



Test Report issued under the responsibility of:



IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No......: **30792801.009**
Date of issue: **12/15/2011**
Total number of pages: **202**

CB Testing Laboratory.....: TUV Rheinland of North America, Inc.
Address: 12 Commerce Road, Newtown, CT 06470

Applicant's name.....: Elpac Electronics Inc.,
 Elpac Power Systems, Div of
Address: 17672 Armstrong Ave, Irvine, CA 92614

Test specification:
Standard: **IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)**
Test procedure.....: **CB Scheme**
Non-standard test method.....:

Test Report Form No......: **IEC60601_1G**
Test Report Form Originator: **Underwriters Laboratories Inc.**
Master TRF: **Dated 2010-11**

Copyright © 2010 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.

This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo shall be removed

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

Test item description: Medical switch mode power supply

Trade Mark: 


Manufacturer.....: Elpac Electronics Inc.,
 Elpac Power Systems, Div of
 17672 Armstrong Ave, Irvine, CA 92614

Model/Type reference.....: MWAx0yz and MWBx0yz and MVAx0yz and MVBx0yz (x = 050 to 100, y = 12 to 24, z = A – Z or blank, not safety related)

Ratings	Input: AC 100-240 V, 50/60Hz, 2.3 Amps Output: DC 12 to 24 V, 8.3 Amps Max, 100 Watt Max
----------------------	--

Testing procedure and testing location:	
☒	CB Testing Laboratory: Testing location/ address : TUV Rheinland of North America, Inc. 1279 Quarry Lane, Ste. A, Pleasanton, CA 94566
☐	Associated CB Test Laboratory: Testing location/ address : Tested by (name + signature).. : Ricardo Felix Approved by (+ signature) : Daniel Ruth
☐	Testing procedure: TMP Tested by (name + signature).. : Approved by (+ signature) : Testing location/ address :
☐	Testing procedure: WMT Tested by (name + signature).. : Witnessed by (+ signature) : Approved by (+ signature) : Testing location/ address :
☐	Testing procedure: SMT Tested by (name + signature).. : Approved by (+ signature) : Supervised by (+ signature) : Testing location/ address :
☐	Testing procedure: RMT Tested by (name + signature).. : Approved by (+ signature) : Supervised by (+ signature) : Testing location/ address :

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

Attachment 1 – Photographs
Attachment 2 – Schematics
Attachment 3 – PCB Layout
Attachment 4 – Transformer construction
Attachment 5 – Enclosure
Attachment 6 – National Differences
Attachment 7 – 60601-1 2nd edition report
Attachment 8 –Heat Sink and Copper Shield Drawing

Summary of testing
Tests performed (name of test and test clause):
Testing location:

Power Input Test: 4.11
Humidity Preconditioning Treatment: 5.7
Determination of accessible parts: 5.9.2
Legibility of Marking Test: 7.1.2
Marking Durability Test: 7.1.3
Working Voltage / Power Measurement: 8.4.2
Voltage Limitation (PART 1): 8.4.3
Impedance and current-carrying capability of protective earth connections: 8.6.4
Leakage Current: 8.7.3
Dielectric Strength: 8.8.3
Ball pressure test of thermoplastic parts: 8.8.4.1
Temperature: 11.1.1
Abnormal Operation and Fault Conditions: 13.2
Mechanical Strength tests: 15.3
Transformer short circuit test: 15.5.1.2
Transformer overload test: 15.5.1.3
Transformer dielectric strength after humidity preconditioning: 15.5.2

TUV Rheinland of North
America, Inc.
1279 Quarry Lane, Ste.
A, Pleasanton, CA 94566

[date of performance of tests during original testing according to report number
30792801.001, .003]

Summary of compliance with National Differences: CA, CH, US

CA=Canada, CH=Switzerland, US=United States of America.

☒ The product fulfils the requirements of
EN 60601-1:2006
ANSI/AAMI ES60601-1:2005
CAN/CSA-C22.2 No. 60601-1:08

Copy of marking plate

 **ELPAC POWER SYSTEMS**

MODEL: MWA100012A POWER SUPPLY
INPUT: 100-240V ~ 50/60Hz, 2.3 A
OUTPUT: 12V = , 8.3A



 **ELPAC POWER SYSTEMS**

MODEL: MWA100024A POWER SUPPLY
INPUT: 100-240V ~ 50/60Hz, 2.3 A
OUTPUT: 24V = , 4.2A



 **ELPAC POWER SYSTEMS**

MODEL: MWB100012A POWER SUPPLY
INPUT: 100-240V ~ 50/60Hz, 2.3 A
OUTPUT: 12V = , 8.3A



REV. X
00/00
MADE IN CHINA
SERIAL NO. 000000

 **ELPAC POWER SYSTEMS**

MODEL: MWB100024A POWER SUPPLY
INPUT: 100-240V ~ 50/60Hz, 2.3 A
OUTPUT: 24V = , 4.2A



REV. X
00/00
MADE IN CHINA
SERIAL NO. 000000

 **ELPAC POWER SYSTEMS**

Model: MVA100012A Power Supply
Input: 100-240V ~ , 50/60Hz, 2.3A
Output: 12V = , 8.3A

 **ELPAC POWER SYSTEMS**

Model: MVA100024A Power Supply
Input: 100-240V ~ , 50/60Hz, 2.3A
Output: 24V = , 4.2A

 **ELPAC POWER SYSTEMS**

Model: MVB100012A Power Supply
Input: 100-240V ~ , 50/60Hz, 2.3A
Output: 12V = , 8.3A

 **ELPAC POWER SYSTEMS**

Model: MVB100024A Power Supply
Input: 100-240V ~ , 50/60Hz, 2.3A
Output: 24V = , 4.2A



MODEL: MWA100024A POWER SUPPLY
INPUT: 100-240V ~ 50/60Hz, 2.3 A
OUTPUT: 24V = , 4.2A
ELPAC POWER SYSTEMS



MODEL: MWA100012A POWER SUPPLY
INPUT: 100-240V ~ 50/60Hz, 2.3 A
OUTPUT: 12V = , 8.3A
ELPAC POWER SYSTEMS



MODEL: MWB100012A POWER SUPPLY
INPUT: 100-240V ~ 50/60Hz, 2.3 A
OUTPUT: 12V = , 8.3A
ELPAC POWER SYSTEMS



REV. X
00/00

MADE IN CHINA
SERIAL NO. 000000



MODEL: MWB100024A POWER SUPPLY
INPUT: 100-240V ~ 50/60Hz, 2.3 A
OUTPUT: 24V = , 4.2A
ELPAC POWER SYSTEMS



REV. X
00/00

MADE IN CHINA
SERIAL NO. 000000



Model: MVA100012A Power Supply
Input: 100-240V ~ , 50/60Hz, 2.3A
Output: 12V = , 8.3A **ELPAC POWER SYSTEMS**



Model: MVA100024A Power Supply
Input: 100-240V ~ , 50/60Hz, 2.3A
Output: 24V = , 4.2A **ELPAC POWER SYSTEMS**



Model: MVB100012A Power Supply
Input: 100-240V ~ , 50/60Hz, 2.3A
Output: 12V = , 8.3A **ELPAC POWER SYSTEMS**



Model: MVB100024A Power Supply
Input: 100-240V ~ , 50/60Hz, 2.3A
Output: 24V = , 4.2A **ELPAC POWER SYSTEMS**

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use	MWAx0yz and MWBx0yz: transportable MVAx0yz and MVBx0yz: Unit is a component and dependant on end use device
Device type (component/sub-assembly/ equipment/ system)	Component
Intended use (Including type of patient, application location).....	Device is a component power supply to be determined in the end use
Mode of operation	Continuous
Supply connection	MWAx0yz and MWBx0yz : Appliance inlet MVAx0yz and MVBx0yz: AMP type connector
Accessories and detachable parts included	None
Other options include	None
Testing	
Date of receipt of test item(s).....	October 22, 2007 (30792801.001), April 30, 2008 (30792801.003)
Dates tests performed	October 23, 2007 to October 26, 2007 (30792801.001), April 30, 2008 (30792801.003)
Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement	Pass (P)
- test object was not evaluated for the requirement.....	N/E
- test object does not meet the requirement	Fail (F)
Abbreviations used in the report:	
- normal condition	N.C.
- means of Operator protection	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection	MOPP
General remarks:	
"(see Attachment #)" refers to additional information appended to the report. "(see appended table)" refers to a table appended to the report. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.	
Throughout this report a ☐ comma / ☒ point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 6.2.5 of IEC 60601-1:	

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided..... : ☒ Yes ☐ Not applicable

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies)..... :

ICC Electronics (Dongguan) Ltd
3rd Row, Block A, Shang Yuan Road, 2nd Industrial Zone,
Quingxi Town, DongGuan City, Guangdong, China

General product information:

The MWAx0yz series are mains powered, single phase, Class I fully enclosed switch mode power supplies. Mains are connected via a three prong (Class I) AC inlet.

The MWBx0yz series are mains powered, single phase, Class II fully enclosed switch mode power supplies. Mains are connected via a two prong (Class II) AC inlet

The MVAx0yz series are mains powered, single phase, Class I open frame switch mode power supplies. Mains are connected via an AMP type mains connector.

The MVBx0yz series are mains powered, single phase, Class II open frame switch mode power supplies. Mains are connected via an AMP type mains connector.

The x can be any number between and including 050 and 100 and represents the output power. The y can be any number between and including 12 and 24 and represents the output voltage. The z can be A – Z or blank, not safety related.

. The units are rated a maximum of 8.3 Amps and all output power is limited to 100 Watts Max.

The MWAx0yA and MVAx0yA can be provided with an earthed output via a jumper or an unearthed output via capacitor C41. Both configurations were considered during this evaluation

MWAx0yz and MWBx0yz and MVAx0yz and MVBx0yz (x = 050 to 100, y = 12 to 24, z = A – Z or blank, not safety related)

Revision history:

Date:	Amendment No.	Technical/ non-technical	Amendment Description
October 31, 2007	30792801.001	Technical	The original CB test report
April 30, 2008	30792801.003	Technical	This report is the first amendment to original report no. 30792801.001 and covers the addition of two new models MVAx0yA and MVBx0yA which are similar to models MWAx0yA and MWBx0yA without the enclosure and input terminal are used instead of power inlet. Update the components table for input terminal and heat sink. Change the ambient temperature rating from 40°C to 49°C for models MWAx0yA and MWBx0yA and ambient temperature rated for 60°C for new models MVAx0yA and MVBx0yA .
November 15, 2011	30792801.009	Technical	This report covers the upgrade of standard to IEC 60601-1: 2005, the change of model number from MWAx0yA, MWBx0yA, MVAx0yA and MVBx0yA to MWAx0yz, MWBx0yz, MVAx0yz and MVBx0yz, removal of factory (761116) Elpac Electronics (Shenzhen) Inc. and addition of trademark ICC/Nexergy

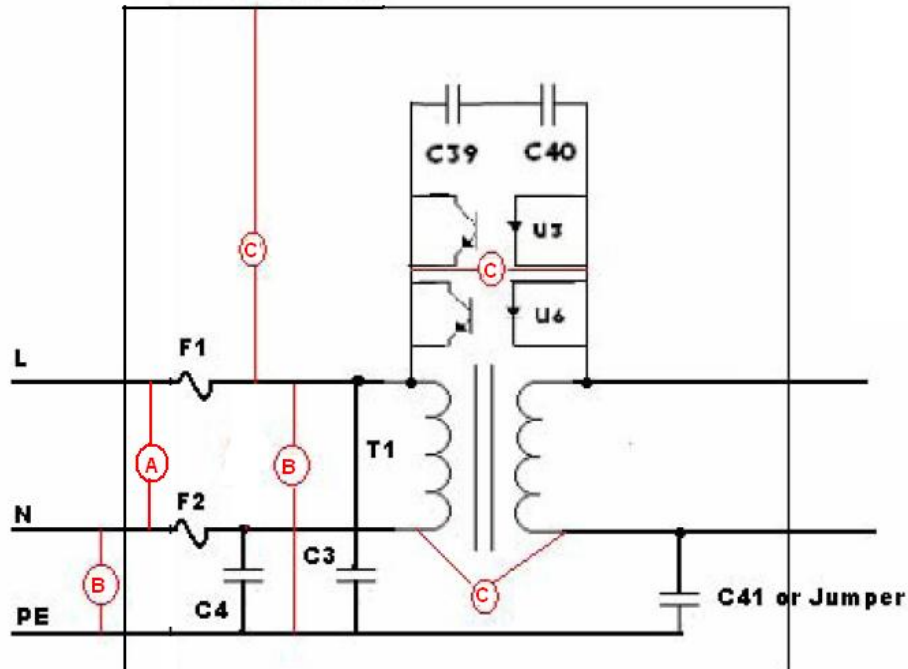
Technical Considerations/ Conditions of Acceptability

- a. Models MWAx0yz and MVAx0yz are considered class I devices,
- b. Models MWBx0yz and MVBx0yz are considered class II devices.
- c. Power supply MWAx0yz and MWBx0yz were evaluated for a maximum working temperature (Tmra) of 49°C.
- d. Power supply MVAx0yz and MVBx0yz were evaluated for a maximum working temperature (Tmra) of 60°C.
- e. Models MVAx0yz and MVBx0yz requirements for enclosures (accessibility/protective/fire/mechanical/etc) need to be considered in the end use application.
- f. Models MVAx0yz and MVBx0yz are intended for build in use.
- g. Models MVAx0yz and MVBx0yz: Suitable disconnect to be provided and evaluated in end use application
- h. Models MVAx0yz and MVBx0yz: Additional requirement for separation/spacings to be considered in the end use application
- i. Accompanying document requirements are to be considered and evaluated end use application.
- j. Device is not intended to be used in a permanently connected device
- k. Leakage current shall be considered at end product.
- l. Pollution degree 2 was considered

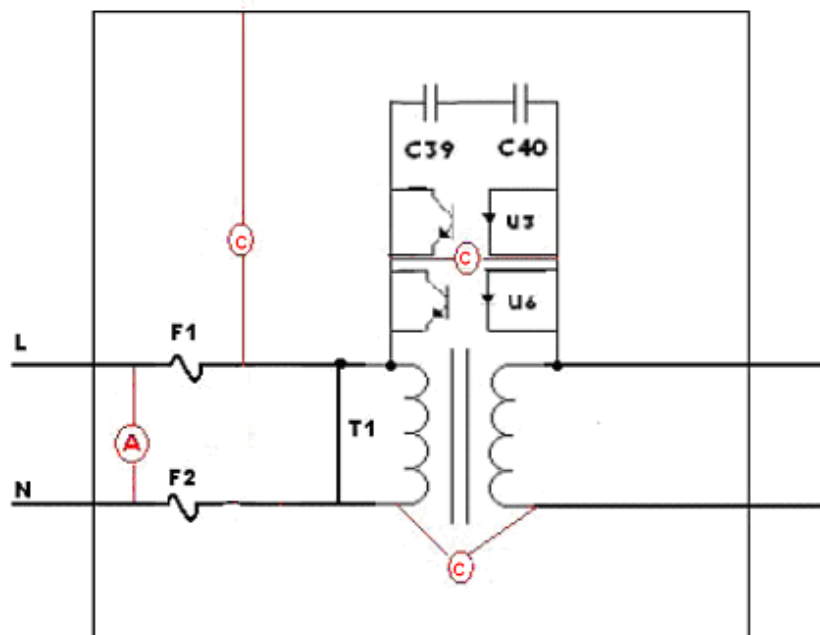
IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

MWA: Plastic enclosure
MVA: Open frame



MWB: plastic enclosure
MVB: open frame



IEC 60601-1									
Clause		Requirement + Test				Result - Remark			Verdict
TABLE: To insulation diagram									Pass
Pollution degree					2				—
Overvoltage category					II				—
Altitude.....					2000 meters or less				—
Additional details on parts considered as applied parts					☒ None ☐ Areas (See Clause 4.6 for details)				—
Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
A	1POOP	-	250	280	3.0	1.6	13.2	13.2	MWAx0yz/ MWBx0yz: Line to Neutral before fuse
A	1POOP	-	250	280	3.0	1.6	8.7	8.7	MVAx0yz/ MVBx0yz: Line to Neutral before fuse
B	1MOPP	-	250	280	4.0	2.5	4.6	4.0	MWAx0yz: PE trace to Line trace
B	1MOPP	-	250	280	4.0	2.5	9.2	9.2	MVAx0yz: PE trace to Line trace
C	2MOPP	-	378	276	12.0	7.0	13.0	13.0	MWAx0yz/ MWBx0yz:T1 pin2 to pin 7/8
C	2MOPP	-	378	276	12.0	7.0	17.0	17.0	MVAx0yz/ MVBx0yz: T1 pin2 to pin 7/8
Supplementary information: MWAx0yz/ MWBx0yz: Isolation between live parts and outside of enclosure is provided by plastic enclosure									

