Maximum allowed values: 100 μ A NC; 500 μ A SFC
	--	--	--	--	--
	--	--	--	--	--
	Fig. 15 - Patient Leakage Current (P)	-	-	-	Maximum allowed values: Type B or BF AP: 10 μ A NC; 50 μ A SFC (d.c. current); 100 μ A NC; 500 μ A SFC (a.c.) Type CF AP: 10 μ A NC; 50 μ A 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 μ A Type CF AP: 50 μ A
	--	--	--	--	--
	Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP)	-	-	-	Maximum allowed values: Type B or BF AP: 10 μ A NC; 50 μ A SFC(d.c. current); 100 μ A NC; 500 μ A SFC (a.c.) ; Type CF AP: 10 μ A NC; 50 μ A SFC (d.c. or a.c. current)
	--	--	--	--	--
	Fig. 18 - Patient leakage current with	-	-	-	Maximum allowed values: Type B

IEC 60601				
Clause	Requirement + Test	Result - Remark		Verdict

	external voltage on metal Accessible Part that is not Protectively Earthed				or BF AP: 500 µA Type CF: N/A
--	--	--	--	--	--
	Fig. 19 - Patient Auxiliary Current	-	-	-	Maximum allowed values: Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current); 100 µA NC; 500 µA SFC (a.c.) ; Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current)
--	--	--	--	--	--
	Fig. 15 and 20 - Total Patient Leakage Current with all AP of same type connected together	-	-	-	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC; 1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
--	--	--	--	--	--
	Fig. 17 and 20 - Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP	-	-	-	Maximum allowed values: Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current); 500 µA NC;1000 µA SFC (a.c.); Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current)
--	--	--	--	--	--
	Fig. 16 and 20 - Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP	-	-	-	Maximum allowed values: Type B: NA Type BF: 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).

Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function - MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				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
A: L to N (Fuse F1 Removed)	MOP	354	--	1500	No
A: L to N (Fuse F2 Removed)	MOP	354	--	1500	No
B: L/N to Earth	1 MOOP	354	--	1500	No
C: Primary to Secondary	2 MOOP	564	--	3000	No
All types of Insulating Tape except Type WF (1 layer for test)	2 MOOP	564	--	3000	No
Insulating Tape (Model WF, Sample# 1677421-15) (1 layer for test)	2 MOOP	564	--	5000	No
All types of TIW	2 MOOP*1.5	564	--	7500	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).					
Dielectric strength tests conducted: - Before Humidity - After Humidity - After SFC					

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts			N/A
	Allowed impression diameter (mm) :	=<2 mm		-
	Force (N) :	20		-
Part/material			Test temperature (°C)	Impression diameter (mm)
Supplementary information:				

IEC 60601			
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-RM2013-003, Issued: 2013-10-24, Rev A.0) (Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment.	P
4.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 4 (EL4))	Hazard of insulation failure identified.	P
4.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 4 (EL4))	Estimation of risk associated with insulation failure provided.	P
5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 4 (EL4))	Risk of insulation failure evaluated.	P
6.2	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.1 Risk reduction analysis" - Column "Risk Reduction Plan" (Risk No 4 (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)	P
6.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.1 Risk reduction analysis" - Columns "Evaluation"; "Verification" (Risk No 4 (EL4))	Risk control measure implemented and evaluated, effectiveness verified, and results provided in RMF.	P
6.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.2 Residual risk evaluation" (Risk No 4 (EL4))	Residual risk analysed using defined criteria. All residual risk judged to be acceptable.	P
6.5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.3 Risk/benefit analysis"	No risk / benefit analysis conducted.	NA

IEC 60601			
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		Pass
Specific areas of circuits short-circuited and test conditions	Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE ¹	HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No	Remarks
--	--	--	--
Supplementary information: Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE			
Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).			

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.			

IEC 60601			
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-RM2013-003, Issued: 2013-10-24, Rev A.0) (Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment.	P
4.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 3 (EL3))	Hazard of component movement identified.	P
4.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 3 (EL3))	Estimation of risk associated with component movement provided.	P
5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 3 (EL3))	Risk of component movement evaluated.	P
6.2	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, 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

IEC 60601			
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-RM2013-003, Issued: 2013-10-24, 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	P
4.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, 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.	P
5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, 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.	P
6.2	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.1 Risk reduction analysis" - Column "Risk Reduction Plan" (Risk No 6 (EL6))	Risk control measure identified, selected, and recorded in RMF. Glue and tubing employed.	P
6.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.1 Risk reduction analysis" - Columns "Evaluation"; "Verification" (Risk No 6 (EL6))	Risk control measure implemented and evaluated, effectiveness verified, and results provided in RMF.	P
6.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.2 Residual risk evaluation" (Risk No 6 (EL6))	Residual risk analysed using defined criteria. All residual risk judged to be acceptable.	P
6.5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.3 Risk/benefit analysis"	No risk / benefit analysis conducted.	NA