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

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

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

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
4	GENERAL REQUIREMENTS		Pass
4.1	Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse	Normal use and reasonably foreseeable misuse are considered accordingly	Pass
4.2	A RISK MANAGEMENT PROCESS complying with ISO 14971 was performed	Device is a component power supply risk management to be evaluated in the end use	N/A
4.3	ESSENTIAL PERFORMANCE functions identified according to MANUFACTURER'S policy for RISK acceptability in RISK MANAGEMENT FILE.....	Device is a component power supply risk management to be evaluated in the end use	N/A
	ESSENTIAL PERFORMANCE functions maintained following particular tests as applicable	Device is a component power supply risk management to be evaluated in the end use	N/A
4.4	EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE	Device is a component power supply risk management to be evaluated in the end use	N/A
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 provided	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.....	Device is a component power supply risk management to be evaluated in the end use	N/A
4.7	ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2.....	Device is a component power supply risk management to be evaluated in the end use	N/A
	Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically	Device is a component power supply risk management to be evaluated in the end use	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	Device is a component power supply risk management to be evaluated in the end use	N/A
4.8	All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, except as specified, or by RISK MANAGEMENT PROCESS	Components and wiring were used in accordance with their applicable rating.	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 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Applicable safety requirements of a relevant IEC or ISO standard	IEC components provided as listed in Table 8.10	Pass
	b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard	Primary transformer complies with the requirements of this 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 provided	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	Device is a component power supply risk management to be evaluated in the end use	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	Powered directly by mains only	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)	Not hand-held	N/A
	– 250 V d.c. or single-phase a.c., or 500 V polyphase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V)	Single phase equipment rated 100-240Vac	Pass
	– 500 V for all other ME EQUIPMENT and ME SYSTEMS	See above	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% ..	Measurements did not exceed marked ratings by more than 10%. See appended Table 4.11	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	Measurements made at -10% of the lower and +10% of the upper voltage range	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	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage	Power input not expressed in volt-amps	N/A
5	GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT		Pass
5.1	TYPE TESTS determined in consideration of Clause 4, in particular 4.2	Type testing performed	Pass
	Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods	Testing performed	N/A
	Results of RISK ANALYSIS used to determine combination(s) of simultaneous faults to be tested	RISK ANALYSIS NOT used	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	Multiple samples tested	Pass
5.3	a) Tests conducted within the environmental conditions specified in technical description	Tested to customer specified conditions	N/A
	Temperature (°C), Relative Humidity (%)	MWAx0yz and MWBx0yz=49, 5 to 95 MVAx0yz and MVBx0yz=60, 5 to 95	—
	Atmospheric Pressure (kPa)	94.2 to 101.3 (2000m to sea level)	—
	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	Testing results corrected to maximum rated ambient temperature	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	Tested under least favourable working conditions	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	Not such type of equipment	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 cooling liquids used	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) Potable water used for cooling	No cooling liquids used	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)	Tested at 90 and 264V	Pass
	ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :	Tested at 50 and 60 Hz as rated	Pass
	ME EQUIPMENT with more than one RATED voltage, or both a.c./ d.c. tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current..... :	Tested at 90 and 264V	Pass
	ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions..... :	No such accessories	N/A
	ME EQUIPMENT connected to a separate power supply as specified in instructions for use	No separate power supply used	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	No such failures occurred during testing	N/A
	Alternatively, upon repair and modification of the sample, only the relevant tests conducted	See above	N/A
5.7	ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3..... :	Humidity pre-conditioning performed	Pass
	Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened and detached	No such parts	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	Tested 93%, 25°C, for 48 hours	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)	Extended exposure to high humidity is not considered likely	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	Followed sequence in annex B	Pass
5.9	Determination of APPLIED PARTS and ACCESSIBLE PARTS		Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
5.9.1	APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS :	No applied part	N/A
5.9.2	ACCESSIBLE PARTS		Pass
5.9.2.1	Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position	MWAx0yz and MWBx0yz: No hazardous parts accessible with test finger. Output connector is the only accessible part with test finger MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, to be evaluated in end use application	Pass
	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	MWAx0yz and MWBx0yz: No such openings MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, to be evaluated in end use application	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	See above	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	MWAx0yz and MWBx0yz: No such openings MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, to be evaluated in end use application	N/A
	All additional parts that became accessible checked using standard test finger and by inspection	See above	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 electrical controls. No accessible conductive 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 electrical controls. No accessible conductive parts.	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
6	CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS		Pass
6.2	CLASS I ME EQUIPMENT, externally powered	MWx0yz and MVx0yz: Class I	Pass
	CLASS II ME EQUIPMENT, externally powered	MWBx0yz and MVBx0yz: Class II	Pass
	INTERNALLY POWERED ME EQUIPMENT	Not internally powered	N/A
	EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements	See above	N/A
	TYPE B APPLIED PART	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	TYPE BF APPLIED PART	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	TYPE CF APPLIED PART	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	DEFIBRILLATION-PROOF APPLIED PARTS	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
6.3	ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN₁N₂) as per IEC 60529 :	Ordinary equipment	Pass
6.4	ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use..... :	No parts intended to be sterilized	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 for use in oxygen rich environments	N/A
6.6	CONTINUOUS or Non-CONTINUOUS OPERATION :	Continuous operation	Pass
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..... :	Adequate markings provided on power supply for installation purposes	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.1.2	Legibility of Markings Test for Markings specified in Clause 7.2-7.6..... :	MWAx0yz and MWBx0yz: Markings are clearly legible after turning device upside down MVAx0yz and MVBx0yz: Device is a component power supply, to be evaluated in end use application	Pass
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..... :		Pass
	b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test ... :	See appended Table 7.1.3	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 :	Size of equipment permits all marking on enclosure of equipment	Pass
	Remaining markings fully recorded in ACCOMPANYING DOCUMENTS :	See above	N/A
	Markings applied to individual packaging when impractical to apply to ME EQUIPMENT	See above	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)..... :	Not such type of equipment	N/A
7.2.2	MANUFACTURER's name or trademark marked on ME EQUIPMENT and detachable components..... :	 	Pass
	Misidentification does not present an unacceptable risk	See below	N/A
	MODEL OR TYPE REFERENCE also marked, except when misidentification would not present an unacceptable RISK..... :	Model also marked: MWAx0yz, MWBx0yz and MVAx0yz and MVBx0yz (x = 050 to 100, y = 12 to 24, z = A – Z or blank, not safety related)	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	Not 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	Symbol 11 not used	N/A
	Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted	Symbol 10 not used	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	See above	N/A
7.2.5	MODEL OR TYPE REFERENCE of equipment to be connected to ME EQUIPMENT to provide power, is marked adjacent to the relevant connection point when this connection could result in an unacceptable RISK	Not such type of equipment	N/A
7.2.6	Connection to the Supply Mains		Pass
	Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point	MWAX0yz and MWBX0yz: Marking plate attached to bottom of power supply enclosure MVAx0yz and MVBx0yz: Device is a component power supply, to be evaluated in end use application	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 equipment	N/A
	– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V).....	100-240 Vac	Pass
	Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)....	Single range	N/A
	– Nature of supply (e.g., No. of phases, except single-phase) and type of current	Single phase, Marking not required	N/A
	Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all DB: 2002-10) used, optionally, for same parameters:	See copy of marking plate in page 5 and 6	Pass
	– RATED supply frequency or RATED frequency range in hertz.....	50/60	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Symbol 9 of Table D.1 (symbol IEC 60417-5172, DB: 2003-02) used for CLASS II ME EQUIPMENT	MWBx0yz and MVBx0yz: Class II device marked with symbol 9 MWAx0yz and MVAx0yz: Class I	Pass
7.2.7	RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W)	2.3 Amps	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)	Rated 100-240	Pass
	Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W)	Rated 100-240	Pass
	Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)	No such difference in rating	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 means for connection to other electrical equipment	N/A
7.2.8	Output connectors		
7.2.8.1	See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT	No outlet provided	N/A
7.2.8.2	Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment		N/A
	Rated Voltage (V), Rated Current (A)		—
	Rated Power (W), Output Frequency (Hz)		—
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)	Equipment for indoor use only, No IP test conducted in this report.	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):	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	TYPE B APPLIED PARTS with symbol 19 of Table D.1 (IEC 60417-5840, DB: 2002-10), not applied in such a way as to give the impression of being inscribed within a square in order to distinguish it from symbol IEC 60417-5333	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	TYPE BF APPLIED PARTS with symbol 20 of Table D.1 (IEC 60417-5333, DB: 2002-10)	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	TYPE CF APPLIED PARTS with symbol 21 of Table D.1 (IEC 60417-5335, DB: 2002-10)	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	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):	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	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	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	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	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	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	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
7.2.11	ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION	Continuous operation	N/A
	DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time	See above	N/A
7.2.12	Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder	MWAx0yz and MWBx0yz: No such fuses provided MVAx0yz and MVBx0yz: Device is a component power supply, to be evaluated in end use application	N/A
	Fuse type.....	See above	—
	Voltage (V) and Current (A) rating	See above	—
	Operating speed (s) and Breaking capacity.....	See above	—
7.2.13	A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR ...	Does not produce physiological effects	N/A
	Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.2.14	HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10)	No high voltage terminal device	N/A
7.2.15	Requirements for cooling provisions marked (e.g., supply of water or air).....:	No cooling required	N/A
7.2.16	ME EQUIPMENT with limited mechanical stability	MWAx0yz and MWBx0yz: Not limited stability MVAx0yz and MVBx0yz: Device is a component power supply, to be evaluated in end use application	N/A
7.2.17	Packaging marked with special handling instructions for transport and/or storage.....:	No special handling measures have to be taken during transport and storage.	N/A
	Permissible environmental conditions for transport and storage marked on outside of packaging.....:	See above	N/A
	Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK	Not such type of equipment	N/A
	Packaging of sterile ME EQUIPMENT OR ACCESSORIES marked sterile	Not provided	N/A
7.2.18	RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector	No pressure involved	N/A
7.2.19	Symbol 7 of Table D.1 (IEC 60417-5017, DB:2002-10) marked on FUNCTIONAL EARTH TERMINAL.....:	No such terminal provided	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	No such construction	N/A
	No marking applied when an interlock provided	See above	N/A
7.3	Marking on the inside of ME EQUIPMENT OR ME EQUIPMENT parts		N/A
7.3.1	Maximum power loading of heating elements or lamp-holders designed for use with heating lamps marked near or in the heater (W)	No heating element or lamp-holders	N/A
	A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL	See above	N/A
7.3.2	Symbol 24 of Table D.1 (symbol IEC 60417-5036, DB: 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts	No parts with a voltage over 1000 Vac or over 1500 Vdc or 1500 Vpeak value	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.3.3	Type of battery and mode of insertion when applicable is marked	No batteries provided	N/A
	An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL	See above	N/A
	A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement by inadequately trained personnel would result in an unacceptable RISK (e.g., excessive temperatures, fire or explosion).....	See above	N/A
	An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS	See above	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	No replaceable fuse, thermal cut-out or over-current releases.	N/A
	Type	See above	—
	Voltage (V) and Current (A) rating	See above	—
	Operating speed (s) and Breaking capacity.....	See above	—
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	MWx0yz: Appliance inlet provided. MWBx0yz and MVBx0yz: Class II devices MVAx0yz: The protective earthing terminal is provided by an eyelet for connection via a screw. Marking provided next to eyelet	Pass
	Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made	MWx0yz and MVAx0yz: Appropriately marked MVBx0yz and MVBx0yz: Class II device	Pass
7.3.6	Symbol 7 of Table D.1 (IEC 60417-5017, DB: 2002 -10) marked on FUNCTIONAL EARTH TERMINALS	No such terminal provided	N/A
7.3.7	Terminals for supply conductors marked adjacent to terminals, except when no HAZARD would result when interchanging connections	MWx0yz and MWBx0yz series: Provided with an appliance inlet MVAx0yz and MVBx0yz: Device is a component power supply provided with AMP type mains connector. Additional consideration and requirements for connection of power supply cords are to be evaluated in end use application	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings	See above	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)	Equipment not intended for use in permanently installed equipment	N/A
	Marking for connection to a 3-phase supply, if necessary, complies with IEC 60445	Single phase device	N/A
	Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made		N/A
7.3.8	“For supply connections, use wiring materials suitable for at least X °C” (where X > than max temperature measured in terminal box or wiring compartment under NORMAL USE), or equivalent, marked at the point of supply connections	No such supply terminal in equipment	N/A
	Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made	See above	N/A
7.4	Marking of controls and instruments		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	Device is not provided with controls or instruments, requirements for Marking of controls and instruments to be evaluated in end use application	N/A
	– indicated by an adjacent indicator light, or	See above	N/A
	– indicated by other unambiguous means	See above	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	See above	N/A
	– status indicated by adjacent indicator light	See above	N/A
	– status indicated by other unambiguous means	See above	N/A
	The “on/off” positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 DB: 2002-10), or	See above	N/A
	– status indicated by adjacent indicator light	See above	N/A
	– status indicated by other unambiguous means	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.4.2	Different positions of control devices/switches indicated by figures, letters, or other visual means	Device is not provided with controls or instruments, requirements for Marking of controls and instruments to be evaluated in end use application	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	See above	N/A
	– an indication of direction in which magnitude of the function changes	See above	N/A
7.4.3	Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 31 except the base quantities listed in Table 1 expressed in the indicated units	Device is not provided with controls or instruments, requirements for Marking of controls and instruments to be evaluated in end use application	N/A
	ISO 1000 applied for application of SI units, their multiples, and certain other units	See above	N/A
	All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3	See above	N/A
7.5	Safety signs		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 safety signs used	N/A
	Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT	See above	N/A
	Specified colours in ISO 3864-1 used for safety signs.....:	See above	N/A
	Safety notices include appropriate precautions or instructions on how to reduce RISK(S)	See above	N/A
	Safety signs including any supplementary text or symbols described in instructions for use	See above	N/A
7.6	Symbols		Pass
7.6.1	Meanings of symbols used for marking described in instructions for use.....:	Device is a component power supply not provided with instructions	N/A
7.6.2	Symbols required by this standard conform to IEC or ISO publication referenced	Symbols conform with IEC standards	Pass
7.6.3	Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable	No such symbols are provided	N/A
7.7	Colours of the insulation of conductors		Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.7.1	PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation	Power cord is not part of this evaluation.	N/A
7.7.2	Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations	MWAx0yz: Green and yellow insulation is used for insulation on conductor inside ME equipment forming protective earth connection MWBx0yz and MVBx0yz: Class II devices MVAx0yz: PE conductors are traces on PCB	Pass
7.7.3	Green and yellow insulation identify only following conductors:		Pass
	– PROTECTIVE EARTH CONDUCTORS	Power cord is not part of this evaluation.	N/A
	– conductors specified in 7.7.2	MWAx0yz: Green and yellow insulation is used for insulation on conductor inside ME equipment forming protective earth connection MWBx0yz and MVBx0yz: Class II devices MVAx0yz: PE conductors are traces on PCB	Pass
	– POTENTIAL EQUALIZATION CONDUCTORS	No potential equalization conductors are provided	N/A
	– FUNCTIONAL EARTH CONDUCTORS	Not provided with FE conductors	N/A
7.7.4	Neutral conductors of POWER SUPPLY CORDS are “light blue” specified in IEC 60227-1 or IEC 60245-1	Power cord is not part of this evaluation.	N/A
7.7.5	Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1	Power cord is not part of this evaluation.	N/A
7.8	Indicator lights and controls		N/A
7.8.1	Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required)	No red indicator used	N/A
	Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required)	No yellow indicator used	N/A
	Green indicator lights mean: Ready for use	No green indicator used	N/A
	Other colours, if used: Meaning other than red, yellow, or green (colour, meaning).....:	No other indicators used	N/A
7.8.2	Red used only for emergency control	No red indicator used	N/A
7.9	ACCOMPANYING DOCUMENTS		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
7.9.1	ME EQUIPMENT accompanied by documents containing at least instructions for use, and a technical description	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:	See above	N/A
	– Name or trade-name of MANUFACTURER and an address the RESPONSIBLE ORGANIZATION can be referred to	See above	N/A
	– MODEL OR TYPE REFERENCE	See above	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)	See above	N/A
	ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use	See above	N/A
	ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended	See above	N/A
7.9.2	Instructions for use include the required information		N/A
7.9.2.1	– intended use of ME EQUIPMENT,	Instructions for use are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	– frequently used functions, and	See above	N/A
	– known contraindication(s) to use of ME EQUIPMENT	See above	N/A
	Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT	See above	N/A
	Instructions for use are in a language acceptable to the intended operator	See above	N/A
7.9.2.2	Instructions for use include all warning and safety notices	Instructions for use are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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”	See above	N/A
	Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments	See above	N/A
	Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference	See above	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”	See above	N/A
	The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS	See above	N/A
7.9.2.3	Statement on ME EQUIPMENT for connection to a separate power supply indicating “power supply is specified as a part of ME EQUIPMENT or combination is specified as a ME SYSTEM”	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	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	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	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..... :	See above	N/A
	Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided :	See above	N/A
	Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK..... :	See above	N/A
7.9.2.5	Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Information provided on materials and ingredients PATIENT or OPERATOR is exposed to when such exposure can constitute an unacceptable RISK	See above	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	See above	N/A
	APPLIED PARTS specified	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	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	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	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)	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	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	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	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	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
7.9.2.11	Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	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	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	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	See above	N/A
7.9.2.13	Instructions provided on preventive inspection, calibration, maintenance and its frequency	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT	See above	N/A
	Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application	See above	N/A
	Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL	See above	N/A
7.9.2.14	A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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)	See above	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 :	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	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)	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
7.9.3	Technical description		N/A
7.9.3.1	All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use including the following:	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	– information as in clause 7.2	See above	N/A
	– permissible environmental conditions of use including conditions for transport and storage	See above	N/A
	– all characteristics of ME EQUIPMENT including range(s), accuracy, and precision of displayed values or where they can be found	See above	N/A
	– special installation requirements such as max. permissible apparent impedance of SUPPLY MAINS	See above	N/A
	– permissible range of values of inlet pressure and flow, and chemical composition of cooling liquid used for cooling	See above	N/A
	– a description of means of isolating ME EQUIPMENT from SUPPLY MAINS, when such means not in ME EQUIPMENT	See above	N/A
	– a description of means for checking oil level in partially sealed oil filled ME EQUIPMENT or its parts when applicable	See above	N/A
	– a warning statement addressing HAZARDS that can result from unauthorized modification of ME EQUIPMENT according to following examples	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	“WARNING: No modification of this equipment is allowed”	See above	N/A
	“WARNING: Do not modify this equipment without authorization of the manufacturer”	See above	N/A
	“WARNING: If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment”	See above	N/A
	Technical description separable from instructions for use contains required information, as follows		N/A
	– information as in clause 7.2	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT	See above	N/A
	– a brief description of ME EQUIPMENT, how it functions, and its significant physical and performance characteristics	See above	N/A
	MANUFACTURER’S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description	See above	N/A
7.9.3.2	The technical description contains the following required information		N/A
	–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT, when type and rating of fuses are not apparent from information on RATED current and mode of operation of ME EQUIPMENT :	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and if so, instructions for correct connection and anchoring to ensure compliance with 8.11.3	See above	N/A
	– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and	See above	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	See above	N/A

IEC 60601-1			
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	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
7.9.3.4	Means used to comply with requirements of 8.11.1 clearly identified in technical description	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A

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	Limits specified in Clause 8.4 were not exceeded	Pass
	NORMAL CONDITION considered as simultaneous occurrence of situations identified in 8.1a)	Normal condition was considered accordingly	Pass
	SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)... :	Considered	Pass
	ACCESSIBLE PARTS determined according to 5.9	MWAx0yz and MWBx0yz: See Clause 5.9.2.1 MVAx0yz and MVBx0yz: Device is a built in power supply not provided with enclosure, to be evaluated in end use application	Pass
	LEAKAGE CURRENTS measured according to 8.7	Leakage currents measured accordingly	Pass
8.2	Requirements related to power sources		N/A
8.2.1	When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM	No separate power supply	N/A
	Tests performed with ME EQUIPMENT connected to separate power supply when one specified	See above	N/A
	When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined	See above	N/A
8.2.2	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	AC mains only	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT connected with correct polarity did not present an unacceptable RISK	See above	N/A
	Protective devices that can be reset by anyone without a TOOL restore correct operation on reset	No such devices provided	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	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	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	See above	N/A
	c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, OR CF	See above	N/A
	d) Requirements of a TYPE B APPLIED PART applied to a part in 4.6 to be subjected to requirements for an APPLIED PART (except marking)	See above	N/A
	Requirements for a TYPE BF OR CF APPLIED PART applied as in RISK MANAGEMENT PROCESS	See above	N/A
8.4	Limitation of voltage, current or energy		N/A
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, however outputs are separated from live parts by reinforced insulation. Device is a component power supply, to be evaluated in end use application	N/A
8.4.2	ACCESSIBLE PARTS including APPLIED PARTS		Pass
	a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT and PATIENT AUXILIARY CURRENT per Tables 3 and 4 when measured according to Clause 8.7.4..... :	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	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) :	MWAx0yz and MWBx0yz: Touch current did not exceed limits in Cl. 8.7.3 c) MVAx0yz and MVBx0yz: Device is a component power supply provided without an enclosure, to be evaluated in end use application	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	Device is a component power supply, to be evaluated in end use application	N/A
	– accessible contacts of connectors	See above	N/A
	– contacts of fuseholders accessible during replacement of fuse	See above	N/A
	– contacts of lampholders accessible after removal of lamp	See above	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	See above	N/A
	Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.) :	See above	N/A
	Limit of 60 V d.c applied with no more than 10% peak-to-peak ripple, and when ripple larger than specified value, 42.4 V peak limit applied (V d.c.) :	See above	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) :	See above	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) :	See above	N/A
	d) Voltage and energy limits specified in c) above also applied to the following:	MWAx0yz and MWBx0yz: There are no such internal parts that can be touched by a test pin or a test rod. MVAx0yz and MVBx0yz: Device is a component power supply, to be evaluated in end use application	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	See above	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	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N	See above	N/A
	Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N	See above	N/A
	Test repeated with a TOOL specified in instructions for use	See above	N/A
	Test rod freely and vertically suspended through openings on top of ENCLOSURE	See above	N/A
	e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION	See above	N/A
	A TOOL is required when it is possible to prevent the devices from operating	See above	N/A
8.4.3	Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one s after disconnecting the plug of ME EQUIPMENT or its parts (V) :	See appended Table 8.4.3	Pass
	A triggering circuit used to ensure disconnection occurred at peak of supply voltage waveform	Test was repeated until worst case was observed	N/A
	When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC .. :	No such voltage after tests.	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 45µC .. :	No such capacitive circuit used	N/A
	A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL	See above	N/A
	Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, DB: 2002-10), and manual discharging device specified in technical description..... :	See above	N/A
8.5	Separation of parts		Pass
8.5.1	MEANS OF PROTECTION (MOP)		Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	MWAx0yz and MWBx0yz: Two means of protection for accessible parts provided by reinforced insulation of plastic enclosure. Power supply output separated from live parts by double/reinforced insulation MVAx0yz and MVBx0yz: Device is a component power supply, to be evaluated in end use application	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	Each means of protection categorized as MOPP	Pass
	Varnishing, enameling, oxidation, and similar protective finishes and coatings with sealing compounds replasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION	Not used as means of protection	Pass
	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	Not used as means of protection	Pass
	RISK MANAGEMENT PROCESS taken into consideration for MEANS OF PATIENT PROTECTION		N/A
	Components and wiring forming a MEANS OF PROTECTION comply with 8.10	Compliance with clause 8.10 confirmed.	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	Considered accordingly	Pass
8.5.1.2	MEANS OF PATIENT PROTECTION (MOPP)		Pass
	Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6	MWAx0yz and MWBx0yz series: Complies with dielectric strength test of Clause 8.8 MVAx0yz and MVBx0yz series: Complies with dielectric strength test of Clause 8.8, however end use application to be considered	Pass
	CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12	See insulation diagram	Pass
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6		Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	Y1 caps are certified according to IEC 60384-14 and considered as one MOPP	Pass
	Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	Y1 capacitors in series are rated for working voltage across the pair and have the same nominal capacitance	Pass
	Voltage Total Working (V) and C Nominal (μF) :	240, 0.0022	—
8.5.1.3	MEANS OF OPERATOR PROTECTION (MOOP)	Device evaluated to MOPP requirements	N/A
	Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:	See above	N/A
	– dielectric strength test of 8.8 at test voltage of Table 6; or	See above	N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	See above	N/A
	CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:	See above	N/A
	– limits of Tables 13 to 16 (inclusive); or	See above	N/A
	– requirements of IEC 60950-1 for INSULATION CO-ORDINATION	See above	N/A
	PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6, or	See above	N/A
	– requirements and tests of IEC 60950-1 for protective earthing :	See above	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 above	N/A
	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 above	N/A
	Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance	See above	N/A
	Voltage Total Working (V) and C Nominal (μF) :	See above	—

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	See above	N/A
	A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION..... :	See above	N/A
	A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION :	See above	N/A
8.5.2	Separation of PATIENT CONNECTIONS		N/A
8.5.2.1	PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to maximum MAINS VOLTAGE and complied with limit for PATIENT LEAKAGE CURRENT at 110 % of max. MAINS VOLTAGE :	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART	See above	N/A
	PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function	See above	N/A
	MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS :	See above	N/A
	Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART	See above	N/A
	LEAKAGE CURRENT tests conducted per 8.7.4 :	See above	N/A
	Dielectric strength test conducted per 8.8.3.... :	See above	N/A
	CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable	See above	N/A
	A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s	See above	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 :	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low	See above	N/A
	LEAKAGE CURRENT tests conducted per 8.7.4 :	See above	N/A
	Dielectric strength test conducted per 8.8.3.... :	See above	N/A
	Relevant CREEPAGE and CLEARANCES measured per 8.9 and Tables 11 to 16 as applicable	See above	N/A
	The RISK MANAGEMENT FILE reviewed	Device is a component power supply risk management to be evaluated in the end use	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	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter	See above	N/A
	– CLEARANCE between connector pins and a flat surface is at least 0.5 mm	See above	N/A
	– conductive part pluggable into a mains socket protected from 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	See above	N/A
	– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N, except when RISK MANAGEMENT PROCESS indicated no unacceptable RISK existed from contact with objects other than a mains socket or a flat surface	See above	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)..... :	Maximum rated voltage 240Vac	Pass
	When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for poly-phase ME EQUIPMENT (V)	Single phase	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 240V	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).....	AC mains only	N/A
	– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V).....	Met by approved components	Pass
	– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	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)	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	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	N/A
8.5.5	DEFIBRILLATION-PROOF APPLIED PARTS		N/A
8.5.5.1	Classification “DEFIBRILLATION-PROOF APPLIED PART” applied to one APPLIED PART in its entirety, but not separate functions of same APPLIED PART	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	Possibility of an OPERATOR receiving a shock from such parts taken into consideration in RISK MANAGEMENT PROCESS	See above	N/A
	Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) No hazardous electrical energies appear during a discharge of cardiac defibrillator	See above	N/A
	b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS	See above	N/A
8.5.5.2	Means provided to limit energy delivered to a 100 Ω load to at least 90% of energy delivered to this load with ME EQUIPMENT disconnected ..	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	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	MWAx0yz and MVAx0yz: Requirements were applied accordingly MWBx0yz and MVBx0yz: Class II devices	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	Method not used	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..... :	MWAx0yz: Protective earth terminal is provided in an approved appliance inlet MVAx0yz: Device provided with an eyelet for connection to the protective earth via a screw. Additional consideration and requirements are to be evaluated in end use application MWBx0yz and MVBx0yz: Class II devices	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	MWAx0yz: Protective earth terminal is provided in an approved appliance inlet MVAx0yz: Device provided with an eyelet for connection to the protective earth via a screw. Additional consideration and requirements are to be evaluated in end use application MWBx0yz and MVBx0yz: Class II devices	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside..... :	MWAx0yz: Protective earth terminal is provided in an approved appliance inlet MVAx0yz: Screw used for connection of protective earth to power supply eyelet is not part of this evaluation, consideration and requirements are to be evaluated in end use application MWBx0yz and MVBx0yz: Class II devices	N/A
	Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL	MWAx0yz: Protective earth terminal is provided in an approved appliance inlet MVAx0yz: Device provided with an eyelet for connection to the protective earth via a screw. MWBx0yz and MVBx0yz: Class II devices	Pass
	PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing	MWAx0yz and MVAx0yz: Protective earth terminal not used for any purpose other than earthing MWBx0yz and MVBx0yz: Class II devices	Pass
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	MWAx0yz and MVAx0yz: PROTECTIVE EARTH CONNECTION not used for a moving part MWBx0yz and MVBx0yz: Class II devices	Pass
8.6.4	a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop	MWAx0yz and MVAx0yz: See appended Table 8.6.4 MWBx0yz and MVBx0yz: Class II devices	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	MWAx0yz and MVAx0yz: Impedance of protective earth connection doesn't exceed values stated in clause 8.6.4 a) MWBx0yz and MVBx0yz: Class II devices	N/A
8.6.5	Surface coatings		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Poorly conducting surface coatings on conductive elements removed at the point of contact	No surface coating used	N/A
	Coating not removed when requirements for impedance and current-carrying capacity met	See above	N/A
8.6.6	Plugs and sockets		Pass
	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	MWAx0yz: Protective earth terminal makes first and breaks last. MVAx0yz: Not provided with plug and socket connection to mains MWBx0yz and MVBx0yz: Class II devices	Pass
	- applied also where interchangeable parts are PROTECTIVELY EARTHED	No such interchangeable parts are provided	Pass
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 terminals for potential equalization provided	N/A
	– Risk of accidental disconnection minimized in NORMAL USE	See above	N/A
	– Terminal allows conductor to be detached without a TOOL	See above	N/A
	– Terminal not used for a PROTECTIVE EARTH CONNECTION	See above	N/A
	– Terminal marked with symbol 8 of Table D.1 (i.e., symbol IEC 60417-5021)	See above	N/A
	– Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard	See above	N/A
	POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR	See above	N/A
8.6.8	FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION		Pass
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	MWAx0yz and MVAx0yz: Class I devices MWBx0yz and MVBx0yz: No such internal screens provided	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Two MEANS OF PROTECTION provided by insulation of internal screens and all internal wiring connected to them with a related explanation in technical description :	MWAx0yz and MVAx0yz: Class I devices MWBx0yz and MVBx0yz: No such internal screens provided	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 Tables 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 Tables 8.7	Pass
8.7.2	Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except	Allowable values in 8.7.3 were applied	Pass
	– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)	MWAx0yz and MVAx0yz: See clause 8.6.4 b) MWBx0yz and MVBx0yz: Class II devices	N/A
	– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time	MWAx0yz and MVAx0yz: Interruption of one supply conductor was tested MWBx0yz and MVBx0yz: Class II devices	Pass
	– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION	Single fault condition of short circuiting of one constituent part of double insulation was not measured	Pass
	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	Single fault conditions were not applied with special test conditions	Pass
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. :	Measuring device was used accordingly	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 :	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	c) TOUCH CURRENT did not exceed 100 μ A in NORMAL CONDITION and 500 μ A in SINGLE FAULT CONDITION (I_{TNC} , I_{TSFC})..... :	MWAx0yz and MWBx0yz: Values were not exceeded. See appended table 8.7B MVAx0yz and MVBx0yz: Device is a built in power supply, to be evaluated in end use application	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I_{ENC}, I_{ESFC})	MWAx0yz and MVAx0yz: Values were not exceeded. See appended table 8.7B MWBx0yz and MVBx0yz: Class II devices	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 equipment	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	No such device used for measurement.	N/A
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	Outputs are separated from live parts by reinforced insulation	Pass
	Insulation exempted from test (complies with clause 4.8)	No such insulation provided	N/A
	Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8	Device tested to MOPP requirements	N/A
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	MWAx0yz and MWBx0yz: Enclosure	Pass
	b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:	MWAx0yz and MWBx0yz: Three layers of tape used on isolation transformer T1 and wrapped around heat sinks HS1 and HS2 MVAx0yz and MVBx0yz: Three layers of tape used on isolation transformer T1 and wrapped around heat sink HS2	Pass
	– at least two layers of material, each passed the appropriate dielectric strength test, or	See below	N/A
	– three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test	Three layers of approved tape plus approved triple insulated wire used on primary windings	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION	See below	N/A
	Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION	Two layers tested for two MOPP	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	No such wires used	N/A
	c) Wire with solid insulation, other than solvent based enamel, complying with a)	No such wires used	N/A
	d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L	No such wires used	N/A
	e) Finished wire with spirally wrapped or multi-layer extruded insulation, complying with Annex L	Approved triple insulated wire complies with annex L	Pass
	– BASIC INSULATION: minimum two wrapped layers or one extruded layer	See below	N/A
	– SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded	See below	N/A
	– REINFORCED INSULATION: minimum three layers, wrapped or extruded	Approved triple insulated wire complies with annex L	Pass
	In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values	No such wires used	N/A
	Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension..... :	See above	N/A
	Finished component complied with routine dielectric strength tests of 8.8.3..... :	See above	N/A
	Tests of Annex L not repeated since material data sheets confirm compliance..... :	See above	N/A
8.8.3	Dielectric Strength		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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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 :	Device is a component power supply risk management to be evaluated in the end use	N/A
	Satisfactory evidence of compliance provided by manufacturer for resistance to heat :	See below	N/A
	Tests conducted in absence of satisfactory evidence for resistance to heat :	Test was conducted	Pass
	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	MWAx0yz and MWBx0yz: Enclosure was subjected to ball pressure test. Tested at 100°C	Pass
	b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C) :	Transformer bobbins were subjected to ball pressure test. Tested at 125°C	Pass
	Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION	See above	Pass
8.8.4.2	Resistance to environmental stress		N/A
	Insulating characteristics and mechanical strength of all MEANS OF PROTECTION not likely to be impaired by environmental stresses including deposition of dirt resulting from wear of parts within EQUIPMENT, potentially reducing CREEPAGE and CLEARANCES below 8.9	MWAx0yz and MWBx0yz series: No impairment by environmental stress is expected No deposition of dirt or dust is expected over the life expectancy of the equipment MVAx0yz and MVBx0yz series: No impairment by environmental stress is expected No deposition of dirt or dust is expected over the life expectancy of the equipment however end use application to be considered	N/A
	Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY OR REINFORCED INSULATION	No such beads used	N/A
	Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION	No heating conductors used	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa $\pm$ 70 kPa, with an effective capacity of at least 10 times volume of samples	No rubber used	N/A
	There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C $\pm$ 2 °C for 96h, and afterwards, left at room temperature for at least 16h	See above	N/A
8.9	CREEPAGE DISTANCES and AIR CLEARANCES		Pass
8.9.1.1	CREEPAGE DISTANCES and AIR CLEARANCES are $\geq$ to values in Tables 11 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15	Creepage distances and air clearances between parts of opposite polarity are greater than values in table 11 See insulation diagram	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	No means of protection per IEC 60950-1	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 inorganic insulating materials	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	Method not used	N/A
8.9.1.5	ME EQUIPMENT RATED to operate at an altitude of 2000 m	No specified altitude was declared by manufacturer Equipment is rated to operate at an altitude $\leq$ 2000m	Pass
	ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m) :	See above	N/A
	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	Power supply is not intended to be used in pressurized environments	N/A
	CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE	See above	N/A
8.9.1.6	When WORKING VOLTAGE was between those in Tables 11 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:		Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– 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)..... :	Linear interpolation was taken into account See insulation diagram	Pass
	– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm)..... :	No such working voltages above 2800 V peak or d.c.	N/A
	– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied	In the case, higher values were applied.	Pass
8.9.1.7	Material groups classified in accordance with Table 9 (Material Group)..... :	No comparative tracking index is provided Assuming class IIIb	Pass
	Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112	No test data for material according to IEC 60112 provided	N/A
	Material of unknown group considered IIIb	Assuming class IIIb	Pass
8.9.1.8	– Pollution degree 1: Micro-environment sealed to exclude dust and moisture		N/A
	– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation	Pollution degree 2 was applied	Pass
	– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation	See above	N/A
	– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions	See above	N/A
	Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION	See above	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	See above	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	Mains transient voltage determined accordingly	Pass
	V _{MT} Peak (V)	2,500 V _{peak}	—
	V _{MN} r.m.s (V)	240 V _{rms}	—

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	Additional clearance were not applied	N/A
8.9.1.11	SUPPLY MAINS overvoltage category II applied according to IEC 60664-1	Overvoltage category II was applied for mains part	Pass
	For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used	See above	N/A
	When PATIENT protection (Table 12) is required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for Cl. 8.9 used	See above	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)	Overvoltage category I was applied for the secondary circuit	Pass
	Table 15 applied to earthed SECONDARY CIRCUIT OR INTERNALLY POWERED ME EQUIPMENT	No clearance and creepage are required	N/A
	Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS	See above	N/A
	Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I	See above	N/A
	Table 15 column for circuits not subject to transient overvoltages applied to:	See above	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	See above	N/A
	– circuits in INTERNALLY POWERED ME EQUIPMENT	Not such type of equipment	N/A
8.9.1.13	For PEAK WORKING VOLTAGES above 1400 V peak or d.c. Table 15 not applied since all the following conditions were met:	Working voltage does not exceed 1400 V	N/A
	– CLEARANCE was at least 5 mm	See above	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	See above	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	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I	See above	N/A
	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	See above	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	Creepage distance was calculated accordingly	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-proof applied part provided	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..... :	Creepage and clearance between parts of opposite polarity are required before primary fuses	N/A
	b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths	No such grooves	N/A
	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	No reduction of distance was identified	Pass
	Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE	No such movement was identified	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	Insulating compounds not used	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	See above	N/A
8.9.3.2	For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6..... :	Insulating compounds not used	N/A
	Cracks or voids in insulating compound affecting homogeneity of material didn't occur	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.3.3	Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint	Insulating compounds not used	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:	See above	N/A
	– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage	See above	N/A
	– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage	See above	N/A
8.9.3.4	One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times.....	Insulating compounds not used	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	Device is a component power supply risk management to be evaluated in the end use	N/A
8.10.2	Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION	All conductors and connectors securely mounted	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	Device is a component power supply risk management to be evaluated in the end use	N/A
	Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION	Considered as a single fault condition.	Pass
	Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS due to poor contact	Wires not secured by clamping means	N/A
8.10.3	Flexible cords detachable without a TOOL used to 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	No interconnection of equipment used	N/A
8.10.4	Cord-connected HAND-HELD parts and cord-connected foot-operated control devices		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	Not hand-held or foot-operated	N/A
	d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple	See above	N/A
	42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit	See above	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	Not hand-held or foot-operated	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	See above	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	No moving parts	N/A
	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	Appropriate construction used, unlikely for damage to occur during assembly	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 rollers used	N/A
8.10.7	a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed	Insulating sleeve is fixed accordingly	Pass
	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	Method not used	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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 :	MWAx0yz: Approved internal wiring rated 105°C. MWBx0yz, MVAx0yz and MVBx0yz: Not provided with internal wiring	Pass
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..... :	MWAx0yz and MWBx0yz: All parts are disconnected from the supply by the appliance coupler, which is accessible at all times. MVAx0yz and MVBx0yz: Requires a suitable disconnect to be provided and evaluated in end use application	Pass
	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)	MWAx0yz and MWBx0yz series: Not a permanently installed device MVAx0yz and MVBx0yz: Device is a component power supply and will not be installed in permanently installed equipment	N/A
	b) Means of isolation incorporated in ME EQUIPMENT, and external means described in technical description :	Device is a component power supply not provided with instructions	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 :	Mains switch not used	N/A
	d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead	Power cord not part of this 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	Mains switch not used	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) :	MWAx0yz and MWBx0yz: Provided with an appliance inlet complying with IEC 60320-1 MVAx0yz and MVBx0yz: Suitable disconnect device to be provided and evaluated in the end use application	Pass
	g) A fuse or a semiconductor device not used as an isolating means	Fuses were not considered as an isolating means	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device	Such device is not provided	Pass
	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	MWAX0yz and MWBX0yz: All circuits are de-energized by appliance inlet. MVAx0yz and MVBx0yz: Device is a component power supply Additional consideration and requirements are to be evaluated in end use application	Pass
	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)	See above	N/A
	For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause	See above	N/A
	Standard test finger of Fig 6 applied	See above	N/A
8.11.2	MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2	No multiple socket outlets used	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	Power supply cord not evaluated	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).. :	See above	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	See above	N/A
8.11.3.3	NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm² Cu)..... :	See above	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	See above	N/A
8.11.3.5	Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	MWAx0yz and MWBx0yz: Provided with an appliance inlet complying with IEC 60320-1 MVAx0yz and MVBx0yz: Not provided with an appliance coupler	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:	See above	N/A
	– insulating material, or	See above	N/A
	– metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or	See above	N/A
	– metal provided with an insulating lining affixed to cord anchorage, 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	See above	N/A
	c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation	See above	N/A
	d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage	See above	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	See above	N/A
	f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR	See above	N/A
	Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 :	See above	N/A
	Cord subjected to a torque in Table 18 for 1 min immediately after pull tests	See above	N/A
	Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	CREEPAGE and CLEARANCES not reduced below limits in 8.9	See above	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	See above	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	MWAx0yz and MWBx0yz: Provided with an appliance inlet complying with IEC 60320-1 MVAx0yz and MVBx0yz: Device is a component power supply. Additional consideration and requirements are to be evaluated in end use application	N/A
	Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or	See above	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) :	See above	N/A
	Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance	See above	N/A
	Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D :	See above	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	No mains terminal device MWAx0yz and MWBx0yz: Not provided with mains wiring, appliance inlet soldered directly to PWB MVAx0yz and MVBx0yz: Device is a built in power supply provided with one AMP type mains connection (L/N) and eyelet for connection to the protective earth via a screw Additional consideration and requirements for wiring of mains parts are to be evaluated in end use application	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	See above	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	See above	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	See above	N/A
8.11.4.2	Arrangement of MAINS TERMINAL DEVICES		N/A
	a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection	No mains terminal device	N/A
	b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6	See above	N/A
	c) Marking of MAINS TERMINAL DEVICES complied with 7.3	See above	N/A
	d) MAINS TERMINAL DEVICES not accessible without use of a TOOL	See above	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	See above	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 mains terminal device	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 mains terminal device	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	No mains terminal device	N/A
	Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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.... :	Fuse provide in the line and neutral conductor	Pass
	– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT	MWAx0yz and MWBx0yz: Not a permanently installed device MVAx0yz and MVBx0yz: Device is a component power supply and will not be installed in permanently installed equipment	N/A
	– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts of opposite polarity within MAINS PART, and between all parts of MAINS PART and earth, and such provisions continued within all components	Fuses not omitted	N/A
	Effect of short-circuit fault conditions in other circuits taken into consideration before eliminating fuses or OVER-CURRENT RELEASES	See above	N/A
	Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit :	F1 and F2 rated 5.0A, 250V. See appended Table 8.10	Pass
	A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR	MWAx0yz and MVAx0yz: Protective earth conductor not fused MWBx0yz and MVBx0yz: Class II devices	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	No such high breaking capacity is presumed	N/A
	Justification for omission of fuses or OVER-CURRENT RELEASES is in RISK MANAGEMENT FILE	Fuses not omitted	N/A
8.11.6	Internal wiring of the MAINS PART		Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE and protective devices is not less than minimum required for POWER SUPPLY CORD as in clause 8.11.3.3 (mm² Cu)..... :	MWAx0yz and MWBx0yz: Not provided with mains internal wiring. Device is provided with an appliance inlet complying with IEC 60320-1 soldered to PCB MVAx0yz and MVBx0yz: Not provided with mains internal wiring. Device is provided with an AMP type mains connection (L/N) soldered to PWB.	N/A
	b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents..... :	Size of tracks on PWB between mains connector and fuses are sufficient to prevent fire. No hazardous situation occurred during fault testing	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	See appended table 13.2	Pass

9	PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS		Pass
9.1	ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)	MWAx0yz and MWBx0yz: Device complies with Clause 4 and Clause 15.3 MVAx0yz and MVBx0yz: Device complies with Clause 4. Device is a component power supply, to be evaluated in end use application to requirements of Clause 15.3	Pass
9.2	HAZARDS associated with moving parts		N/A
9.2.1	When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level.....:	No moving parts	N/A
	Risk from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)	See above	N/A
	RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its function	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Warnings marked on ME EQUIPMENT or included in instructions for use when HAZARDS persisted after implementing all reasonable protective measures.....:	See above	N/A
9.2.2	TRAPPING ZONE		N/A
9.2.2.1	ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:	No trapping zone	N/A
	– Gaps in Clause 9.2.2.2, or	See above	N/A
	– Safe distances in Clause 9.2.2.3, or	See above	N/A
	– GUARDS and protective measures in 9.2.2.4, or	See above	N/A
	– Continuous activation in Clause 9.2.2.5	See above	N/A
	Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE OF ME EQUIPMENT OR ME SYSTEM	See above	N/A
9.2.2.2	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20 ..:	No trapping zone	N/A
9.2.2.3	A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13852	No trapping zone	N/A
	Distances measured from expected positions of OPERATOR, PATIENT, and others near EQUIPMENT in NORMAL USE or under foreseeable misuse	See above	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 zone	N/A
9.2.2.4.2	FIXED GUARDS held in place by systems that cannot be dismantled without a TOOL	No trapping zone	N/A
9.2.2.4.3	Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open	No trapping zone	N/A
	– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,	See above	N/A
	– absence or failure of one of their components prevents starting, and stops moving parts	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Movable GUARDS complied with all applicable tests as confirmed by review of RISK MANAGEMENT FILE	See above	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 moving parts	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	See above	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	See above	N/A
	RISK MANAGEMENT FILE reviewed and all conditions confirmed	See above	N/A
9.2.2.5	Continuous activation		N/A
	TRAPPING ZONE not considered to present a MECHANICAL HAZARD where impractical to make TRAPPING ZONE inaccessible when:	No trapping zone	N/A
	a) movement was in OPERATOR'S field of view	See above	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	See above	N/A
	Manually operated movements complied with this clause since mass and velocity allowed adequate control of positioning without causing an unacceptable RISK	See above	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 ...:	See above	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 moving parts	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	See above	N/A
9.2.3	Other HAZARDS associated with moving parts		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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 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 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 such devices provided	N/A
	a) Emergency stopping device reduced RISK to an acceptable level	See above	N/A
	b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM	See above	N/A
	c) Emergency stopping device actuator was readily accessible to OPERATOR	See above	N/A
	d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT	See above	N/A
	e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original HAZARD	See above	N/A
	f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like	See above	N/A
	g) Means for stopping of movements operate as a result of one single action	See above	N/A
	h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls	See above	N/A
	i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 (symbol IEC 60417-5638, DB:2002-10) or "STOP"	See above	N/A
	j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	k) Emergency stopping device is suitable for its application	See above	N/A
9.2.5	Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a protective measure, or emergency stopping, and	No moving parts or patient restraints used	N/A
	– Uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented	See above	N/A
	– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented	See above	N/A
	– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way	See above	N/A
9.3	Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in an unacceptable RISK avoided or covered	All edges smooth and round	Pass
9.4	Instability HAZARDS		Pass
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	MWx0yz and MWBx0yz: Does not overbalance MVAx0yz and MVBx0yz: Stability to be evaluated in end use product	Pass
9.4.2	Instability – overbalance		Pass
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)	MWx0yz and MWBx0yz: Equipment did not overbalance at 10° MVAx0yz and MVBx0yz: Stability to be evaluated in end use product	Pass
9.4.2.2	Instability excluding transport		Pass
	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)	MWx0yz and MWBx0yz: Equipment did not overbalance at 5° MVAx0yz and MVBx0yz: Stability to be evaluated in end use product	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	See above	N/A
9.4.2.3	Instability from horizontal and vertical forces		Pass
	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	Equipment is less than 25Kg	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)	See above	N/A
	ME EQUIPMENT did not overbalance when placed on a horizontal plane, and a force of 25% of its weight, but not more than 220 N, applied in different directions, except a direction with an upward component	See above	N/A
	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)	Equipment did not overbalance	Pass
	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	Equipment did not overbalance	Pass
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	Device is a component power supply, to be evaluated in end use application	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)....:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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 $\pm$ 0.1 m/s for manual or with max speed for motor driven MOBILE ME EQUIPMENT.....:	See above	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.....:	See above	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	See above	N/A
	– Assessment criteria in Clause 9 and 11.6 used	See above	N/A
	– Dielectric strength test of 8.8.3 conducted to evaluate integrity of solid SUPPLEMENTARY or REINFORCED INSULATION	See above	N/A
	– CREEPAGE DISTANCES and AIR CLEARANCES measured compared favourably with min distances in clause 8.9	See above	N/A
	Small chips not adversely affecting protection against electric shock or moisture, disregarded	See above	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	Device is a component power supply, to be evaluated in end use application	N/A
	b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements of ME EQUIPMENT or its parts in transport position	See above	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	See above	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).....:	See above	N/A
	RISK due to any initial movement assessed taking into consideration NORMAL USE of ME EQUIPMENT	See above	N/A
9.4.3.2	Instability excluding transport		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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).....:	Device is a component power supply, to be evaluated in end use application	N/A
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT	See above	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	See above	N/A
	Further movement of ME EQUIPMENT (after initial elastic movement), was no more than 50 mm when a force of 25 % of weight of unit, but less than 220 N, applied in different directions, except a direction with an upwards component, at highest point of ME EQUIPMENT but ≤ 1.5 m from floor	See above	N/A
	RISK due to initial movements assessed taking into consideration NORMAL USE of ME EQUIPMENT	See above	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	Equipment mass is less than 20 kg	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	See above	N/A
	b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying	Equipment mass is less than 20 kg	N/A
	c) Carrying handles and grips and their means of attachment withstood loading test	No handles or grips	N/A
9.5	Expelled parts HAZARD		N/A
9.5.1	Suitability of means of protecting against unacceptable RISK of expelled parts determined by assessment and examination of RISK MANAGEMENT FILE.....:	No expelled parts	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.5.2	Cathode ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965	No CRTs	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	Equipment does not produce acoustic energy or vibration	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	Equipment does not produce acoustic energy	N/A
	– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA).....	See above	—
	- 83 dBA (when halving the cumulative exposure time) (dBA)	See above	—
	– 140 dB un-weighted sound pressure level for impulsive or impact acoustic energy (dB).....	See above	—
9.6.2.2	RISK MANAGEMENT FILE examined for RISKS associated with infrasound or ultrasound, when present, addressed in RISK MANAGEMENT PROCESS	Equipment does not produce infrasound or ultrasound	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	Equipment does not produce vibration	N/A
	– 2.5 m/s ² for a cumulative time of 8 h during a 24 h period (m/s ²)	See above	N/A
	– Accelerations for different times, inversely proportional to square root of time (m/s ²).....	See above	N/A
9.7	Pressure vessels and parts subject to pneumatic and hydraulic pressure		N/A
9.7.1	Requirements of this clause applied to vessels and parts of ME EQUIPMENT subject to pressure resulting in rupture and unacceptable RISK	No pressure vessels or parts subjected to pressure	N/A
	Parts of a pneumatic or hydraulic system used as a support system, comply with 9.8	See above	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 or parts subjected to pressure	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– No unacceptable RISK resulted from loss of pressure or loss of vacuum	See above	N/A
	– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure	See above	N/A
	– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects	See above	N/A
	– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply	See above	N/A
	Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible	See above	N/A
	– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity	See above	N/A
9.7.3	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 or parts subjected to pressure	N/A
	a) RATED maximum supply pressure from an external source	See above	N/A
	b) Pressure setting of a pressure-relief device provided as part of assembly	See above	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	See above	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 or parts subjected to pressure	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 kPaL	No pressure vessels or parts subjected to pressure	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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 or parts subjected to pressure	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 or parts subjected to pressure	N/A
	a) Connected as close as possible to pressure vessel or parts of system it is to protect	See above	N/A
	b) Installed to be readily accessible for inspection, maintenance, and repair	See above	N/A
	c) Could be adjusted or rendered inoperative without a TOOL	See above	N/A
	d) With discharge opening located and directed as to not to release material towards any person	See above	N/A
	e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK	See above	N/A
	f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure	See above	N/A
	g) No shut-off valve provided between a pressure-relief device and parts it is to protect	See above	N/A
	h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)	See above	N/A
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 incorporated in equipment	N/A
	– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD	See above	N/A
	– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– 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	See above	N/A
	– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES	See above	N/A
	– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials	See above	N/A
	Additional instructions provided on checking adequacy of surface of structure parts will be attached to	See above	N/A
9.8.2	Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest	No support systems incorporated in equipment	N/A
	Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing...	See above	N/A
	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 ...:	See above	N/A
9.8.3	Strength of PATIENT or OPERATOR support or suspension systems		N/A
9.8.3.1	ME EQUIPMENT parts supporting or immobilizing PATIENTS minimize RISK of physical injuries and accidental loosening of secured joints	No support systems incorporated in equipment	N/A
	SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts	See above	N/A
	Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications	See above	N/A
	Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS	See above	N/A
	Max allowable PATIENT mass > 135 kg stated in ACCOMPANYING DOCUMENTS	See above	N/A
	Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance	See above	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 incorporated in equipment	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	See above	N/A
	a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 m ² on a foot rest temporarily supporting a standing PATIENT or OPERATOR	See above	N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and tests	See above	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 m ² for 1 min (Kg).....	See above	N/A
	Damage or deflection resulting in an unacceptable RISK did not occur on foot rest and its secured joints	See above	N/A
	b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK.....	See above	N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing, and by a test	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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)	See above	N/A
	Deflection of support/suspension system resulting in an unacceptable RISK not occur	See above	N/A
9.8.3.3	Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE did not result in an unacceptable RISK as confirmed by following test:	No support systems incorporated in equipment	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.....	See above	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 $\geq$ to values in Table 21, rows 5 and 6, but less than 3 and 4	No MECHANICAL PROTECTIVE DEVICES	N/A
	b) MECHANICAL PROTECTIVE complies with the requirements as follows:	See above	N/A
	– Designed based on TOTAL LOAD, and includes effects of SAFE WORKING LOAD when applicable	See above	N/A
	– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7	See above	N/A
	– Activated before travel (movement) produced an unacceptable RISK	See above	N/A
	– Takes into account Clauses 9.2.5 and 9.8.4.3	See above	N/A
	Compliance confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications of materials and their processing	See above	N/A
9.8.4.2	Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE (e.g., a secondary cable)	No MECHANICAL PROTECTIVE DEVICES	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced	See above	N/A
9.8.4.3	MECHANICAL PROTECTIVE DEVICE intended to function once		N/A
	– Further use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE	No MECHANICAL PROTECTIVE DEVICES	N/A
	– 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	See above	N/A
	– ME EQUIPMENT permanently marked with safety sign 2 of Table D.2 (i.e., safety sign 7010-W001)	See above	N/A
	– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE or its location relative to MECHANICAL PROTECTIVE DEVICE is obvious to service personnel	See above	N/A
	– Compliance confirmed by examination of ME EQUIPMENT, ACCOMPANYING DOCUMENTS, RISK MANAGEMENT FILE, specifications and processing of materials, and following test	See above	N/A
	A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT	See above	N/A
	Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT OR OPERATOR	See above	N/A
	No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function	See above	N/A
9.8.5	Systems without MECHANICAL PROTECTIVE DEVICES		N/A
	Support system parts have TENSILE SAFETY FACTORS $\geq$ to values in Table 21, rows 1 and 2, and are not impaired by wear	No support systems	N/A
	Support system parts impaired by wear, however, they have TENSILE SAFETY FACTORS $\geq$ to values in Table 21, rows 3 and 4	See above	N/A
	Examination of ME EQUIPMENT and RISK MANAGEMENT FILE confirmed compliance	See above	N/A
10	PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS		N/A
10.1	X-Radiation		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
10.1.1	X-radiation dose-rate was $\leq 36 \text{ pA/kg}$ ($5 \text{ }\mu\text{Sv/h}$) (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 x-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	See above	N/A
	ME EQUIPMENT operated as in NORMAL USE at most unfavourable RATED MAINS VOLTAGE and controls adjusted to emit maximum radiation	See above	N/A
	Internal pre-set controls not intended for adjustment during EXPECTED SERVICE LIFE of ME EQUIPMENT not taken into consideration	See above	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) :	Equipment does not produce such radiation	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 x-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	Equipment does not produce visible electromagnetic radiation	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 infrared 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 indicated in RISK MANAGEMENT FILE :	Equipment does not produce x-radiation	N/A
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 ultraviolet radiation	N/A
11	PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS		Pass
11.1	Excessive temperatures in ME EQUIPMENT		Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	Pass
	Surfaces of test corner did not exceed 90 °C	Temperature of test corner did not exceed 90 °C	Pass
	THERMAL CUT-OUTS did not operate in NORMAL CONDITION	Thermal fuse did not operate	Pass
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 :	Device is a component power supply, to be evaluated in end use application	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 :	Device is a component power supply, to be evaluated in end use application	N/A
	Surfaces of APPLIED PARTS cooled below ambient temperatures that can also result in HAZARD evaluated as part of RISK MANAGEMENT PROCESS	See above	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 :	Device is a component power supply, to be evaluated in end use application	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	See above	N/A
	Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE	See above	N/A
11.1.4	GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL	No guards provided	N/A
11.2	Fire prevention		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	MWAX0yz and MWBX0yz: The equipment is well constructed and is sufficient to avoid fire hazards MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass
11.2.2	Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS		N/A
11.2.2.1	RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of fire under NORMAL OR SINGLE FAULT CONDITIONS when source of ignition in contact with ignitable material .. :	Not for use in oxygen rich 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	See above	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..... :	See above	N/A
	1) when temperature of material raised to its ignition temperature	See above	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	See above	N/A
	3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating	See above	N/A
	4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton	See above	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	See above	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	See above	N/A
	Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively	See above	N/A