IEC 60601			
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-RM2013-003, Issued: 2013-10-24, 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.	P
4.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, 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.	P
5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, 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.	P
6.2	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.1 Risk reduction analysis" - Column "Risk Reduction Plan" (Risk No 6 (EL6))	Risk control measure identified, selected, and recorded in RMF. Glue and Tubing provided.	P
6.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.1 Risk reduction analysis" - Columns "Evaluation"; "Verification" (Risk No 6 (EL6))	Risk control measure implemented and evaluated, effectiveness verified, and results provided in RMF.	P
6.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.2 Residual risk evaluation" (Risk No 6 (EL6))	Residual risk analysed using defined criteria. All residual risk judged to be acceptable.	P
6.5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.3 Risk/benefit analysis"	No risk / benefit analysis conducted.	NA

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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

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

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	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	No trapping zones.		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

9.2.2.4.4	RM TABLE: Protective measures			N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks		Verdict
4.2	NA	No trapping zones.		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

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	No trapping zones.	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	No trapping zones.	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

9.2.3.2	RM TABLE: Over travel		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. and paragraph)	Result - Remarks	Verdict
4.2	NA	No such moving 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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	No emergency stopping devices.	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	NA	NA	NA

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	No emergency stopping devices.	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

9.3	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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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

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:			

IEC 60601			
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	Not mobile equipment	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:			

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	ME Equipment is component for building-in. To be determined in End Product Evaluation.	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

9.6.1	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	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

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	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	No pressure vessels.	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	No pressure vessels.	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

9.7.5	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	No pressure vessels.	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

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	No pressure vessels.	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	No support systems 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

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	No support systems used	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

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	No support systems 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

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	No support systems used	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	

9.8.3.3	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:					

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	No support systems used	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	No support systems used	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	No support systems used	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

10.1.1	TABLE: Measurement of X - radiation		N/A
	Maximum allowable radiation pA/kg (μ Sv/h) (mR/h)	36 (5 μ Sv/h) (0.5 mR/h)	
	Surface area under test Surface no./ Description1	Measured Radiation, pA/kg (μ Sv/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	Equipment does not produce such radiation.	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	Equipment does not produce such radiation.	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

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	Equipment does not produce such radiation.	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

10.5	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	Equipment does not produce such radiation.	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	Equipment does not produce such radiation.	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

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	Equipment does not produce such radiation.	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

11.1.1	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	
--	--	--	--	--	--	
<p>Supplementary information:</p> <p>1 Maximum allowable temperature on surfaces of test corner is 90 °C</p> <p>2 Max temperature determined in accordance with 11.1.3e)</p> <p>3 When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.</p> <p>4 Supply voltage:</p> <ul style="list-style-type: none"> - 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. <p>5 APPLIED PARTS intended to supply heat to a PATIENT - See RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.</p>						
<p>Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).</p>						

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	No applied 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

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	No applied 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

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	No applied 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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	No applied 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

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	Not used with oxygen or oxygen enriched environments	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

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.			

IEC 60601			
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-RM2013-003, Issued: 2013-10-24, Rev A.0) (Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment.	P
4.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 6 (H2))	Hazard of fire enclosure failure identified.	P
4.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 6 (H2))	Estimation of risk associated with fire enclosure failure provided.	P
5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 6 (H2))	Risk of fire enclosure failure evaluated.	P
6.2	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.1 Risk reduction analysis" - Column "Risk Reduction Plan" (Risk No 6 (H2))	Risk control measure identified, selected, and recorded in RMF.	P
6.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.1 Risk reduction analysis" - Columns "Evaluation"; "Verification" (Risk No 6 (H2))	Risk control measure implemented and evaluated, effectiveness verified, and results provided in RMF.	P
6.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.2 Residual risk evaluation" (Risk No 6 (H2))	Residual risk analysed using defined criteria. All residual risk judged to be acceptable.	P
6.5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "8.3 Risk/benefit analysis"	No risk / benefit analysis conducted.	NA

IEC 60601			
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	Not intended for use with flammable agents.	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	Does not use liquids in normal use	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	Does not use liquids in normal use	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