IEC 60601-1			
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..... :	See above	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 :	See above	N/A
	1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3..... :	See above	N/A
	2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%) :	See above	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	See above	N/A
	Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE..... :	See above	N/A
	4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases :	See above	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	See above	N/A
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)	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques	See above	N/A
	– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means	See above	N/A
11.2.3	SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered		N/A
	– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2)	Not for use in oxygen rich environments	N/A
	– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3)	See above	N/A
	– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a)	See above	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)	See above	N/A
	– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas.....	See above	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	MWAx0yz and MWBx0yz series: Plastic enclosure, rated V-0, is well constructed with regard to avoid fire hazard MVAx0yz and MVBx0yz: Equipment not provided with a complete enclosure. Will need to be evaluated in final product.	Pass
	Constructional requirements were met, or	MWAx0yz and MWBx0yz series: Plastic enclosure, rated V-0, is well constructed with regard to avoid fire hazard MVAx0yz and MVBx0yz: Equipment not provided with a complete enclosure. Will need to be evaluated in final product.	Pass
	- constructional requirements specifically analysed in RISK MANAGEMENT FILE	Risk management not used	N/A
	Justification, when requirement not met	Requirements were met	N/A
	a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials	Flammability classification of insulating wire is FV-1, or better.	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data :	Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better.	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	See above	N/A
	b) Fire ENCLOSURE met following:		Pass
	1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh $\leq 2 \times 2$ mm centre to centre and wire diameter of at least 0.45 mm	MWAX0yz and MWBX0yz: No openings in the bottom of enclosure MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass
	2) No openings on the sides within the area included within the inclined line C in Fig 39	MWAX0yz and MWBX0yz: No openings on the sides of enclosure MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass
	3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and made of appropriate metal or of non-metallic materials, except constructions based on Table 25 and a mesh; FV-2 or better for TRANSPORTABLE ME EQUIPMENT, FV-1 or better for fixed EQUIPMENT, or STATIONARY EQUIPMENT per IEC 60695-11-10, determined by ENCLOSURE examination or flammability classification based on 11.3a)..... :	MWAX0yz and MWBX0yz: Enclosure is plastic rated V-0. See appended Table 8.10 MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass
11.4	ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics		N/A
	ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable anaesthetics (CATEGORY AP) or anaesthetics with oxidants (CATEGORY APG) comply with Annex G	Not for use with flammable anaesthetics	N/A
11.5	ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents		N/A
	MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE :	Not for use with flammable anaesthetics	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
11.6	Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT		N/A
11.6.1	Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT..... :	Not for use with liquids	N/A
11.6.2	Overflow in ME EQUIPMENT		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..... :	No liquid reservoir	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..... :	See above	N/A
11.6. 3	Spillage on ME EQUIPMENT and ME SYSTEM		N/A
	ME EQUIPMENT and ME SYSTEMS handling liquids in NORMAL USE positioned as in 5.4 a) and liquid with composition, volume, duration of spill, point of contact, and test conditions based on RISK MANAGEMENT PROCESS poured steadily on a point on top of ME EQUIPMENT :	Equipment does not require the use of liquid 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 :	See above	N/A
11.6.4	Leakage	See 13.2.6	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)..... :	Ordinary equipment	N/A
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in a HAZARDOUS SITUATION in NORMAL CONDITION or in a SINGLE FAULT CONDITION	See above	N/A
11.6.6	Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS		N/A
	ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected once using methods specified in instructions for use including any cooling or drying period :	Device is a component power supply, to be evaluated in end use application	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests, with no deterioration resulting in an unacceptable RISK present :	See above	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..... :	See above	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 :	Device is a component power supply, to be evaluated in end use application	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 :	See above	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..... :	See above	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	See above	N/A
11.8	Interruption and restoration of power supply did not result in a HAZARDOUS SITUATION, except interruption of its intended function	See above	N/A
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	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..... :	See above	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 :	See above	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 :	Device is a component power supply risk management to be evaluated in the end use	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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 :	Device is a component power supply risk management to be evaluated in the end use	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 .. :	Device is a component power supply risk management to be evaluated in the end use	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 :	Device is a component power supply risk management to be evaluated in the end use	N/A
12.4.5	Diagnostic or therapeutic radiation		N/A
12.4.5.1	Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation emitted by ME EQUIPMENT designed to produce radiation for diagnostic/therapeutic purposes	No such radiation	N/A
	Radiation safety ensured by compliance with requirements of appropriate standards		N/A
12.4.5.2	RISKS associated with diagnostic X-rays addressed in RISK MANAGEMENT PROCESS as confirmed in RISK MANAGEMENT FILE :	Not X-ray equipment	N/A
12.4.5.3	RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as confirmed by review of RISK MANAGEMENT FILE :	Not radiotherapy equipment	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..... :	No radiation produced	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 :	No acoustic pressure produced	N/A

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	No such events occurred	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur	MWAx0yz and MWBx0yz: No deformation of plastic enclosure occurred MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass
	– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 when measured as in 11.1.3..... :	Not provided with applied parts. Device is a component power supply, to be evaluated in end use application	N/A
	– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3..... :	See appended Tables 11.1.1	Pass
	–Allowable values for “other components and materials” in Table 22 times 1.5 minus 12.5 °C were not exceeded		Pass
	Limits for windings in Tables 26, 27, and 31 not exceeded		Pass
	Table 22 not exceeded in all other cases		Pass
	Temperatures measured according to 11.1.3		Pass
	SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:		Pass
	– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit, or	Output power exceeds 15W	N/A
	– Parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation	MWAx0yz and MWBx0yz: Parts and components are contained within fire enclosure MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable fire enclosure to be provided and evaluated in end use application	Pass
	After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function		Pass
13.1.3	– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed..... :	Did not exceed limits in single fault condition	Pass
	– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed :	See appended Table 8.7	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
13.1.4	ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS	No mechanical hazards were identified	Pass
13. 2	SINGLE FAULT CONDITIONS		Pass
13.2.1	During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) applied in least favourable combination :	See appended Table 13.2	Pass
13.2.2 – 13.2.12	ME EQUIPMENT complied with 13.2.2 -13.2.12..... :	See appended Table 13.2	Pass
13.2.13	ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to room temperature	Transformer tested	Pass
	ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted	No 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).	Plastic bobbins on transformer tested	Pass
13.2.13.2	ME EQUIPMENT with heating elements		N/A
	a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, or for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests of 13.2.13.2 b) & 13.2.13.2 c)	No heating elements provided	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 provided	N/A
	a 3) other ME EQUIPMENT with heating elements met test of 13.2.13.2 b)	No heating elements provided	N/A
	When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively	See above	N/A
	Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration	See above	N/A
	Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part	See above	N/A
	Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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 provided	N/A
	Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY	See above	N/A
	ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted	See above	N/A
	Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION	See above	N/A
	c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and	No heating elements provided	N/A
	1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS	See above	N/A
	2) When more than one control provided, they were disabled in turn	See above	N/A
	3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time	See above	N/A
13.2.13.3	ME EQUIPMENT with motors		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 provided	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	See above	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	See above	N/A
	a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT	See above	N/A
	b) Motor met running overload protection test of this clause when:	See above	N/A
	1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or	See above	N/A
	2) it is likely to be subjected to CONTINUOUS OPERATION while unattended	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C)..... :	See above	N/A
	Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps	See above	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	See above	N/A
	Test not conducted where electronic drive circuits maintained a substantially constant drive current	See above	N/A
	Test not conducted based on other justifications (justification)..... :	See above	N/A
	c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10	See above	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 $\leq 5^{\circ}\text{C}$ in one hour, or a protective device operated	For continuous operation	N/A
	When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle	See above	N/A
	Motor winding temperatures did not exceed values in 13.2.10	See above	N/A
	Insulation Class	See above	—
	Maximum temperature measured ($^{\circ}\text{C}$)..... :	See above	—

14	PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)		N/A
14.1	Requirements of this clause not applied to PEMS when it provided no BASIC SAFETY or ESSENTIAL PERFORMANCE, or	Not such type of equipment	N/A
	- when application of ISO 14971 showed that failure of PEMS does not lead to unacceptable RISK	See above	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	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	See above	N/A
	Assessment of PROCESSES cited in this Clause made by internal audits	See above	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 :	See above	N/A
14.3	RISK MANAGEMENT plan required by 3.5 of ISO 14971 includes reference to PEMS VALIDATION plan	See above	N/A
14.4	A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented	See above	N/A
	At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined	See above	N/A
	Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone	See above	N/A
	PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules	See above	N/A
	PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements	See above	N/A
14.5	A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained where appropriate	See above	N/A
	Problem resolution system meets the prescribed criteria depending on type of product:	See above	N/A
	– it is documented as a part of PEMS DEVELOPMENT LIFE-CYCLE	See above	N/A
	– it allows reporting of potential or existing problems affecting BASIC SAFETY or ESSENTIAL PERFORMANCE	See above	N/A
	– it includes an assessment of each problem for associated RISKS	See above	N/A
	– it identifies criteria that must be met for the issue to be closed	See above	N/A
	– it identifies the action to be taken to resolve each problem	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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	Not such type of equipment	N/A
	In addition to the material in ISO 14971, Annex D, list of possible sources for HAZARDS associated with PEMS includes specified causes	See above	N/A
	– failure of NETWORK/DATA COUPLING to provide characteristics necessary for PEMS to achieve its BASIC SAFETY OR ESSENTIAL PERFORMANCE	See above	N/A
	– undesired feedback [physical and data] (such as unsolicited/ out of range/ inconsistent input or input from electromagnetic interference)	See above	N/A
	– unavailable data	See above	N/A
	– lack of integrity of data	See above	N/A
	– incorrect data	See above	N/A
	– incorrect timing of data	See above	N/A
	– unintended interactions within & among PESS	See above	N/A
	– unknown aspects or quality of third-party software	See above	N/A
	– unknown aspects or quality of third-party PESS	See above	N/A
	– lack of data security, particularly vulnerability to tampering, unintended interaction with other programs and viruses	See above	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..... :	See above	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 :	See above	N/A
14.8	An architecture satisfying the requirement is specified for PEMS and each of subsystems :	See above	N/A
	The architecture specification makes use of considers the specified items to reduce RISK to an acceptable level, where appropriate:	See above	N/A
	a) COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS	See above	N/A
	b) fail-safe functions	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) redundancy	See above	N/A
	d) diversity;	See above	N/A
	e) partitioning of functionality	See above	N/A
	f) defensive design potentially limiting hazardous effects by restricting available output power or by introducing means to limit travel of actuators	See above	N/A
	g) allocation of RISK CONTROL measures to subsystems and components of PEMS	See above	N/A
	h) failure modes of components and their effects;	See above	N/A
	i) common cause failures	See above	N/A
	j) systematic failures	See above	N/A
	k) test interval duration and diagnostic coverage	See above	N/A
	l) maintainability	See above	N/A
	m) protection from reasonably foreseeable misuse	See above	N/A
	n) NETWORK/DATA COUPLING specification, when applicable	See above	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 :	See above	N/A
14.10	A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, OR RISK CONTROL measures :	See above	N/A
	– milestone(s) when VERIFICATION is to be performed for each function	See above	N/A
	– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION	See above	N/A
	– selection and utilization of VERIFICATION tools	See above	N/A
	– coverage criteria for VERIFICATION	See above	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	See above	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	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE providing methods & results of PEMS VALIDATION	See above	N/A
14.12	Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE	See above	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 :	See above	N/A
	a) characteristics of NETWORK/DATA COUPLING necessary for PEMS to achieve its INTENDED USE	See above	N/A
	b) list of HAZARDOUS SITUATIONS resulting from a failure of NETWORK/DATA COUPLING to provide the specified characteristics	See above	N/A
	c) instructions to RESPONSIBLE ORGANIZATION containing required information and warnings	See above	N/A
	– connection of PEMS to a NETWORK/DATA COUPLING that includes other equipment could result in previously unidentified RISKS and RESPONSIBLE ORGANIZATION shall identify, analyze, and control such RISKS	See above	N/A
	– subsequent changes to NETWORK/DATA COUPLING introducing new RISKS and requiring new analysis; and changes to NETWORK/DATA COUPLING include:	See above	N/A
	– NETWORK/DATA COUPLING configuration change	See above	N/A
	– connection of additional items to NETWORK/DATA COUPLING	See above	N/A
	– disconnecting items from NETWORK/DATA COUPLING	See above	N/A
	– update of equipment connected to NETWORK/DATA COUPLING	See above	N/A
	– upgrade of equipment connected to NETWORK/DATA COUPLING	See above	N/A
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 controls or indicators	N/A
15.2	Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance	No such parts	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring		N/A
15.3	Mechanical strength		Pass
15.3.1	Mold stress relief, push, impact, drop, and rough handling tests did not result in unacceptable RISK and ME EQUIPMENT displayed adequate mechanical strength	MWAx0yz and MWBx0yz: Enclosure tested MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass
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 ... :	MWAx0yz and MWBx0yz: No Damage MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass
	No damage resulting in an unacceptable RISK sustained as determined by examination of RISK MANAGEMENT FILE		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 :	MWAx0yz and MWBx0yz: No Damage MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass
	Test not applied to flat panel displays, platen glass of ME EQUIPMENT, or cathode ray tubes	No such displays used	N/A
	No damage resulting in an unacceptable RISK sustained as shown in RISK MANAGEMENT FILE		N/A
15.3.4	Drop test		N/A
15.3.4.1	Sample of HAND-HELD ME EQUIPMENT and HAND-HELD part with SAFE WORKING LOAD allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm $\pm$ 5 mm thick hardwood board lying flat on a concrete or rigid base..... :	Not hand-held equipment	N/A
	No unacceptable RISK resulted	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.3.4.2	Sample of PORTABLE ME EQUIPMENT and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 ± 5 mm thick hardwood board lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE (cm)	MWAx0yz and MWBx0yz: No Damage MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE		N/A
15.3.5	Each sample of MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests	Not such type of equipment	N/A
	a) Ascending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at $0.4 \text{ m/s} \pm 0.1 \text{ m/s}$ against an ascending hardwood step obstruction without the sample going over the obstruction	See above	N/A
	b) Descending step shock test conducted on the sample by pushing it 3 times in its normal direction of travel at $0.4 \text{ m/s} \pm 0.1 \text{ m/s}$ 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	See above	N/A
	c) Door frame shock test conducted on the sample by moving it 3 times in its normal direction of travel at $0.4 \text{ m/s} \pm 0.1 \text{ m/s}$, or for motor driven EQUIPMENT, at maximum possible speed against a hardwood vertical obstacle higher than EQUIPMENT contact point(s)	See above	N/A
	No damage resulting in an unacceptable RISK sustained as determined by examination of sample and RISK MANAGEMENT FILE	See above	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	See below	N/A
	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	MWAx0yz and MWBx0yz: No damage, tested at 100°C for 7 hours MVAx0yz and MVBx0yz series is not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	No damage resulting in an unacceptable RISK		Pass
15.3.7	INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT	Materials were selected in consideration of intended use, expected service life, and conditions for transport	Pass
	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	No such unacceptable risk was identified from corrosion, etc. during expected service life	Pass
15.4	ME EQUIPMENT components and general assembly		N/A
15.4.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular :	No such connectors provided	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 plugs provided	N/A
	b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable as verified by review of RISK MANAGEMENT FILE :	No medical gas connectors provided	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 such component used	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 such component used	N/A
	c) An independent non-SELF-RESETTING THERMAL CUT-OUT is, additionally, provided where a failure of a THERMOSTAT could constitute a HAZARD as verified by examination of design and RISK MANAGEMENT FILE :	Not provided with thermostat	N/A
	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	Operation of thermal fuse does not present a hazard, additional consideration to be evaluated in the end use device	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS	No such component 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:		Pass
	Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 1999, clauses 15, 17, J.15, and J.17 as applicable	No such component used	N/A
	ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13	Thermal fuse did not operated during testing	N/A
	SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified according to appropriate standards ..	No such component used	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 such component used	N/A
	Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards	No such component used	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	See above	N/A
	Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted	Thermal fuse not tested separately	N/A
	g) Protective device, provided on ME EQUIPMENT incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating	No fluid container	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 element	N/A
15.4.2.2	Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS	No such component used	N/A
15.4.3	Batteries		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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 provided	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	See above	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	See above	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	See above	N/A
15.4.3.4	Lithium batteries that could become a HAZARD complied with appropriate tests of IEC 60086-4	See above	N/A
	Tests of IEC 60086-4 waived on the lithium battery based on examination of design	See above	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 :	See above	N/A
	Protective device has adequate breaking capacity to interrupt the maximum fault current	See above	N/A
	Justification for OVER-CURRENT RELEASES OR FUSE exclusion is included in RISK MANAGEMENT FILE	See above	N/A
15.4.4	Indicator lights provided to indicate ME EQUIPMENT is ready for NORMAL USE, except when apparent to OPERATOR from normal operating position, and marking of 7.4.1 are insufficient for this purpose	See above	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	See above	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	See above	N/A
	Requirement not applied to heated stylus-pens for recording purposes	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	See above	N/A
	Colours of indicator lights complied with 7.8.1	See above	N/A
	Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE	See above	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..... :	Device is a component power supply risk management to be evaluated in the end use	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 controls	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	See above	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	See above	N/A
	When torque values per Table 30 applied between control knob and shaft of rotating controls for not less than 2 s, 10 times in each direction, knobs did not rotate :	See above	N/A
	Tests conducted by applying an axial force of 60 N for electrical components and 100 N for other components for 1 min when an axial pull was required in NORMAL USE with no unacceptable RISK :	See above	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 :	See above	N/A
	Torque values in Table 30 applied 10 times in each direction to rotating controls for 2 sec ... :	See above	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 :	See above	N/A
15.4.7	Cord-connected HAND-HELD and foot-operated control devices		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.7.1	a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1	Not hand-held or foot-operated control device	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..... :	See above	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	See above	N/A
	No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position	See above	N/A
15.4.7.3	a) Foot-operated control device is at least IPX1 & complies with tests of IEC 60529 (IP Code) .. :	See above	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)	See above	N/A
	Probability of occurrence estimated as part of RISK MANAGEMENT PROCESS	See above	N/A
15.4.8	Aluminum wires less than 16 mm ² in cross-sectional area are not used	No Aluminum wires used	N/A
15.4.9	a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed to prevent loss of oil in any position	No oil containers	N/A
	b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport	See above	N/A
	A pressure-release device operating during NORMAL USE is, optionally, provided	See above	N/A
	c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage	See above	N/A
	ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements	See above	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	Pass

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31		Pass
	Dielectric strength test of 8.8.3 conducted on transformer after short circuit and overload tests	See appended Table 15.5.2	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	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	One protective device used	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		Pass
	Dielectric strength tests were conducted in accordance with requirements of this clause with no breakdown of insulation system and no detectable deterioration of transformer	See appended Table 15.5.2	Pass
15.5.3	Transformers forming MEANS OF PROTECTION as required by 8.5 comply with IEC 61558-1:1997, Clause 5.12	See appended Table 8.10	Pass

16	ME SYSTEMS		N/A
16.1	After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK	Device is a component power supply, to be evaluated in end use application	N/A
	Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered	See above	N/A
	– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard	See above	N/A
	– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards	See above	N/A
	– tests performed in NORMAL CONDITION, except as specified	See above	N/A
	– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated	See above	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	See above	N/A
	Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards	See above	N/A
	Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM	See above	N/A
16.2	ACCOMPANYING DOCUMENTS of an ME SYSTEM		N/A
	Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM	Device is a component power supply, to be evaluated in end use application	N/A
	ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM	See above	N/A
	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	See above	N/A
	a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER	See above	N/A
	b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER	See above	N/A
	c) the required information is provided:	See above	N/A
	– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM	See above	N/A
	– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard	See above	N/A
	– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM	See above	N/A
	– additional safety measures to be applied during installation of ME SYSTEM	See above	N/A
	– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– additional measures to be applied during preventive maintenance	See above	N/A
	– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor	See above	N/A
	– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM	See above	N/A
	– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM	See above	N/A
	– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM	See above	N/A
	– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM	See above	N/A
	– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer	See above	N/A
	– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET	See above	N/A
	– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage	See above	N/A
	– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT	See above	N/A
	d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:	See above	N/A
	– adjustment, cleaning, sterilization, and disinfection PROCEDURES	See above	N/A
	– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard	See above	N/A
16.3	Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements	Device is a component power supply, to be evaluated in end use application	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
16.4	Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors, 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	Device is a component power supply, to be evaluated in end use application	N/A
16.5	Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed	Device is a component power supply, to be evaluated in end use application	N/A
	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	See above	N/A
	WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :	See above	N/A
16.6	LEAKAGE CURRENTS		N/A
16.6.1	TOUCH CURRENT in NORMAL CONDITION, from or between parts of ME SYSTEM within the PATIENT ENVIRONMENT, did not exceed 100 μ A :	Device is a component power supply, to be evaluated in end use application	N/A
	TOUCH CURRENT did not exceed 500 μ A in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR, from or between parts of ME SYSTEM within PATIENT ENVIRONMENT :	See above	N/A
16.6.2	Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET did not exceed 5 mA.. :	Device is a component power supply, to be evaluated in end use application	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 :	Device is a component power supply, to be evaluated in end use application	N/A
	Measurements made using a device as in clause 8.7.4.4	See above	N/A
16.7	ME SYSTEM complied with applicable requirements of Clause 9 when a MECHANICAL HAZARD existed :	Device is a component power supply, to be evaluated in end use application	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	See above	N/A
16.9	ME SYSTEM connections and wiring		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
16.9.1	Incorrect connection of accessible connectors, removable without a TOOL, prevented where a HAZARDOUS SITUATION could otherwise exist	Device is a component power supply, to be evaluated in end use application	N/A
	– Connectors complied with Clause 15.4.1	See above	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	See above	N/A
16.9.2	MAINS PARTS, components and layout	Device is a component power supply, to be evaluated in end use application	N/A
16.9.2.1	a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or	Device is a component power supply, to be evaluated in end use application	N/A
	– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or	See above	N/A
	– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer	See above	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	See above	N/A
	– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or	See above	N/A
	– marked to indicate the equipment or equipment parts it may safely be attached to	See above	N/A
	– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT	See above	N/A
	c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:	See above	N/A
	– CREEPAGE and CLEARANCES complied with 8.9	See above	N/A
	– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets	See above	N/A
	– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6, except total impedance for ME SYSTEM was up to 400 mΩ, or higher when conditions of 8.6.4 b) met (mΩ).. :	See above	N/A
	– ENCLOSURE complied with 8.4.2 d)	See above	N/A
	– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	– RATINGS of components are not in conflict with conditions of use	See above	N/A
	– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL	See above	N/A
	– POWER SUPPLY CORD complied with 8.11.3	See above	N/A
	d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:	See above	N/A
	– Separating transformer complied with IEC 61558-2-1, except requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 were not applied	See above	N/A
	– Separating transformer is CLASS I	See above	N/A
	– Degree of protection against ingress of water specified as in IEC 60529	See above	N/A
	– Separating transformer assembly marked according to 7.2 and 7.3	See above	N/A
	– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083	See above	N/A
16.9.2.2	Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part	See above	N/A
	Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL	See above	N/A
16.9.2.3	Conductors connecting different items within an ME SYSTEM protected against mechanical damage	See above	N/A

17	ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS		N/A
	RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review . :	Device is a component power supply risk management to be evaluated in the end use	N/A
	– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS	Device is a component power supply risk management to be evaluated in the end use	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	No such introduction	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
ANNEX G	PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES		N/A
G.2	Locations and basic requirements		N/A
G.2.1	Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5	The equipment is not an AP or APG category equipment	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	See above	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	See above	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	See above	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	See above	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	See above	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..... :	The equipment is not an AP or APG category equipment	N/A
	Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case	See above	N/A
	When above marking not possible, relevant information included in instructions for use ... :	See above	N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	See above	N/A
G.3.2	CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle ≥ 2 cm in diameter, with characters "AP" according to symbol 22 in Table D.1..... :	See above	N/A
	Marking is as large as possible for the particular case	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	When above marking not possible, the relevant information included in instructions for use ... :	See above	N/A
	Marking complied with tests and criteria of 7.1.2 and 7.1.3	See above	N/A
G.3.3	The marking 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	See above	N/A
G.3.4	ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts	See above	N/A
G.3.5	Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG	See above	N/A
G.4	Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT		N/A
G.4.1	a) CREEPAGE and CLEARANCES between points of POWER SUPPLY CORD connection are according to Table 12 for one MEANS OF PATIENT PROTECTION	The equipment is not an AP or APG category equipment	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	See above	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	See above	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	The equipment is not an AP or APG category equipment	N/A
	b) ENCLOSURE complies with requirements to minimize arcing and sparking due to penetration of foreign objects	See above	N/A
	– no openings on top covers of ENCLOSURE, except for openings for controls covered by control knobs	See above	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	See above	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	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	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	See above	N/A
G.4.3	a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures	See above	N/A
	– Use of antistatic materials with a limited electrical resistance as specified in G.4.3 b) ... :	See above	N/A
	– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor of medical room	See above	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 :	See above	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	See above	N/A
G.5	Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components		N/A
G.5.1	ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5 (inclusive)	The equipment is not an AP or APG category equipment	N/A
	Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 :	See above	N/A
G.5.2	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 :	See above	N/A
G.5.3	ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and U_{max} and I_{max} occurring in their circuits, and complied as follows:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Measured $U_{\max} \leq U_{zR}$ with I_{zR} as in Fig. G.1..... :	See above	N/A
	Measured $U_{\max} \leq U_c$ with $C_{\max}$ as in Fig. G.2 ... :	See above	N/A
	Measured $I_{\max} \leq I_{zR}$ with U_{zR} as in Fig G.1 :	See above	N/A
	Measured $I_{\max} \leq I_{zL}$ with $L_{\max}$ and a $U_{\max} \leq 24 \text{ V}$ as in Fig G.3 :	See above	N/A
	– Combinations of currents and corresponding voltages within the limitations $I_{zR} \cdot U_{zR} \leq 50 \text{ W}$ extrapolated from Fig G.1	See above	N/A
	No extrapolation made for voltages above 42 V	See above	N/A
	– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2 \text{ mJ}$ extrapolated from Fig G.2	See above	N/A
	No extrapolation made for voltages above 242V	See above	N/A
	$U_{\max}$, additionally, determined using actual resistance R when the equivalent resistance R was less than 8000 Ω	See above	N/A
	– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3 \text{ mJ}$ extrapolated from Fig G.3	See above	N/A
	No extrapolation made for inductances larger than 900 mH	See above	N/A
	– $U_{\max}$ was the highest supply voltage occurring in circuit under investigation with sparking contact open, taking into consideration MAINS VOLTAGE variations in 4.10	See above	N/A
	– $I_{\max}$ was the highest current flowing in circuit under investigation with sparking contact closed, taking into consideration MAINS VOLTAGE variations required in 4.10	See above	N/A
	– $C_{\max}$ and $L_{\max}$ taken as values occurring at the component under investigation producing sparks	See above	N/A
	– Peak value considered when a.c. supplied	See above	N/A
	– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent $U_{\max}$ and $I_{\max}$, either as d.c. or a.c. peak values in case of a complicated circuit... :	See above	N/A
	Temperature measurements made according to 11.1, and $U_{\max}$, $I_{\max}$, R, $L_{\max}$, and $C_{\max}$ determined with application of Figs G.1-G.3 .. :	See above	N/A
	Alternatively, compliance was verified by examination of design data:	See above	N/A
G.5.4	External ventilation with internal overpressure		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:	The equipment is not an AP or APG category equipment	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)	See above	N/A
	b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)..... :	See above	N/A
	Overpressure maintained at the site of potential ignition even when air or inert gas could escape through openings in ENCLOSURE necessary for normal operation of ME EQUIPMENT or its parts	See above	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	See above	N/A
	ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present	See above	N/A
	c) Ignition sources de-energized automatically by means used where G.4 does not apply, or complied with G.5 when during operation overpressure dropped below 50 Pa (Pa)..... :	See above	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) :	See above	N/A
G.5.5	ENCLOSURES with restricted breathing		N/A
	ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:	The equipment is not an AP or APG category equipment	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	See above	N/A
	b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h :	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained when the cords were stressed by bending or pulling	See above	N/A
	Cords are fitted with adequate anchorages to limit stresses	See above	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	See above	N/A
	Overpressure not reduced below 200 Pa	See above	N/A
	Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)	See above	N/A
	Operating temperature of external surface of ENCLOSURE was $\leq 150\text{ °C}$ in 25 °C (°C) :	See above	N/A
	Steady state operating temperature of ENCLOSURE also measured (°C) :	See above	N/A
G.6	CATEGORY APG ME EQUIPMENT, parts and components thereof		N/A
G.6.1	ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION	The equipment is not an AP or APG category equipment	N/A
	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	See above	N/A
G.6.2	Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION..... :	See above	N/A
G.6.3	Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS..... :	See above	N/A
	a) no sparks produced and temperatures did not exceed 90 °C , or	See above	N/A
	b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except $U_{\max}$ and $I_{\max}$ occurring in their circuits complied with requirements, taking $C_{\max}$ and $L_{\max}$ into consideration:	See above	N/A
	Measured $U_{\max} \leq U_{zR}$ with I_{zR} as in Fig. G.4 :	See above	N/A
	Measured $U_{\max} \leq U_{zC}$ with $C_{\max}$ as in Fig. G.5... :	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Measured $I_{\max} \leq I_{zR}$ with U_{zR} as in Fig G.4 :	See above	N/A
	Measured $I_{\max} \leq I_{zL}$ with $L_{\max}$ and a $U_{\max} \leq 24 \text{ V}$ as in Fig G.6 :	See above	N/A
	– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated	See above	N/A
	– $U_{\max}$ was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10	See above	N/A
	– $I_{\max}$ was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10	See above	N/A
	– $C_{\max}$ and $L_{\max}$ are values occurring in relevant circuit	See above	N/A
	– $U_{\max}$ additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000Ω	See above	N/A
	– Peak value taken into consideration when a.c. supplied	See above	N/A
	– An equivalent circuit calculated to determine max capacitance, inductance, and $U_{\max}$ and $I_{\max}$, either as d.c. or a.c. peak values in case of a complicated circuit :	See above	N/A
	– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components	See above	N/A
	Above requirement not applied to transformers complying with this standard	See above	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	See above	N/A
	Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or	See above	N/A
	Temperature measurements made in accordance with 11.1, or	See above	N/A
	$U_{\max}$, $I_{\max}$, R, $L_{\max}$ and $C_{\max}$ determined together with application of Figs G.4-G.6..... :	See above	N/A
	Alternatively, compliance verified by comparison with design data:	See above	N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
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..... :	The equipment is not an AP or APG category equipment	N/A
	Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE	See above	N/A
G.7	Test apparatus for flammable mixtures		N/A
	Test apparatus used was in accordance with this Clause and Fig G.7	The equipment is not an AP or APG category equipment	N/A

ANNEX 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	Approved triple insulated wire provided	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	No such insulation used	N/A
	Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap	See above	N/A
L.3	Type Test		N/A
	The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified	Approved triple insulated wire provided	N/A
	Temperature (°C)..... :	See above	—
	Humidity (%)..... :	See above	—
L.3.1	Dielectric strength		N/A
	Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted 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:	Approved triple insulated wire provided	N/A
	– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See above	N/A
	– 6000 V for REINFORCED INSULATION (V) :	See above	N/A
L.3.2	Flexibility and adherence		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1	Approved triple insulated wire provided	N/A
	Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown	See above	N/A
	Test voltage was at least the voltage in Tables 6 and 7 but not less than the following:	See above	N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See above	N/A
	– 3000 V for REINFORCED INSULATION (V) :	See above	N/A
	Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa :	See above	N/A
L.3.3	Heat Shock		N/A
	Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3, except test voltage applied between the wire and mandrel	Approved triple insulated wire provided	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	See above	N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See above	N/A
	– 3000 V for REINFORCED INSULATION (V) :	See above	N/A
	Oven temperature based on Table L.2 (°C)..... :	See above	—
	Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm ²)..... :	See above	N/A
	Dielectric strength test conducted at room temperature after removal from the oven	See above	N/A
L.3.4	Retention of electric strength after bending		N/A
	Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests	Approved triple insulated wire provided	N/A
	Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:	See above	N/A
	– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :	See above	N/A
	– 3000 V for REINFORCED INSULATION (V) :	See above	N/A
	Test voltage applied between the shot and conductor.	See above	N/A
	Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm ²) :	See above	N/A
L.4	Tests during manufacture		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
L.4.1	Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3	Approved triple insulated wire provided	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:	Approved triple insulated wire provided	N/A
	– 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)	See above	N/A
	– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V)	See above	N/A
L.4.3	Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1)	Approved triple insulated wire provided	N/A
	Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:	See above	N/A
	– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION	See above	N/A
	– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION	See above	N/A

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

4.2	RM RESULTS TABLE: Risk Management Process for ME Equipment or ME Systems		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
3.3a			
3.5e			
4.1			
4.2			
4.3			
4.4			
5			
6.1			
6.2			
6.3			
6.4			
6.5			
6.6			
6.7			
7			

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

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

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

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

4.7	RM RESULTS TABLE: Single Fault Condition for ME Equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			

4.8	RM RESULTS TABLE: Components of ME Equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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

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

4.11	TABLE: Power Input					Pass
Operating Conditions / Ratings		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Power factor (cos ϕ)
MWA100012z, 12Vdc@8.3A		90	50	2.146	113.84	-
MWA100012z, 12Vdc@8.3A		100	50	1.964	112.89	-
MWA100012z, 12Vdc@8.3A		115	50	1.582	111.56	-
MWA100012z, 12Vdc@8.3A		230	50	1.010	110.14	-
MWA100012z, 12Vdc@8.3A		240	50	0.981	110.03	-
MWA100012z, 12Vdc@8.3A		264	50	0.919	109.88	-
MWA100012z, 12Vdc@8.3A		90	60	2.182	115.05	-
MWA100012z, 12Vdc@8.3A		100	60	1.985	114.20	-
MWA100012z, 12Vdc@8.3A		115	60	1.757	112.91	-
MWA100012z, 12Vdc@8.3A		230	60	1.024	110.23	-
MWA100012z, 12Vdc@8.3A		240	60	0.984	110.15	-
MWA100012z, 12Vdc@8.3A		264	60	0.917	109.82	-
MWA100024z, 24Vdc@4.2A		90	50	2.128	113.03	-
MWA100024z, 24Vdc@4.2A		100	50	1.810	111.58	-
MWA100024z, 24Vdc@4.2A		115	50	1.583	110.75	-
MWA100024z, 24Vdc@4.2A		230	50	1.010	108.70	-
MWA100024z, 24Vdc@4.2A		240	50	0.981	108.55	-

IEC 60601-1						
Clause	Requirement + Test			Result - Remark		Verdict
4.11	TABLE: Power Input					Pass
Operating Conditions / Ratings		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Power factor (cos φ)
MWA100024z, 24Vdc@4.2A		264	50	0.921	108.43	-
MWA100024z, 24Vdc@4.2A		90	60	2.142	112.89	-
MWA100024z, 24Vdc@4.2A		100	60	1.941	111.80	-
MWA100024z, 24Vdc@4.2A		115	60	1.539	111.36	-
MWA100024z, 24Vdc@4.2A		230	60	1.008	108.93	-
MWA100024z, 24Vdc@4.2A		240	60	0.977	108.81	-
MWA100024z, 24Vdc@4.2A		264	60	0.915	108.36	-
MWB100012z, 12Vdc@8.3A		90	50	2.146	113.84	
MWB100012z, 12Vdc@8.3A		100	50	1.964	112.89	
MWB100012z, 12Vdc@8.3A		115	50	1.582	111.56	
MWB100012z, 12Vdc@8.3A		230	50	1.010	110.14	
MWB100012z, 12Vdc@8.3A		240	50	0.981	110.03	
MWB100012z, 12Vdc@8.3A		264	50	0.919	109.88	
MWB100012z, 12Vdc@8.3A		90	60	2.182	115.05	
MWB100012z, 12Vdc@8.3A		100	60	1.985	114.20	
MWB100012z, 12Vdc@8.3A		115	60	1.757	112.91	
MWB100012z, 12Vdc@8.3A		230	60	1.024	110.23	
MWB100012z, 12Vdc@8.3A		240	60	0.984	110.15	
MWB100012z, 12Vdc@8.3A		264	60	0.917	109.82	
MWB100024z, 24Vdc@4.2A		90	50	2.128	113.03	
MWB100024z, 24Vdc@4.2A		100	50	1.810	111.58	
MWB100024z, 24Vdc@4.2A		115	50	1.583	110.75	
MWB100024z, 24Vdc@4.2A		230	50	1.010	108.70	
MWB100024z, 24Vdc@4.2A		240	50	0.981	108.55	
MWB100024z, 24Vdc@4.2A		264	50	0.921	108.43	

IEC 60601-1						
Clause	Requirement + Test			Result - Remark		Verdict
4.11	TABLE: Power Input					Pass
Operating Conditions / Ratings		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Power factor (cos ϕ)
MWB100024z, 24Vdc@4.2A		90	60	2.142	112.89	
MWB100024z, 24Vdc@4.2A		100	60	1.941	111.80	
MWB100024z, 24Vdc@4.2A		115	60	1.539	111.36	
MWB100024z, 24Vdc@4.2A		230	60	1.008	108.93	
MWB100024z, 24Vdc@4.2A		240	60	0.977	108.81	
MWB100024z, 24Vdc@4.2A		264	60	0.915	108.36	
Supplementary Information:						

5.1	RM RESULTS TABLE: Type Tests		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			

5.4 a)	RM RESULTS TABLE: Other Conditions		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			

5.7	RM RESULTS TABLE: Humidity preconditioning treatment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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

5.9.2	TABLE: Determination of ACCESSIBLE parts		Pass
Location		Determination method (NOTE1)	Comments
Enclosure (MWAx0yz and MWBx0yz)		Visual	Model MWAx0yz and MWBx0yz fully enclosed
Output connector (MWAx0yz and MWBx0yz)		Rigid test finger	Maximum output voltage at connector is 24Vdc
Supplementary information:			
NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.			

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

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

7.1.2	TABLE: Legibility of Marking		Pass
Markings tested		Ambient illuminance (lx)	Remarks
Outside Markings (Clause 7.2)		500	Markings are legible
Inside Markings (Clause 7.3)		N/A	
Controls & Instruments (Clause 7.4)		N/A	
Safety Signs (Clause 7.5)		N/A	
Symbols (Clause 7.6)		N/A	
Supplementary information: Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20), 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.			

7.1.3	TABLE: Durability of marking test		Pass
Characteristics of the Marking Label tested:		Remarks	
Material of Marking Label	Plastic w/ adhesive backing	Pass	
Ink/other printing material or process	Ink	Pass	
Material (composition) of Warning Label	N/A		
Ink/other printing material or process	N/A		
Other.....	N/A		
Supplementary information: Markings remained legible and corners intact			
Webber Marking System Ultraplate II and 3M Marking System 7815 tested on enclosures made with Lexan 500, Lexan 945 and Lexan 940 material (MWAx0yz and MWBx0yz models)			
Webber Marking System Ultraplate II and 3M Marking System 7815 tested on heat sinks (MVAx0yz and MVBx0yz models)			
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.			