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	Rated with no ingress protection (IP0X or IPX0)	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	Equipment not intended to be cleaned, disinfected, or sterilised.	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	Equipment not intended to be cleaned, disinfected, or sterilised.	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

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	Equipment not intended to be cleaned, disinfected, or sterilised.	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

12.1	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	No controls or instruments.	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	No controls or instruments.	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

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	No controls or instruments.	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

12.4.2	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	No controls or instruments.	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	No controls or instruments.	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

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	No controls or instruments.	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

12.4.5.2	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	Equipment does not produce such radiation.	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	Equipment does not produce such radiation.	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

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	Equipment does not produce such radiation.	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

12.4.6	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	Equipment does not produce such radiation.	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:				

IEC 60601			
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)
13.2.2	Electrical SINGLE FAULT CONDITIONS per Clause 8.1:	-	-
--	Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).	--	--
13.2.3	Overheating of transformers per Clause 15.5:	-	-
--	Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).	--	--
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:	-	-
Single ventilation	Test Duration: T1 coil: 56.6°C T1 core:53.3°C Ambient:25.2°C Dielectric	NO	GTM9200 P35048-

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
fans locked consecutively (Fan Stopped)	Test: Pass Leakage: Pass		X.X-S [Output: 48 V dc, 350 W] Input: 90 Vac, 60 Hz
Single ventilation fans locked consecutively (Fan Stopped)	Test Duration: T1 coil: 141.8°C T1 core: 135.6°C Ambient: 25.1°C Dielectric Test: Pass Leakage: Pass	NO	GTM9200 P2313.3-X.X [Output: 3.3 V dc, 231 W]] Input: 90 Vac, 60 Hz
13.2.8	Locking of moving parts - Only one part locked at a time - Also see 13.2.10 below:	-	-
--	Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).	--	--
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:	-	-
--	--	--	--
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	-	-
--	--	--	--
Supplementary information:			
1 Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.			
Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).			

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	Does not use liquids in normal use	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	No PEMS or PESS.	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	No PEMS or PESS.	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	No PEMS or PESS.	NA

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	No PEMS or PESS.	NA

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	No PEMS or PESS.	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	No PEMS or PESS.	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	No PEMS or PESS.	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	No PEMS or PESS.	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	No such controls.	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

15.3	TABLE: Mechanical Strength tests 1)			N/A
Clause	Name of Test	Test conditions	Observed results/Remarks	
Supplementary information: 1)As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).				

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	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

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	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	Not portable or mobile	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	Not portable or mobile	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

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	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

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	No automatically resetting thermal cut-outs.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA
5	NA	NA	NA

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	No thermal cut-outs used	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	No thermostats used	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	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

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	No heating elements.	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	No batteries used	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	No batteries used	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	No batteries used	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	No batteries used	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

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	No batteries 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

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	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

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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	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

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	No hand-held or foot-operated parts.	NA
4.3	NA	NA	NA
4.4	NA	NA	NA

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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							
Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).							

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

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.					
Test conducted per UL 60601-1: 1st ed, 2006-04-26, and CAN/CSA-C22.2 No. 601.1-M90 (R2005) in previous evaluation E341350-A14-UL. Test method and data were considered representative of the corresponding tests required by ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) and CAN/CSA-C22.2 No. 60601-1 (2008).					

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	The ME Equipment is not part of an ME System as defined by the manufacturer		NA
4.3	NA	NA		NA
4.4	NA	NA		NA
5	NA	NA		NA

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

16.6.1	TABLE: Leakage Currents in ME System - Touch Current Measurements			N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (µA)	Measured TOUCH CURRENT in NORMAL CONDITION (µA)	Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)	Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (µA)
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	The ME Equipment is not part of an ME System as defined by the manufacturer	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

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-RM2013-003, Issued: 2013-10-24, Rev A.0) (Sections "Device Description"; 6.1 - 6.2.7 "Risk analysis")	Intended use and reasonably foreseeable misuse identified for the ME Equipment.	P
4.3	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.3 Estimation of the risk(s) for each hazardous situation" (Risk No 7 (M1))	Hazard of EMI identified.	P
4.4	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.4 Estimation of the risk situation" (Risk No 7 (M1))	Estimation of risk associated with EMI provided.	P
5	Risk Management Report (GT-RM2013-003, Issued: 2013-10-24, Rev A.0); Sections "6.4 Estimation of the risk situation"; "7 Risk evaluation" (Risk No 7 (M1))	Risk of EMI evaluated.	P
6.2	Risk Management Report of GTM9200P (Issued: 2013-08-19) (Risk No 7 (M1))	Risk control measure identified, selected, and recorded in RMF.	P
6.3	Risk Management Report of GTM9200P (Issued: 2013-08-19) (Risk No 7 (M1))	Risk control measure implemented and evaluated, effectiveness verified, and results provided in RMF.	P
6.4	Risk Management Report of GTM9200P (Issued: 2013-08-19) (Risk No 7 (M1))	Residual risk analysed using defined criteria. All residual risk judged to be acceptable.	P
6.5	Risk Management Report of GTM9200P (Issued: 2013-08-19)	No risk / benefit analysis conducted.	NA

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict

SP	TABLE: Additional or special tests conducted		Pass
Clause and Name of Test	Test type and condition	Observed results	
HUMIDITY PRECONDITIONING TREATMENT (Clause 5.7)	Humidity preconditioning treatment: 95%RH, 25 deg. C, 48 hours Complete Unit, Model GTM9200P35048-X.X-S [Output: 48 V dc, 350 W]	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 GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W]	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)	T1 Pin 1 to FL1 (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	209 Vrms, 456 Vpk, 480 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 1 to FL2 (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	213 Vrms, 560 Vpk, 588 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 2 to FL1 (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	213 Vrms, 476 Vpk, 520 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 2 to FL2 (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	211 Vrms, 548 Vpk, 560 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 3/4 to FL1 (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	218 Vrms, 408 Vpk, 784 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 3/4 to FL2 (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	156 Vrms, 360 Vpk, 624 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 5/6 to FL1 (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	178 Vrms, 344 Vpk, 648 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 5/6 to FL2 (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	252 Vrms, 564 Vpk, 920 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	CY3 Pri Pin to Sec Pin (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	170 Vrms, 364 Vpk, 384 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	Choke L6 Pri Pin to Sec Pin (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	158 Vrms, 368 Vpk, 708 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U203 Pri Pin C to Sec Pin A (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	NOTE @	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U203 Pri Pin C to Sec Pin B (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	NOTE @	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U203 Pri Pin D to Sec Pin A	NOTE @	

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
MEASUREMENT (Clause 8.5.4)	(GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])		
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U203 Pri Pin D to Sec Pin B (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	NOTE @	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U204 Pri Pin C to Sec Pin A (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	NOTE @	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U204 Pri Pin C to Sec Pin B (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	NOTE @	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U204 Pri Pin D to Sec Pin A (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	NOTE @	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U204 Pri Pin D to Sec Pin B (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	NOTE @	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 1 to FL1 (GTM9200P35048-X.X-S [Output: 48 V dc, 350 W])	177 Vrms, 380 Vpk, 404 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 1 to FL2 (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	177 Vrms, 384 Vpk, 404 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 2 to FL1 (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	178 Vrms, 396 Vpk, 440 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 2 to FL2 (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	177 Vrms, 392 Vpk, 424 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 3/4 to FL1 (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	206 Vrms, 376 Vpk, 788 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 3/4 to FL2 (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	198 Vrms, 396 Vpk, 760 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 5/6 to FL1 (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	196 Vrms, 404 Vpk, 764 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	T1 Pin 5/6 to FL2 (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	205 Vrms, 412 Vpk, 784 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	CY6 Pri Pin to Sec Pin (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	177 Vrms, 392 Vpk, 412 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	Choke L6 Pri Pin to Sec Pin (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	194 Vrms, 488 Vpk, 832 Vpk-pk	
WORKING VOLTAGE	U203 Pri Pin C to Sec Pin A	165 Vrms, 356 Vpk, 400 Vpk-pk	

IEC 60601			
Clause	Requirement + Test	Result - Remark	Verdict
MEASUREMENT (Clause 8.5.4)	(GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])		
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U203 Pri Pin C to Sec Pin B (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	206 Vrms, 364 Vpk, 380 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U203 Pri Pin D to Sec Pin A (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	126 Vrms, 308 Vpk, 492 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U203 Pri Pin D to Sec Pin B (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	208 Vrms, 364 Vpk, 376 Vpk-pk	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U204 Pri Pin C to Sec Pin A (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	NOTE @	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U204 Pri Pin C to Sec Pin B (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	NOTE @	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U204 Pri Pin D to Sec Pin A (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	NOTE @	
WORKING VOLTAGE MEASUREMENT (Clause 8.5.4)	U204 Pri Pin D to Sec Pin B (GTM9200P2313.3-X.X [Output: 3.3 V dc, 231 W])	NOTE @	
Supplementary information:			
NOTE @: Cannot measure because the power supply will shut down once put the probe on.			