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

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

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

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

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

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

7.3.7	RM RESULTS TABLE: Supply terminals		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3			

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

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

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

7.9.1	RM RESULTS TABLE: General accompanying documents (See Table C.4)		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			

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

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

7.9.3.2	RM RESULTS TABLE: Replacement of fuses, power supply cords, other parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

8.1 b(1)	RM RESULTS 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. & paragraph)	Result - Remarks	Verdict
4.3			
4.4			

8.1 b(2)	RM RESULTS TABLE: Fundamental rule of protection against electric shock - unintended movement of a component		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

8.1 b(3)	RM RESULTS TABLE: Fundamental rule of protection against electric shock - accidental detachment of conductors and connectors		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3			

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

8.2.2	RM RESULTS TABLE: Connection to an external d.c. power sources		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			

8.3 d	RM RESULTS TABLE: Requirements of Type BF or CF Applied Parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2		See also RM Table for 4.6	

8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					Pass
Test supply voltage/frequency (V/Hz) ¹ :					240V/60Hz	
Location From/To	Measured values					Remarks
	Vrms	Vpk or Vdc	Peak-to-peak ripple ²	Power W/VA	Energy (J)	
GND to T1 pin2	256	350	-	-	-	
GND to T1 pin3	184	228	-	-	-	
GND to T1 pin4	224	292	-	-	-	
GND to T1 pin5	176	184	-	-	-	
GND to T1 pin6	197	218	-	-	-	
T1 pin2 to T1 pin7/8	276	378	-	-	-	
T1 pin2 to T1 pin9/10	236	348	-	-	-	
T1 pin2 to T1 pin11	236	346	-	-	-	
T1 pin2 to T1 pin12	252	350	-	-	-	
T1 pin3 to T1 pin7/8	206	238	-	-	-	
T1 pin3 to T1 pin9/10	168	220	-	-	-	
T1 pin3 to T1 pin11	168	224	-	-	-	
T1 pin3 to T1 pin12	208	248	-	-	-	
T1 pin4 to T1 pin7/8	244	350	-	-	-	
T1 pin4 to T1 pin9/10	214	274	-	-	-	

IEC 60601-1						
Clause	Requirement + Test			Result - Remark		Verdict
8.4.2	TABLE: TABLE: Working Voltage / Power Measurement					Pass
T1 pin4 to T1 pin11	208	274	-	-	-	
T1 pin4 to T1 pin12	212	236	-	-	-	
T1 pin5 to T1 pin7/8	214	240	-	-	-	
T1 pin5 to T1 pin9/10	165	168	-	-	-	
T1 pin5 to T1 pin11	166	168	-	-	-	
T1 pin5 to T1 pin12	162	206	-	-	-	
T1 pin6 to T1 pin7/8	248	282	-	-	-	
T1 pin6 to T1 pin9/10	186	202	-	-	-	
T1 pin6 to T1 pin11	186	200	-	-	-	
T1 pin6 to T1 pin12	166	170	-	-	-	
U3 pin1 to pin3	157	178	-	-	-	
U3 pin1 to pin4	157	170	-	-	-	
U3 pin2 to pin3	158	174	-	-	-	
U3 pin2 to pin4	155	170	-	-	-	
U6 pin1 to pin3	165	170	-	-	-	
U6 pin1 to pin4	159	168	-	-	-	
U6 pin2 to pin3	165	170	-	-	-	
U6 pin2 to pin4	158	170	-	-	-	
C39	98	132	-	-	-	
C39 to R6/R8	96	204	-	-	-	
C39 to R8/D7	94	294	-	-	-	
C40	62	94	-	-	-	
C40 to J2B	72	112	-	-	-	
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						

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.4.2 c	RM RESULTS TABLE: Accessible parts including applied parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			

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
MWB100012z Plug pins 1 and 2	24	22	25	26	23	24	24	23	22	22
MWB100012z Plug pin 1 and plug earth pin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MWB100012z Plug pin 2 and plug earth pin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MWB100012z Plug pin 1 and enclosure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MWB100012z Plug pin 2 and enclosure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MWB100024z Plug pins 1 and 2	22	22	26	24	23	24	24	26	25	24
MWB100024z Plug pin 1 and plug earth pin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MWB100024z Plug pin 2 and plug earth pin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MWB100024z Plug pin 1 and enclosure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MWB100024z Plug pin 2 and enclosure	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
MWA100012z Plug pins 1 and 2	26	22	22	24	25	22	26	22	26	25
MWA100012z	2	1	1	2	2	4	2	4	1	4

IEC 60601-1										
Clause	Requirement + Test				Result - Remark				Verdict	
Plug pin 1 and plug earth pin										
MWA100012z	6	2	3	3	6	6	3	2	2	5
Plug pin 2 and plug earth pin										
MWA100012z	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 1 and enclosure										
MWA100012z	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 2 and enclosure										
MWA100024z	22	22	24	22	26	26	24	23	22	24
Plug pins 1 and 2										
MWA100024z	4	4	2	1	4	3	3	4	4	1
Plug pin 1 and plug earth pin										
MWA100024z	4	2	2	3	2	4	1	2	3	2
Plug pin 2 and plug earth pin										
MWA100024z	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 1 and enclosure										
MWA100024z	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Plug pin 2 and enclosure										
Maximum allowable stored charge when measured voltage exceeded 60 v (µc) :								45		
Calculated stored charge (µc)										
Voltage Measured Between:	1	2	3	4	5	6	7	8	9	10
Plug pins 1 and 2										
Plug pin 1 and plug earth pin										
Plug pin 2 and plug earth pin										
Plug pin 1 and enclosure										
Plug pin 2 and enclosure										
Supplementary information: Device provided with plastic enclosure, test between pin1/pin2 and plastic enclosure not performed										

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		Measured residual voltage (V)	Calculated stored charge (μC)	Remarks	

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
	parts)		
Supplementary information:			

8.5.2.2	RM RESULTS TABLE: Type B applied parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			

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

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

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

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

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

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

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

8.6.4	TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS			Pass
Type of ME EQUIPMENT & impedance measured between parts	Test current (A) /Duration (s)	Voltage drop measured between parts (V)	Maximum calculated impedance (mΩ)	Maximum allowable impedance (mΩ)
ME EQUIPMENT with an APPLIANCE INLET, MWAx0yz: impedance between earth pin in the APPLIANCE INLET and J2B solder pad	40/120	0.28	7	100
MVAx0yz: impedance between PE eyelet and PE trace at C4	40/120	0.20	5	100
Supplementary information: Testing was conducted according to CAN/CSA C22.2 No. 0.4				

8.7	TABLE: leakage current			Pass
Type of leakage current and test condition (including single faults)	Supply voltage (V)	Supply frequency (Hz)	Measured max. value (μA)	Remarks
Fig. 13 - Earth Leakage (ER)	—	—	—	Maximum allowed values: 5 mA NC; 10 mA SFC
ER –B, NC (S1=1, S5=1)	264	60	185	MWA/MVA100012z floating output
ER –B, NC (S1=1, S5=0)	264	60	185	MWA/MVA100012z floating output
ER –B, SFC (S1=0, S5=1)	264	60	350	MWA/MVA100012z floating output
ER –B, SFC (S1=0, S5=0)	264	60	349	MWA/MVA100012z floating output
ER –A, NC (S1=1, S5=1)	264	60	185	MWA/MVA100012z floating output
ER –A, NC (S1=1, S5=0)	264	60	186	MWA/MVA100012z floating output
ER –A, SFC (S1=0, S5=1)	264	60	350	MWA/MVA100012z floating output
ER –A, SFC (S1=0, S5=0)	264	60	349	MWA/MVA100012z floating output
ER –B, NC (S1=1, S5=1)	264	60	187	MWA/MVA100012z grounded output
ER –B, NC (S1=1, S5=0)	264	60	186	MWA/MVA100012z grounded output
ER –B, SFC (S1=0, S5=1)	264	60	358	MWA/MVA100012z grounded output
ER –B, SFC (S1=0, S5=0)	264	60	358	MWA/MVA100012z grounded output
ER –A, NC (S1=1, S5=1)	264	60	188	MWA/MVA100012z grounded output
ER –A, NC (S1=1, S5=0)	264	60	187	MWA/MVA100012z grounded output

IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
ER –A, SFC (S1=0, S5=1)	264	60	358	MWA/MVA100012z grounded output
ER –A, SFC (S1=0, S5=0)	264	60	358	MWA/MVA100012z grounded output
ER –B, NC (S1=1, S5=1)	264	60	181	MWA/MVA100024z floating output
ER –B, NC (S1=1, S5=0)	264	60	180	MWA/MVA100024z floating output
ER –B, SFC (S1=0, S5=1)	264	60	348	MWA/MVA100024z floating output
ER –B, SFC (S1=0, S5=0)	264	60	348	MWA/MVA100024z floating output
ER –A, NC (S1=1, S5=1)	264	60	180	MWA/MVA100024z floating output
ER –A, NC (S1=1, S5=0)	264	60	180	MWA/MVA100024z floating output
ER –A, SFC (S1=0, S5=1)	264	60	348	MWA/MVA100024z floating output
ER –A, SFC (S1=0, S5=0)	264	60	348	MWA/MVA100024z floating output
ER –B, NC (S1=1, S5=1)	264	60	188	MWA/MVA100024z grounded output
ER –B, NC (S1=1, S5=0)	264	60	188	MWA/MVA100024z grounded output
ER –B, SFC (S1=0, S5=1)	264	60	355	MWA/MVA100024z grounded output
ER –B, SFC (S1=0, S5=0)	264	60	354	MWA/MVA100024z grounded output
ER –A, NC (S1=1, S5=1)	264	60	188	MWA/MVA100024z grounded output
ER –A, NC (S1=1, S5=0)	264	60	188	MWA/MVA100024z grounded output
ER –A, SFC (S1=0, S5=1)	264	60	355	MWA/MVA100024z grounded output
ER –A, SFC (S1=0, S5=0)	264	60	355	MWA/MVA100024z grounded output
Fig. 14 - Touch Current (TC)	—	—	—	Maximum allowed values: 100 uA NC; 500 uA SFC
TC –B, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100012z floating output
TC –B, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100012z floating output
TC –B, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100012z floating output
TC –B, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100012z floating output
TC –B, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100012z floating output
TC –B, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100012z floating output
TC –A, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100012z floating output

IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
TC –A, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100012z floating output
TC –A, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100012z floating output
TC –A, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100012z floating output
TC –A, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100012z floating output
TC –A, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100012z floating output
TC –B, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100012z grounded output
TC –B, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100012z grounded output
TC –B, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100012z grounded output
TC –B, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100012z grounded output
TC –B, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100012z grounded output
TC –B, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100012z grounded output
TC –A, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100012z grounded output
TC –A, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100012z grounded output
TC –A, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100012z grounded output
TC –A, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100012z grounded output
TC –A, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100012z grounded output
TC –A, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100012z grounded output
TC –B, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100024z floating output
TC –B, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100024z floating output
TC –B, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100024z floating output
TC –B, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100024z floating output
TC –B, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100024z floating output
TC –B, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100024z floating output
TC –A, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100024z floating output
TC –A, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100024z floating output
TC –A, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100024z floating output
TC –A, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100024z floating output

IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
				output
TC –A, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100024z floating output
TC –A, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100024z floating output
TC –B, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100024z grounded output
TC –B, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100024z grounded output
TC –B, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100024z grounded output
TC –B, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100024z grounded output
TC –B, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100024z grounded output
TC –B, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100024z grounded output
TC –A, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100024z grounded output
TC –A, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100024z grounded output
TC –A, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100024z grounded output
TC –A, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100024z grounded output
TC –A, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100024z grounded output
TC –A, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100024z grounded output

IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
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 external voltage on metal Accessible Part that is not Protectively Earthed	—	—	—	Maximum allowed values: Type B or BF AP: 500 μ A Type CF: N/A
Fig. 19 – Patient Auxiliary Current	—	—	—	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)

IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
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 uA NC; 100uA SFC (d.c. current); 500 uA NC; 1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA 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 uA NC; 100uA SFC (d.c. current); 500 uA NC; 1000 uA SFC (a.c.); Type CF AP: 50 uA NC; 100 uA 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: 5000uA Type CF: 100 uA
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 uA 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 & disinfection, & sterilization). ER - Earth leakage current TC – Touch current P - Patient leakage current PA – Patient auxiliary current TP – Total Patient current PM - Patient leakage current with mains on the applied parts MD - Measuring device A - After humidity conditioning B - Before humidity conditioning 1 - Switch closed or set to normal polarity 0 - Switch open or set to reversed polarity NC - Normal condition SFC - Single fault condition				

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
8.8.3	TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP)				Pass
Insulation under test (area from insulation diagram)	Insulation Type (1 or 2 MOOP/MOPP)	Reference Voltage		A.C. test voltages in V r.m.s ¹	Dielectric breakdown after 1 minute Yes/No ²
		PEAK WORKING VOLTAGE (U) V _{peak}	PEAK WORKING VOLTAGE (U) V d.c.		
B: Primary to PE: MWAx0yz and MVAx0yz	1MOPP	350	-	1512	No
C: Primary to secondary: MWAx0yz and MWBx0yz and MVAx0yz and MVBx0yz	2MOPP	378	-	4104	No
C: Primary to enclosure: MWAx0yz and MWBx0yz	2MOPP	378	-	4104	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 reaching steady state operating temperature as during heating test of 11.1.1, and					
C) after relevant single fault tests of 13.2.					

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

8.8.4.1	TABLE: Resistance to heat - Ball pressure test of thermoplastic parts		Pass
	Allowed impression diameter (mm)	≤ 2 mm	—
	Force (N)	20	—
Part/material		Test temperature (°C)	Impression diameter (mm)
Enclosure/External insulating parts			
Enclosure; GE, Lexan 940.		100°C	0.98mm
Enclosure; GE, Lexan 945.		100°C	0.97mm
Enclosure; GE, Lexan 500.		100°C	1.0mm
Insulating material supporting uninsulated Mains Parts			
Bobbin; Chang Chu Plastic, T375J.		125°C	0.45mm
Bobbin; Hitachi Chemical, CP-J-8800.		125°C	0.47mm
Bobbin; Sumitomo Bakelite, PM-9630.		125°C	0.49mm
Bobbin; Sumitomo Bakelite, PM-9720		125°C	0.52mm
Bobbin; Sumitomo Bakelite, PM-9750		125°C	0.44mm
Bobbin; Sumitomo Bakelite, PM-9850		125°C	0.46mm
Bobbin; Sumitomo Bakelite, PM-9870		125°C	0.45mm
Bobbin; Sumitomo Bakelite, PM-9820		125°C	0.47mm
Bobbin; Chang Chu Plastic, T357		125°C	0.46mm
Bobbin; Chang Chu Plastic, T375HF.		125°C	0.44mm
Supplementary information:			

8.8.4.1	RM RESULTS TABLE: Mechanical strength and resistance to heat		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.9.3.2	Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts		N/A
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
1	68 h at $T1 \pm 2\text{ °C} = \text{___ °C}^1$		
	1 h at $25\text{ °C} \pm 2\text{ °C}$		
	2 h at $0\text{ °C} \pm 2\text{ °C}$		
	1 or more h at $25\text{ °C} \pm 2\text{ °C}$		
2	68 h at $T1 \pm 2\text{ °C} = \text{___ °C}^1$		
	1 h at $25\text{ °C} \pm 2\text{ °C}$		
	2 h at $0\text{ °C} \pm 2\text{ °C}$		
	1 or more h at $25\text{ °C} \pm 2\text{ °C}$		
3	68 h at $T1 \pm 2\text{ °C} = \text{___ °C}^1$		
	1 h at $25\text{ °C} \pm 2\text{ °C}$		
	2 h at $0\text{ °C} \pm 2\text{ °C}$		
	1 or more h at $25\text{ °C} \pm 2\text{ °C}$		
4	68 h at $T1 \pm 2\text{ °C} = \text{___ °C}^1$		
	1 h at $25\text{ °C} \pm 2\text{ °C}$		
	2 h at $0\text{ °C} \pm 2\text{ °C}$		
	1 or more h at $25\text{ °C} \pm 2\text{ °C}$		

Supplementary information:

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

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

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
1	68 h at $T1 \pm 2\text{ °C} = \text{___ °C}^1$		
	1 h at $25\text{ °C} \pm 2\text{ °C}$		
	2 h at $0\text{ °C} \pm 2\text{ °C}$		
	1 or more h at $25\text{ °C} \pm 2\text{ °C}$		
2	68 h at $T1 \pm 2\text{ °C} = \text{___ °C}^1$		
	1 h at $25\text{ °C} \pm 2\text{ °C}$		
	2 h at $0\text{ °C} \pm 2\text{ °C}$		
	1 or more h at $25\text{ °C} \pm 2\text{ °C}$		
3	68 h at $T1 \pm 2\text{ °C} = \text{___ °C}^1$		
	1 h at $25\text{ °C} \pm 2\text{ °C}$		
	2 h at $0\text{ °C} \pm 2\text{ °C}$		
	1 or more h at $25\text{ °C} \pm 2\text{ °C}$		
4	68 h at $T1 \pm 2\text{ °C} = \text{___ °C}^1$		
	1 h at $25\text{ °C} \pm 2\text{ °C}$		
	2 h at $0\text{ °C} \pm 2\text{ °C}$		
	1 or more h at $25\text{ °C} \pm 2\text{ °C}$		

Supplementary information:

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

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

8.10	TABLE: List of critical components					Pass
Component/ Part No.	Manufacturer/ Trademark	Type No./model No./	Technical data	Standard No./, Edition	Mark(s) & Certificates of conformity ¹	
Enclosure	GE	Lexan 500	Rated 94V-0, 1.5mm thick min. dimensions	UL 746C, IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1-M90	UL, Evaluated as part of system	
Enclosure (Alternate)	GE	Lexan 940	Rated 94V-0, 1.5mm thick min. dimensions	UL 74C, IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1-M90	UL, Evaluated as part of system	
Enclosure (Alternate)	SABIC/GE	Lexan 945	Rated 94V-0, 1.5mm thick min. dimensions	UL 746C, IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1-M90	UL, Evaluated as part of system	
Input connector for P1 MWAx0yA	Supercom Electronics Co Ltd	SC-8R series (three prong)	250V, 10A	UL1977 IEC 60320-1	UL, VDE	
Input connector for P1 MWAx0yA (Alternate)	Rong Feng	SS-120-PCB series (three prong)	250V, 10A	UL1977 IEC 60320-1	UL, VDE	
Input connector for P1 MWAx0yA (Alternate)	TECX-UNIONS Technology Corp	TU-301-SP series (three prong)	250V, 10A	UL1977 IEC 60320-1	UL, VDE	
Input connector for P1 MWBx0yA	Supercom Electronics Co Ltd	SC-8R series (two prong)	250V, 10A	UL1977 IEC 60320-1	UL, VDE	
Input connector for P1 MWBx0yA (Alternate)	Rong Feng	SS-120A series (two prong)	250V, 10A	UL1977 IEC 60320-1	UL, VDE	
Input connector for P1 MWBx0yA (Alternate)	TECX-UNIONS Technology Corp	TU-318 series (two prong)	250V, 10A	UL1977 IEC 60320-1	UL, TÜVR	
Input connector P1 for models MVAx0yA and MVBx0yA	TE Connectivity Ltd /AMP	MTA sries	600V, 7A	UL1977 IEC 60320-1	UL, VDE	
Input connector P1 for models MVAx0yA	Molex	5273/09-65-20xx sries	600V, 7A	UL1977 IEC 60320-1	UL, TUR	

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
and MVBx0yA (Alternate)					
Input connector P1 for models MVAx0yA and MVBx0yA (Alternate)	Landwin	3061P sries	600V, 7A	UL1977 IEC 60320-1	UL, TUV
Transformer T1	Elpac Electronics	97661-123(F11A-400294) for MWA/MWBx012A and MVA/MVBx012A 97661-126(F11A-400297) for MWA/MWBx024A and MVA/MVBx024A	Class B. DASH 2 B-19	IEC/UL 60601	Evaluated as part of system
Transformer T1 (Alternate)	BaoCheng/Cheng Yang	97661-123(F11A-400294) for MWA/MWBx012A and MVA/MVBx012A 97661-126(F11A-400297) for MWA/MWBx024A and MVA/MVBx024A	Class B. DASH 2 B-19	IEC/UL 60601	Evaluated as part of system
Transformer T1 (Alternate)	BaoCheng/Cheng Yang	97661-123(F11A-400294) for MWA/MWBx012A and MVA/MVBx012A 97661-126(F11A-400297) for MWA/MWBx024A and MVA/MVBx024A	Class B. HIS-8A	IEC/UL 60601	Evaluated as part of system
Transformer T1 (Alternate)	Shenzhen Highlight	97661-123(F11A-400294) for MWA/MWBx012A and MVA/MVBx012A 97661-126(F11A-400297) for MWA/MWBx024A and MVA/MVBx024A	Class B. HLB88	IEC/UL 60601	Evaluated as part of system
Transformer T1 (Alternate)	Xepex Electronics	97661-123(F11A-400294) for MWA/MWBx012A and MVA/MVBx012A 97661-126(F11A-	Class B. SPB-6	IEC/UL 60601	Evaluated as part of system

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
		400297) for MWA/MWBx024A and MVA/MVBx024A			
Transformer T1 (Alternate)	Jingquanhua	97661-123(F11A-400294) for MWA/MWBx012A and MVA/MVBx012A 97661-126(F11A-400297) for MWA/MWBx024A and MVA/MVBx024A	Class B. SBI4.2	IEC/UL 60601	Evaluated as part of system
Transformer T1 (Alternate)	Rong Chyuan	97661-123(F11A-400294) for MWA/MWBx012A and MVA/MVBx012A 97661-126(F11A-400297) for MWA/MWBx024A and MVA/MVBx024A	Class B. SBI4.2	IEC/UL 60601	Evaluated as part of system
Inductor L1	Elpac Electronics	97661-314 (F11B-400298)	Class B. DASH 2 B-19	IEC/UL 60601	Evaluated as part of system
Inductor L1 (Alternate)	BaoCheng/Chen g Yang	97661-314 (F11B-400298)	Class B. DASH 2 B-19	IEC/UL 60601	Evaluated as part of system
Inductor L1 (Alternate)	BaoCheng/Chen g Yang	97661-314 (F11B-400298)	Class B. HIS-8A	IEC/UL 60601	Evaluated as part of system
Inductor L1 (Alternate)	Shenzhen Highlight	97661-314 (F11B-400298)	Class B. HLB88	IEC/UL 60601	Evaluated as part of system
Inductor L1 (Alternate)	Xepex Electronics	97661-314 (F11B-400298)	Class B. SPB-6	IEC/UL 60601	Evaluated as part of system
Inductor L1 (Alternate)	Jingquanhua	97661-314 (F11B-400298)	Class B. SBI4.2	IEC/UL 60601	Evaluated as part of system
Inductor L1 (Alternate)	Rong Chyuan	97661-314 (F11B-400298)	Class B. SBI4.2	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MWAx0yA and MWBx0yA	Elpac Electronics	97661-315 (F11B-400299)	Class B. DASH 2 B-19	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MWAx0yA and MWBx0yA (Alternate)	BaoCheng/Chen g Yang	97661-315 (F11B-400299)	Class B. DASH 2 B-19	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MWAx0yA and MWBx0yA (Alternate)	BaoCheng/Chen g Yang	97661-315 (F11B-400299)	Class B. HIS-8A	IEC/UL 60601	Evaluated as part of system
Inductor L2	Shenzhen	97661-315	Class B. HLB88	IEC/UL 60601	Evaluated as part

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
For MWAx0yA and MWBx0yA (Alternate)	Highlight	(F11B-400299)			of system
Inductor L2 For MWAx0yA and MWBx0yA (Alternate)	Xepex Electronics	97661-315 (F11B-400299)	Class B. SPB-6	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MWAx0yA and MWBx0yA (Alternate)	Jingquanhua	97661-315 (F11B-400299)	Class B. SBI4.2	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MWAx0yA and MWBx0yA (Alternate)	Rong Chyuan	97661-315 (F11B-400299)	Class B. SBI4.2	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MVAx0yA and MVBx0yA	Elpac Electronics	97661-300 (F11B-400262)	Class B. DASH 2 B-19	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MVAx0yA and MVBx0yA (Alternate)	BaoCheng/Chen g Yang	97661-300 (F11B-400262)	Class B. DASH 2 B-19	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MVAx0yA and MVBx0yA (Alternate)	BaoCheng/Chen g Yang	97661-300 (F11B-400262)	Class B. HIS-8A	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MVAx0yA and MVBx0yA (Alternate)	Shenzhen Highlight	97661-300 (F11B-400262)	Class B. HLB88	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MVAx0yA and MVBx0yA (Alternate)	Xepex Electronics	97661-300 (F11B-400262)	Class B. SPB-6	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MVAx0yA and MVBx0yA (Alternate)	Jingquanhua	97661-300 (F11B-400262)	Class B. SBI4.2	IEC/UL 60601	Evaluated as part of system
Inductor L2 For MVAx0yA and MVBx0yA	Rong Chyuan	97661-300 (F11B-400262)	Class B. SBI4.2	IEC/UL 60601	Evaluated as part of system

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
(Alternate)					
Transformer T1	Chang Chun Plastic Co.	T375J	Rated V-1, 150C, minimum 0.45mm thick	UL746C	UL
Transformer T1 (Alternate)	Hitachi Chemical	CP-J-8800	Rated V-0, 150C, minimum 0.38mm thick	UL746C	UL
Transformer T1 (Alternate)	Sumitomo Bakelite Co.	PM-9630	Rated V-0, 150C, minimum 0.16mm thick	UL746C	UL
Transformer T1 (Alternate)	Sumitomo Bakelite Co.	PM-9820	Rated V-0, 150C, minimum 0.51mm thick	UL746C	UL
Transformer T1 (Alternate)	Sumitomo Bakelite Co.	PM-9720	Rated V-0, 150C, minimum 0.28mm thick	UL746C	UL
Transformer T1 (Alternate)	Sumitomo Bakelite Co.	PM-9750	Rated V-0, 150C, minimum 0.30mm thick	UL746C	UL
Transformer T1 (Alternate)	Sumitomo Bakelite Co.	PM-9850	Rated V-0, 150C, minimum 0.29mm thick	UL746C	UL
Transformer T1 (Alternate)	Sumitomo Bakelite Co.	PM-9870	Rated V-0, 150C, minimum 0.61mm thick	UL746C	UL
Transformer T1 (Alternate)	Chang Chun Plastic Co.	T357	Rated V-0, 150C, minimum 0.75mm thick	UL746C	UL
Transformer T1 (Alternate)	Chang Chun Plastic Co.	T375HF	Rated V-0, 150C, minimum 0.43mm thick	UL746C	UL
Windings for all models (Alternate)	Rubadue Wire Co.	TCA3	Rated 155C, 250V	UL1446	UL
Windings for all models (Alternate)	Totoku Electric Co.	TIW-E	Rated 155C, 250V	UL1446	UL
Windings for all models (Alternate)	Totoku Electric Co.	TIW-3	Rated 155C, 250V	UL1446	UL
Windings for all models (Alternate)	Totoku Electric Co.	TIW-2	Rated 130C, 250V	UL1446	UL
Windings for all models (Alternate)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(B)	Rated 130C, 250V	UL1446	UL
Windings for all models (Alternate)	GREAT LEOFLON INDUSTRIAL CO LTD	TRW(F)	Rated 155C, 250V	UL1446	UL
Windings for all models (Alternate)	Furukawa Electric Co., LTD	TEX-FS	Rated 155C, 250V	UL1446	UL
Tape	3M	56	Min 130C	UL510	UL

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
Tape (Alternate)	Permacel	P256	Min 130C	UL510	UL
Tape (Alternate)	3M	1350	Min 130C	UL510	UL
Tape (Alternate)	Sybio Inc /Four Pillars	MY9Y,35660	Min 130C	UL510	UL
Tape (Alternate)	P. Leo	1P801	Min 130C	UL510	UL
Tape (Alternate)	P. Leo	1P802	Min 130C	UL510	UL
Tape (Alternate)	Yahua	CT	Min 130C	UL510	UL
Printed Circuit Board	-	-	Rated minimum 130C, V-0. Meets DSR requirement	UL796	UL
Bridge diode D1	-	-	Min 600V, 4A	UL1012 IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1-M90	UL, Evaluated as part of system
Mosfet Q3	-	-	Min 600V, 11A	IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1-M90	Evaluated as part of system
Optocoupler U3, U6	Lite-on	LTV-817	Rated 5000V isolation voltage. Distance through insulation 0.4 mm	UL1577, VDE0884	UL, VDE, CSA, VDE, CSA
Optocoupler U3, U6 (Alternate)	NEC	PS2561-1	Rated 5000V isolation voltage. Distance through insulation 0.4 mm	UL1577, VDE0884	UL, VDE, CSA, VDE, CSA
Optocoupler U3, U6 (Alternate)	Vishay	TCET1107	Rated 5000V isolation voltage. Distance through insulation 0.4 mm	UL1577, VDE0884	UL, VDE, CSA, VDE, CSA
Optocoupler U3, U6 (Alternate)	Sharp	PC123	Rated 5000V isolation voltage. Distance through insulation 0.4 mm	UL1577, VDE0884	UL, VDE, CSA, VDE, CSA
Bleed resistors R2 and R3	-	-	820K ohms, 1/4 W	IEC 60601-1, UL 60601-1, CAN/CSA C22.2	Evaluated as part of system

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
				No. 601.1-M90	
Capacitor C39, C40	Vishay/Ceramite	440L series	Min 250V, 0 - 2200pF, Y1	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C39, C40 (Alternate)	TDK	CD series	Min 250V, 0 - 2200pF, Y1	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C39, C40 (Alternate)	Murata	KX series	Min 250V, 0 - 2200pF, Y1	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C39, C40 (Alternate)	Vishay/BC component	VY1 series	Min 250V, 0 - 2200pF, Y1	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C39, C40 (Alternate)	Xiamen Wanming Electronics	HJ series	Min 250V, 0 - 2200pF, Y1	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C3, C4	Vishay/Ceramite	440L series	Min 250V, 0 - 1000 pF, Y1	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C3, C4 (Alternate)	TDK	CD series	Min 250V, 0 - 1000 pF, Y1	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C3, C4 (Alternate)	Murata	KX series	Min 250V, 0 - 1000 pF, Y1	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C3, C4 (Alternate)	Vishay/BC component	VY1 series	Min 250V, 0 - 1000 pF, Y1	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C3, C4 (Alternate)	Xiamen Wanming Electronics	HJ series	Min 250V, 0 - 1000 pF, Y1	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C9, C10 (bulk cap)	Various	Various	Min 200V, Min 220uF, 105C	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C5	Epcos	B32922 series	Min 250V, 0 - 0.47uF, X2	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C5 (Alternate)	Vishay	F1778 series	Min 250V, 0 - 0.47uF, X2	UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C5 (Alternate)	Carli	MPX series	Min 250V, 0 - 0.47uF, X2	UL 60384-14, CAN/CSA-E60384-1,	UL, CSA, VDE

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
				IEC60384-14	
Capacitor C5 (Alternate)	Faratronic	MKP62 (C42) series	Min 250V, - 0.47uF, X2	0 UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Capacitor C5 (Alternate)	Kemet/Arcotronics	R46	Min 250V, - 0.47uF, X2	0 UL 60384-14, CAN/CSA-E60384-1, IEC60384-14	UL, CSA, VDE
Thermistor R1 (optional)	-	-	Max10 ohms, 3A	IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1-M90	Evaluated as part of system
Fuse F1, F2	Littelfuse	392 series	250Vac, 5.0A	UL248 IEC 60127-1,	UL-R/C, cUL-R/C, VDE, CCC, PSE
Fuse F1, F2 (Alternate)	Belfuse	RST series	250Vac, 5.0A	UL248 IEC 60127-1,	UL-R/C, cUL-R/C, VDE, CCC, PSE
Fuse F1, F2 (Alternate)	Walter	2010 series	250Vac, 5.0A	UL248 IEC 60127-1,	UL-R/C, cUL-R/C, VDE, CCC, PSE
Fuse F1, F2 (Alternate)	Walter	FAP5	250Vac, 5.0A	UL248 IEC 60127-1,	UL-R/C, cUL-R/C, VDE, CCC, PSE
Fuse F1, F2 (Alternate)	Sunfuse	5QP5	250Vac, 5.0A	UL248 IEC 60127-1,	UL-R/C, cUL-R/C, VDE, CCC, PSE
Fuse F1, F2 (Alternate)	Conquer	PBU series	250Vac, 5.0A	UL248 IEC 60127-1,	UL-R/C, cUL-R/C, VDE, CCC, PSE
Fuse F1, F2 (Alternate)	Conquer	PGU series	250Vac, 5.0A	UL248 IEC 60127-1,	UL-R/C, cUL-R/C, VDE, CCC, PSE
Thermal Fuse F3	Matsushita Electric (Panasonic)	E series F series N series	102C	UL60691 IEC60691	UL, CSA, VDE, PSE, CQC
Thermal Fuse F3	Uchihashi Estec (Elcut)	44 series	108C	UL60691 IEC60691	UL, CSA, VDE, PSE, CQC
Thermal Fuse F3 (Alternate)	Aupo Electronics	P2 series	115C	UL60691 IEC60691	UL, CSA, VDE, PSE, CQC
Heat sink HS1 for models MWAx0yA and MWBx0yA	-	-	L shaped 110.3mm X 28mm X 23mm, 2.3mm thick aluminum.	IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1-M90	Evaluated as part of system
Heat sink HS2 for models MWAx0yA and MWBx0yA	-	-	L shaped 93.7mm X 27mm X 23mm, 2.3mm thick aluminum.	IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1-M90	Evaluated as part of system
Heat sink HS3 for	-	-	120.2mm X 70.2mm (Max	IEC 60601-1, UL 60601-1,	Evaluated as part of system

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
models MWAx0yA and MWBx0yA			LXW),0.25mm thick copper	CAN/CSA C22.2 No. 601.1-M90	
Heat sink HS1 for models MVAx0yz and MVBx0yz	-	-	72.1mm X 26.5mm, 2.3mm thick aluminum.	IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1-M90	Evaluated as part of system
Heat sink HS2 for models MVAx0yz and MVBx0yz	-	-	69.6mm X 26.5mm, 2.3mm thick aluminum.	IEC 60601-1, UL 60601-1, CAN/CSA C22.2 No. 601.1-M90	Evaluated as part of system
Marking Label	Weber Marking System	Ultraplate II	Adhesive backed	UL696	UL-R/C
Marking Label (Alternate)	3M	7815	Adhesive backed	UL696	UL-R/C
VDR V1	Uppermost	V10Kyyy (yyy=300, 320)	300Vac, 60J min.	UL1449, IEC61051-2	UL, VDE
VDR V1 (Alternate)	Thinking	TVR14yyy series (yyy=471, 511)	300Vac, 125J min.	UL1449, IEC61051-2	UL, VDE
VDR V1 (Alternate)	Thinking	TVR10yyy-D series (yyy=471, 511)	300Vac, 99J min.	UL1449, IEC61051-2	UL, VDE
VDR V1 (Alternate)	Thinking	TVR10yyy-V series (yyy=471, 511)	300Vac, 85J min.	UL1449, IEC61051-2	UL, VDE
VDR V1 (Alternate)	Panasonic	ERZV10yyy (yyy=471, 511)	300Vac, 85J min.	UL1449, IEC61051-2	UL, VDE
VDR V1 (Alternate)	Joyin Co. Ltd	10SyyyK (yyy=471, 511)	300Vac, 85J min.	UL1449, IEC61051-2	UL, VDE
VDR V1 (Alternate)	Brightking	BKyyyxD10 (yyy=471, 511) (x=K or L or M)	300Vac, 85J min.	UL1449, IEC61051-2	UL, VDE
VDR V1 (Alternate)	Epcos	S10KyyyE2 (yyy=300, 320)	300Vac, 60J min.	UL1449, IEC61051-2	UL, VDE
Supplementary information: 1) An asterisk indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.					

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

8.10.1	RM RESULTS TABLE: Fixing of components		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

8.10.2	RM RESULTS TABLE: Fixing of wiring		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

8.10.5	RM RESULTS TABLE: Mechanical protection of wiring		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
8.11.3.6	TABLE: Cord guard		N/A
Cord under test	Test mass	Measured curvature	Remarks
Supplementary information:			

8.11.5	RM RESULTS TABLE: Mains fuses and over-current releases		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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

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

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

designed for use with children, values for children applied.

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

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

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

9.2.2.6	RM RESULTS TABLE: Speed of movement(s)		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			

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

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

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

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

9.2.5	RM RESULTS TABLE: Release of patient		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.2.5	RM RESULTS TABLE: Release of patient		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3			
6.4			
6.5			

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

9.4.2.1	TABLE: Instability—overbalance in transport position		Pass
ME EQUIPMENT preparation	Test Condition (transport position)	Remarks	
MWAx0yz and MWBx0yz	10° tilt	Did not overbalance	
Supplementary information:			

9.4.2.2	TABLE: Instability—overbalance excluding transport position		Pass
ME EQUIPMENT preparation	Test Condition (excluding transport position) Test either 5 ° incline and verify Warning marking or 10 ° incline)	Remarks	
MWAx0yz and MWBx0yz	5° tilt	Did not overbalance	
Supplementary information:			

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.4.2.3	TABLE: Instability—overbalance from horizontal and vertical forces		N/A
ME EQUIPMENT preparation	Test Condition (force used, direction of force, weight of equipment, location of force)	Remarks	
Supplementary information:			

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

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

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
9.4.3.1	TABLE: Instability from unwanted lateral movement (including sliding) in transport position		N/A
ME EQUIPMENT Preparation		Test Condition (transport position, working load, locking device(s), caster position)	Remarks
Supplementary information:			

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

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

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

9.6.1	RM RESULTS TABLE: Acoustic energy - General		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict

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

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

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

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

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

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

9.7.4	RM RESULTS TABLE: Pressure rating of ME equipment parts		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.3			
6.4			
6.5			

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

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

9.8.1	RM RESULTS TABLE: Hazards associated with support systems - General		N/A
-------	---	--	-----

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

Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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

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

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

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

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

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

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

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

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

9.8.4.3	RM RESULTS TABLE: Mechanical protective device for single activation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.5			

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

10.1.1	TABLE: Measurement of X - radiation		N/A
Maximum allowable radiation pA/kg (μSv/h) (mR/h)		36 (5 μSv/h) (0.5 mR/h)	
Surface area under test Surface no./ Description ¹		Measured Radiation, pA/kg (μSv/h) (mR/h)	Remarks
1/ /			
2/ /			
3/ /			
4/ /			
5/ /			
6/ /			
7/ /			
8/ /			
9/ /			
10/ /			
Supplementary information: ¹ Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access			

10.1.2	RM RESULTS TABLE: ME equipment intended to produce diagnostic or therapeutic X-radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			

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

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

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

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

10.5	RM RESULTS TABLE: Other visible electromagnetic radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
10.5	RM RESULTS TABLE: Other visible electromagnetic radiation		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
6.2			
6.3			
6.4			
6.5			
10.6	RM RESULTS 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. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
10.7	RM RESULTS 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. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No..... :	MWA1000 12z				
Test ambient (°C)	29.0				
Test supply voltage/frequency (V/Hz) ⁴ .. :	90/60				
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
MWA100012z	1	T1 Core (Class B)	100	86.7	Pass
	2	T1 Winding (Class B)	100	93.8	Pass
	3	C10 between L2 and C10	85	79.5	Pass
	4	C9	85	75.8	Pass
	5	L2 winding (Class B)	100	90.6	Pass
	6	L1 winding (Class B)	100	89.5	Pass
	7	L3 winding (Class B)	100	79.6	Pass
	8	C34 facing T1	85	82.6	Pass
	9	C32 between C32 and L3	85	71.0	Pass
	10	PWB under R1	110	93.6	Pass
	11	PWB under Q5	110	93.7	Pass
	12	PWB under R8	110	84.8	Pass
	13	HS2 next to Q5	--	79.4	Pass
	14	Enclosure outside above T1	66	64.6	Pass
Supplementary information: ¹ Maximum allowable temperature on surfaces of test corner is 90 °C ² Max temperature determined in accordance with 11.1.3e) ³ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C. Normal operation: 12Vdc @8.3A Max allowable temperature linear calculated for 49°C operating temperature (Tmra) Maximum enclosure temperature (86°C) for contact time less than 1 second					

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

11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No..... :	MWA1000 12z				
Test ambient (°C)	26.0				
Test supply voltage/frequency (V/Hz) ⁴ .. :	264/50				
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
MWA100012z	1	T1 Core (Class B)	97	76.4	Pass
	2	T1 Winding (Class B)	97	84.0	Pass
	3	C10 between L2 and C10	82	60.3	Pass
	4	C9	82	61.1	Pass
	5	L2 winding (Class B)	97	56.9	Pass
	6	L1 winding (Class B)	97	56.4	Pass
	7	L3 winding (Class B)	97	71.5	Pass
	8	C34 facing T1	82	73.4	Pass
	9	C32 between C32 and L3	82	62.9	Pass
	10	PWB under R1	107	61.3	Pass
	11	PWB under Q5	107	85.1	Pass
	12	PWB under R8	107	68.5	Pass
	13	HS2 next to Q5	--	71.0	Pass
	14	Enclosure outside above T1	63	56.1	Pass

Supplementary information:
¹ Maximum allowable temperature on surfaces of test corner is 90 °C

² Max temperature determined in accordance with 11.1.3e)

³ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

Normal operation: 12Vdc @8.3A

Max allowable temperature linear calculated for 49°C operating temperature (Tmra)

Maximum enclosure temperature (86°C) for contact time less than 1 second

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No..... :	MWA1000				
	24z				
Test ambient (°C)	27.0				
Test supply voltage/frequency (V/Hz) ⁴ .. :	90/60				
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
MWA100024z	1	T1 Core (Class B)	98	69.8	Pass
	2	T1 Winding (Class B)	98	73.9	Pass
	3	C10 between L2 and C10	83	67.2	Pass
	4	C9	83	64.0	Pass
	5	L2 winding (Class B)	98	77.6	Pass
	6	L1 winding (Class B)	98	75.3	Pass
	7	L3 winding (Class B)	98	65.9	Pass
	8	C34 facing T1	83	71.1	Pass
	9	C32 between C32 and L3	83	59.1	Pass
	10	PWB under R1	108	91.2	Pass
	11	PWB under Q5	108	77.5	Pass
	12	PWB under R8	108	75.3	Pass
	13	HS2 next to Q5	--	70.0	Pass
	14	Enclosure outside above T1	64	58.9	Pass

Supplementary information:

¹ Maximum allowable temperature on surfaces of test corner is 90 °C

² Max temperature determined in accordance with 11.1.3e)

³ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.

Normal operation: 24Vdc @4.2A

Max allowable temperature linear calculated for 49°C operating temperature (Tmra)

Maximum enclosure temperature (86°C) for contact time less than 1 second

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No..... :	MWA1000				
	24z				
Test ambient (°C)	25.0				
Test supply voltage/frequency (V/Hz) ⁴ .. :	264/50				
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
MWA100024z	1	T1 Core (Class B)	96	62.2	Pass
	2	T1 Winding (Class B)	96	66.9	Pass
	3	C10 between L2 and C10	81	52.0	Pass
	4	C9	81	52.5	Pass
	5	L2 winding (Class B)	96	51.4	Pass
	6	L1 winding (Class B)	96	50.3	Pass
	7	L3 winding (Class B)	96	59.1	Pass
	8	C34 facing T1	81	63.6	Pass
	9	C32 between C32 and L3	81	52.2	Pass
	10	PWB under R1	106	59.7	Pass
	11	PWB under Q5	106	70.6	Pass
	12	PWB under R8	106	64.1	Pass
	13	HS2 next to Q5	--	62.7	Pass
	14	Enclosure outside above T1	62	51.3	Pass
Supplementary information: ¹ Maximum allowable temperature on surfaces of test corner is 90 °C ² Max temperature determined in accordance with 11.1.3e) ³ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C. Normal operation: 24Vdc @4.2A Max allowable temperature linear calculated for 49°C operating temperature (Tmra) Maximum enclosure temperature (86°C) for contact time less than 1 second					

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No. :	MVA100012z				
Test ambient (°C)	24.0				
Test supply voltage/frequency (V/Hz) ⁴ .. :	90/60				
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
MVA100012z	1	T1 Core (Class B)	84	76.0	Pass
	2	T1 Winding (Class B)	84	81.2	Pass
	3	C10 between L2 and C10	69	56.1	Pass
	4	C9	69	59.2	Pass
	5	L2 winding (Class B)	84	59.4	Pass
	6	L1 winding (Class B)	84	64.6	Pass
	7	L3 winding (Class B)	84	48.0	Pass
	8	C34 facing T1	69	61.0	Pass
	9	C32 between C32 and L3	69	44.7	Pass
	10	PWB under R1	94	47.6	Pass
	11	PWB under Q5	94	62.0	Pass
	12	PWB under R8	94	69.3	Pass
	13	HS2 next to Q5	--	56.4	Pass
Supplementary information: ¹ Maximum allowable temperature on surfaces of test corner is 90 °C ² Max temperature determined in accordance with 11.1.3e) ³ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C. Normal operation: 12Vdc @8.3A Max allowable temperature linear calculated for 60°C operating temperature (Tmra)					

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No..... :	MVA100012z				
Test ambient (°C)	25.0				
Test supply voltage/frequency (V/Hz) ⁴ .. :	264/50				
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
MVA100012z	1	T1 Core (Class B)	85	77.0	Pass
	2	T1 Winding (Class B)	85	82.5	Pass
	3	C10 between L2 and C10	70	48.9	Pass
	4	C9	70	52.2	Pass
	5	L2 winding (Class B)	85	44.8	Pass
	6	L1 winding (Class B)	85	49.2	Pass
	7	L3 winding (Class B)	85	49.4	Pass
	8	C34 facing T1	70	61.9	Pass
	9	C32 between C32 and L3	70	45.9	Pass
	10	PWB under R1	95	42.0	Pass
	11	PWB under Q5	95	62.9	Pass
	12	PWB under R8	95	64.9	Pass
	13	HS2 next to Q5	--	57.0	Pass
Supplementary information: ¹ Maximum allowable temperature on surfaces of test corner is 90 °C ² Max temperature determined in accordance with 11.1.3e) ³ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C. Normal operation: 12Vdc @8.3A Max allowable temperature linear calculated for 60°C operating temperature (Tmra)					

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No. :	MVA100024z				
Test ambient (°C)	27.0				
Test supply voltage/frequency (V/Hz) ⁴ .. :	90/60				
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
MVA100024z	1	T1 Core (Class B)	87	71.1	Pass
	2	T1 Winding (Class B)	87	75.7	Pass
	3	C10 between L2 and C10	72	58.4	Pass
	4	C9	72	56.4	Pass
	5	L2 winding (Class B)	87	61.8	Pass
	6	L1 winding (Class B)	87	65.0	Pass
	7	L3 winding (Class B)	87	47.5	Pass
	8	C34 facing T1	72	49.9	Pass
	9	C32 between C32 and L3	72	37.9	Pass
	10	PWB under R1	97	60.4	Pass
	11	PWB under Q5	97	62.8	Pass
	12	PWB under R8	97	65.3	Pass
	13	HS2 next to Q5	--	57.1	Pass
Supplementary information: ¹ Maximum allowable temperature on surfaces of test corner is 90 °C ² Max temperature determined in accordance with 11.1.3e) ³ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C. Normal operation: 24Vdc @4.2A Max allowable temperature linear calculated for 60°C operating temperature (Tmra)					

IEC 60601-1					
Clause	Requirement + Test			Result - Remark	Verdict
11.1.1	TABLE: Excessive temperatures in ME EQUIPMENT				Pass
Model No. :	MVA100024z				
Test ambient (°C)	26.0				
Test supply voltage/frequency (V/Hz) ⁴ .. :	264/50				
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
MVA100024z	1	T1 Core (Class B)	86	72.5	Pass
	2	T1 Winding (Class B)	86	76.7	Pass
	3	C10 between L2 and C10	71	50.1	Pass
	4	C9	71	48.1	Pass
	5	L2 winding (Class B)	86	45.5	Pass
	6	L1 winding (Class B)	86	48.9	Pass
	7	L3 winding (Class B)	86	48.1	Pass
	8	C34 facing T1	71	51.6	Pass
	9	C32 between C32 and L3	71	38.4	Pass
	10	PWB under R1	96	49.0	Pass
	11	PWB under Q5	96	63.9	Pass
	12	PWB under R8	96	62.2	Pass
	13	HS2 next to Q5	--	57.7	Pass
Supplementary information: ¹ Maximum allowable temperature on surfaces of test corner is 90 °C ² Max temperature determined in accordance with 11.1.3e) ³ When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C. Normal operation: 24Vdc @4.2A Max allowable temperature linear calculated for 60°C operating temperature (Tmra)					

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

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

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

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

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

11.1.3	TABLE: Temperature of windings by change-of-resistance method						N/A
Temperature T of winding:	t ₁ (°C)	R ₁ (Ω)	t ₂ (°C)	R ₂ (Ω)	T (°C)	Allowed T _{max} (°C)	Insulation class
Supplementary information:							

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

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

IEC 60601-1			
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	
1.			
2.			
3.			
5.			
6.			
Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):		Remarks	
1.			
2.			
3.			
4.			
5.			
6.			
Test parameters selected representing worst case conditions for ME EQUIPMENT:		Remarks	
Oxygen concentration (%).....:			
Fuel			
Current (A)			
Voltage (V)			
Capacitance (μF)			
Inductance or resistance (h or Ω).....:			
No. of trials (300 Min)			
Sparks resulted in ignition (Yes/No) :			
Supplementary information:			
Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur.			

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

11.3	RM RESULTS TABLE: Constructional requirements for fire enclosures of ME equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

11.5	RM RESULTS 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. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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:				

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

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

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

11.6.5	RM RESULTS 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. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

IEC 60601-1				
Clause	Requirement + Test		Result - Remark	Verdict
13.1.2	TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances			N/A
Power dissipated less than (W)		15		
Energy dissipated less than (J)		900		
Part or component tested	Measured power dissipated (W)	Calculated energy dissipated (J)	SINGLE FAULT CONDITIONS waived (Yes/No)	Remarks
Supplementary information:				

13.2	TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive		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:	—	—
	MWA100012z D3 Short D to G	Unit shut down within 1 sec. F1 and F2 opened. Tested with Littelfuse series 392 fuse. Ambient temperature =26.2°C, 12Vdc@8.3A	No
	MWB100024z Q3 Short D to S	Unit shut down within 1 sec. F1 and F2 opened. Tested with Littelfuse series 392 fuse. Ambient temperature =25.4°C, 24Vdc@4.2A	No

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	MWA100024z D1 Short AC to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Littelfuse series 392 fuse. Ambient temperature =26.4°C, 24Vdc@4.2A	No
	MWA100024z D1 Short + to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Littelfuse series 392 fuse. Ambient temperature =26.3°C, 24Vdc@4.2A	No
	MWA100012z C9 Short	Input power and current increased, F1 and F2 opened after 5 seconds. Tested with Littelfuse series 392 fuse. Ambient temperature =26.3°C, 12Vdc@8.3A	No
	MWB100024z C10 Short	Unit shut down within 1 sec. F1 and F2 opened. Tested with Littelfuse series 392 fuse. Ambient temperature =26.1°C, 24Vdc@4.2A	No
	MWA100012z D3 Short D to G	Unit shut down within 1 sec. F1 and F2 opened. Tested with Sunfuse series 5QP5 fuse. Ambient temperature =26.4°C, 12Vdc@8.3A	No
	MWB100024z Q3 Short D to S	Unit shut down within 1 sec. F1 and F2 opened. Tested with Sunfuse series 5QP5 fuse. Ambient temperature =25.6°C, 24Vdc@4.2A	No
	MWA100024z D1 Short AC to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Sunfuse series 5QP5 fuse. Ambient temperature =26.0°C, 24Vdc@4.2A	No
	MWA100024z D1 Short + to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Sunfuse series 5QP5 fuse. Ambient temperature =26.4°C, 24Vdc@4.2A	No
	MWA100012z C9 Short	Input power and current increased, F1 and F2 opened after 5 seconds. Tested with Sunfuse series 5QP5 fuse. Ambient temperature =26.2°C, 12Vdc@8.3A	No

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	MWB100024z C10 Short	Unit shut down within 1 sec. F1 and F2 opened. Tested with Sunfuse series 5QP5 fuse. Ambient temperature =25.3°C, 24Vdc@4.2A	No
	MWA100012z D3 Short D to G	Unit shut down within 1 sec. F1 and F2 opened. Tested with Conquer series PBU fuse.	No
	MWB100024z Q3 Short D to S	Unit shut down within 1 sec. F1 and F2 opened. Tested with Conquer series PBU fuse.	No
	MWA100024z D1 Short AC to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Conquer series PBU fuse.	No
	MWA100024z D1 Short + to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Conquer series PBU fuse.	No
	MWA100012z C9 Short	Input power and current increased, F1 and F2 opened after 5 seconds. Tested with Conquer series PBU fuse.	No
	MWB100024z C10 Short	Unit shut down within 1 sec. F1 and F2 opened. Tested with Conquer series PBU fuse.	No
	MWA100012z D3 Short D to G	Unit shut down within 1 sec. F1 and F2 opened. Tested with Conquer series PGU fuse.	No
	MWB100024z Q3 Short D to S	Unit shut down within 1 sec. F1 and F2 opened. Tested with Conquer series PGU fuse.	No
	MWA100024z D1 Short AC to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Conquer series PGU fuse.	No
	MWA100024z D1 Short + to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Conquer series PGU fuse.	No

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	MWA100012z C9 Short	Input power and current increased, F1 and F2 opened after 5 seconds. Tested with Conquer series PGU fuse.	No
	MWB100024z C10 Short	Unit shut down within 1 sec. F1 and F2 opened. Tested with Conquer series PGU fuse.	No
	MWA100012z D3 Short D to G	Unit shut down within 1 sec. F1 and F2 opened. Tested with Walter series 2010 fuse.	No
	MWB100024z Q3 Short D to S	Unit shut down within 1 sec. F1 and F2 opened. Tested with Walter series 2010 fuse.	No
	MWA100024z D1 Short AC to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Walter series 2010 fuse.	No
	MWA100024z D1 Short + to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Walter series 2010 fuse.	No
	MWA100012z C9 Short	Input power and current increased, F1 and F2 opened after 5 seconds. Tested with Walter series 2010 fuse.	No
	MWB100024z C10 Short	Unit shut down within 1 sec. F1 and F2 opened. Tested with Walter series 2010 fuse.	No
	MWA100012z D3 Short D to G	Unit shut down within 1 sec. F1 and F2 opened. Tested with Walter series FAP5 fuse.	No
	MWB100024z Q3 Short D to S	Unit shut down within 1 sec. F1 and F2 opened. Tested with Walter series FAP5 fuse.	No
	MWA100024z D1 Short AC to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Walter series FAP5 fuse.	No
	MWA100024z D1 Short + to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Walter series FAP5 fuse.	No
	MWA100012z C9 Short	Input power and current increased, F1 and F2 opened after 5 seconds. Tested with Walter series FAP5 fuse.	No

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	MWB100024z C10 Short	Unit shut down within 1 sec. F1 and F2 opened. Tested with Walter series FAP5 fuse.	No
	MWA100012z D3 Short D to G	Unit shut down within 1 sec. F1 and F2 opened. Tested with Belfuse series RST fuse.	No
	MWB100024z Q3 Short D to S	Unit shut down within 1 sec. F1 and F2 opened. Tested with Belfuse series RST fuse.	No
	MWA100024z D1 Short AC to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Belfuse series RST fuse.	No
	MWA100024z D1 Short + to AC	Unit shut down within 1 sec. F1 and F2 opened. Tested with Belfuse series RST fuse.	No
	MWA100012z C9 Short	Input power and current increased, F1 and F2 opened after 5 seconds. Tested with Belfuse series RST fuse.	No
	MWB100024z C10 Short	Unit shut down within 1 sec. F1 and F2 opened. Tested with Belfuse series RST fuse.	No
	MWB100024z Q3 Short G to S	Unit shut down within 1 sec no hazardous observed. Recovers when short removed	No
	MWB100024z U3 Short pin 1 and 2	Input power and input current from 109.9W to 113.4W, 0.683A to 0.752A. Output voltage increased from 23.86Vdc to 24.79Vdc. T1winding=80.5°C, ambient temperature =25.0°C, test duration=1 hours 30 minutes, 24Vdc@4.2A	No
	MWB100012z U2 Short pin 3 and 4	Unit shuts down (pulsing), recovers after short is removed. T1winding=37.0°C, ambient temperature =25.0°C, test duration=1 hours 30 minutes, 12Vdc@8.3A	No

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

Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	MWB100024z U3 Open pin 3	Unit shuts down (pulsing), unit does not recover after short is removed. T1winding=55.1°C, ambient temperature =25.0°C, test duration=1 hours 30 minutes, 24Vdc@4.2A	No
	MWB100024z U6 Short pin 1 and 2	Unit shuts down (pulsing), recovers after short is removed. T1winding=45.5°C, ambient temperature =25.0°C, test duration=1 hours 30 minutes, 24Vdc@4.2A	
	MWB100024z U6 Short pin 3 and 4	Unit shuts down (pulsing), recovers after short is removed. T1winding=45.5°C, ambient temperature =25.0°C, test duration=2 hours, 24Vdc@4.2A	
	MWB100012z U6 Open pin 3	Input power and input current from 112.3W to 117.8W, 0.672A to 0.706A. Output voltage decreased from 11.69Vdc to 11.59Vdc. T1winding=102.2°C, ambient temperature =25.0°C, test duration=1 hours 30 minutes, 12Vdc@8.3A	No
	Output overload: Model: MWA100012z	Output overloaded to 10.7A. Ambient temperature=25.0°C, T1winding=107.0°C, test duration= 4 hours	No
	Output Short: Model: MWA100012z	Output shuts down (pulsing). Ambient temperature=25.0°C, T1winding=58.3°C, test duration=3 hours, 12Vdc@8.3A	No
	Output overload: Model: MWA100024z	Output overloaded to 5.8A. Ambient temperature=25.0°C, T1winding=91.9°C, test duration= 4 hours	No
	Output Short: Model: MWA100024z	Output shuts down (pulsing). Ambient temperature=25.0°C, T1winding=44.3°C, test duration=3 hours, 24Vdc@4.2A	No
13.2.3	Overheating of transformers per Clause 15.5:	—	—

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
	T1 secondary windings 7/8 and 9/10 overload: MWA100012z	Secondary windings 7/8 and 9/10 overloaded to 10.8 A, auxiliary windings 11 and 12 loaded to 0.7A. T1winding=107.5°C. Ambient temperature=28°C, test duration=2 hour 30 minutes	No
	T1 secondary windings 7/8 and 9/10 overload: MWA100024z	Secondary windings 7/8 and 9/10 overloaded to 5.8 A, auxiliary windings 11 and 12 loaded to 0.7A. T1winding=85.5°C. Ambient temperature=28°C, test duration=2 hour 30 minute	No
13.2.4	Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
		N/A	N/A
13.2.5	Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:	—	—
		N/A	N/A
13.2.6	Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)	—	—
		N/A	N/A
13.2.7	Impairment of cooling that could result in a HAZARD using test method of 11.1:	—	—
	Single ventilation fans locked consecutively	N/A	N/A
	Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls		
	Simulated blocking of filters		
	Flow of a cooling agent interrupted		

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
Clause No.	Description of SINGLE FAULT CONDITION	Results observed	HAZARDOUS SITUATION (Yes/No)
13.2.8	Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:	—	—
		N/A	N/A
13.2.9	Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited ¹ – Also see 13.10	—	—
		N/A	N/A
13.2.10	Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 & 13.2.9:	—	—
	For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT started from COLD CONDITION at RATED voltage or at the upper limit of RATED voltage range for specified time:	N/A	N/A
	Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices		
	Temperatures measured as specified in 11.1.3 d)		
	Temperatures did not exceed limits of Table 26		
13.2.11	Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:	—	—
		N/A	N/A
13.2.12	Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):	—	—
		N/A	N/A
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.			
13.2.6	RM RESULTS TABLE: Leakage of liquid		N/A

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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

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

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

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

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

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

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

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

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

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

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

15.1	RM RESULTS 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. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

15.3	TABLE: Mechanical Strength tests ¹⁾		Pass
Clause	Name of Test	Test conditions	Observed results/Remarks
15.3.2	Push Test	Force = 250 N ± 10 N for 5 s	No hazards result. No access to internal live parts.
15.3.3	Impact Test	Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m	No hazards result. No access to internal live parts.
15.3.4.2	Drop Test (portable)	Drop height (cm) = 122	No hazards result. No access to internal live parts.
15.3.6	Mould Stress Relief	7 h in oven at temperature (°C) = 100	No hazards result. No access to internal live parts.

Supplementary information: Test performed on MWAx0yz and MWBx0yz series, MVAx0yz and MVBx0yz series are open frame power supplies, end use to be considered

Test performed on enclosures made of Lexan 940, Lexan 945 and Lexan 500 material

¹⁾As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows).

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

15.3.2	RM RESULTS TABLE: Push test		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			

15.3.3	RM RESULTS TABLE: Impact test		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			

15.3.4.2	RM RESULTS TABLE: Portable ME equipment		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			

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

15.4.1	RM RESULTS TABLE: Construction of connectors		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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

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

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

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

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

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

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.3.2	RM RESULTS TABLE: Connection		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
15.4.3.3	RM RESULTS TABLE: Protection against overcharging		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
15.4.3.4	RM RESULTS TABLE: Lithium batteries		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
15.4.3.5	RM RESULTS TABLE: Excessive current and voltage protection		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			
15.4.4	RM RESULTS TABLE: Indicators		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
15.4.5	RM RESULTS TABLE: Pre-set controls		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.5	RM RESULTS TABLE: Pre-set controls		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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 RESULTS TABLE: Entry of liquids		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			

IEC 60601-1			
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)
T1 secondary windings 7/8 and 9/10 short: MWA1000 12z	B	F1, F2	No	2.5 hours	175	53.9	26
T1 secondary windings 7/8 and 9/10 short: MWA1000 24z	B	F1, F2	No	2.5 hours	175	44.0	26
Supplementary information: ¹ Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.							

IEC 60601-1					
Clause	Requirement + Test		Result - Remark		Verdict
15.5.1.3	TABLE: transformer overload test – conducted only when protective device under short-circuit test operated				Pass
Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V) ¹:				264	
RATED input frequency (Hz).....:				60	
Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A).....:				N/A	
Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A)				N/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)
T1 secondary windings 7/8 and 9/10: MWA100012z	B	F1, F2	175	107.5	25.0
T1 secondary windings 7/8 and 9/10: MWA100024z	B	F1, F2	175	85.5	25.0
Supplementary information: Protective device did not operate during transformer short circuit test, however transformer overload was performed ¹ Loads on other windings between no load and their NORMAL USE load. Time durations: - IEC 60127-1 fuse: 30 min at current from Table 32. Non IEC 60127-1 fuse: 30 min at the current based on characteristics supplied by fuse manufacturer, specifically, 30 min clearing-time current. When no 30 min clearing-time current data available, test current from Table 32 used until THERMAL STABILITY achieved. - Other types of protective devices: until THERMAL STABILITY achieved at a current just below minimum current operating the protective device in a). This portion concluded at specified time or when a second protective device opened.					

15.5.2	TABLE: Transformer dielectric strength after humidity preconditioning of 5.7				Pass
Transformer Model/Type/ Part No	Test voltage applied between	Test voltage, (V)	Test frequency (Hz)	Breakdown Yes/No	Deterioration Yes/No
MWA100012z	Primary to secondary	1200 Vac	300 Hz	No	No
MWA100024z	Primary to secondary	1200 Vac	300 Hz	No	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					

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
16.1	RM RESULTS TABLE: General requirements for ME Systems		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			

16.6.1	TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS				N/A
Specific area where TOUCH CURRENT measured (i.e., from or between parts of ME SYSTEM within PATIENT ENVIRONMENT)	Allowable TOUCH CURRENT in NORMAL CONDITION (μA)	Measured TOUCH CURRENT in NORMAL CONDITION (μA)	Allowable TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (μA)	Measured TOUCH CURRENT in event of interruption of PROTECTIVE EARTH CONDUCTOR, (μA)	
	100		500		
	100		500		
	100		500		
	100		500		
	100		500		
Supplementary information:					

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

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict
17	RM RESULTS TABLE: Electromagnetic compatibility of ME equipment and ME systems		N/A
Clause of ISO 14971	Document Ref. in RMF (Document No. & paragraph)	Result - Remarks	Verdict
4.2			
4.3			
4.4			
5			
6.2			
6.3			
6.4			
6.5			

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

END OF TEST REPORT

30792801.009

Attachment # 1
Page 1 of 6
Photos

MWA/MWBx0yz



30792801.009

Attachment # 1
Page 2 of 6
Photos

MWA/MWBx0yz



30792801.009

Attachment # 1
Page 3 of 6
Photos

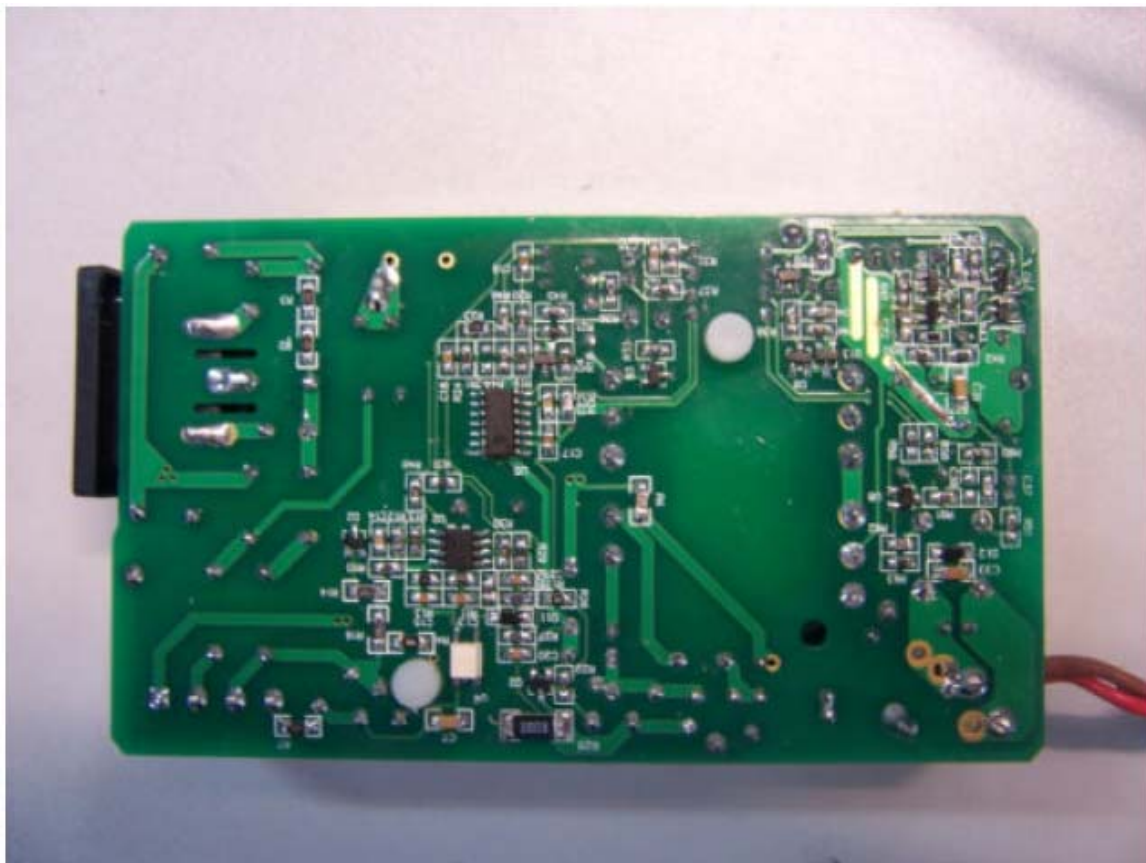
MWA/MWBx0yz



30792801.009

Attachment # 1
Page 4 of 6
Photos

MWA/MWBx0yz



30792801.009

Attachment # 1
Page 5 of 6
Photos

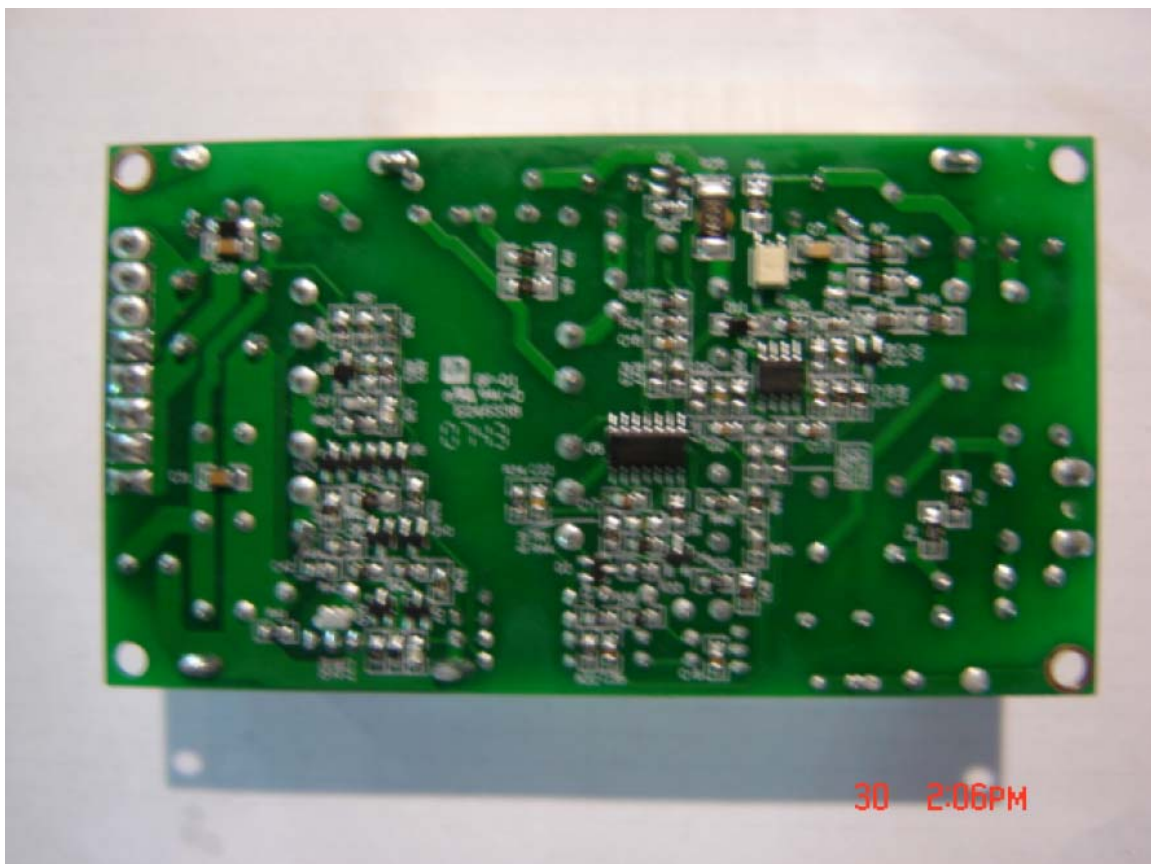
MVA/MVBx0yz



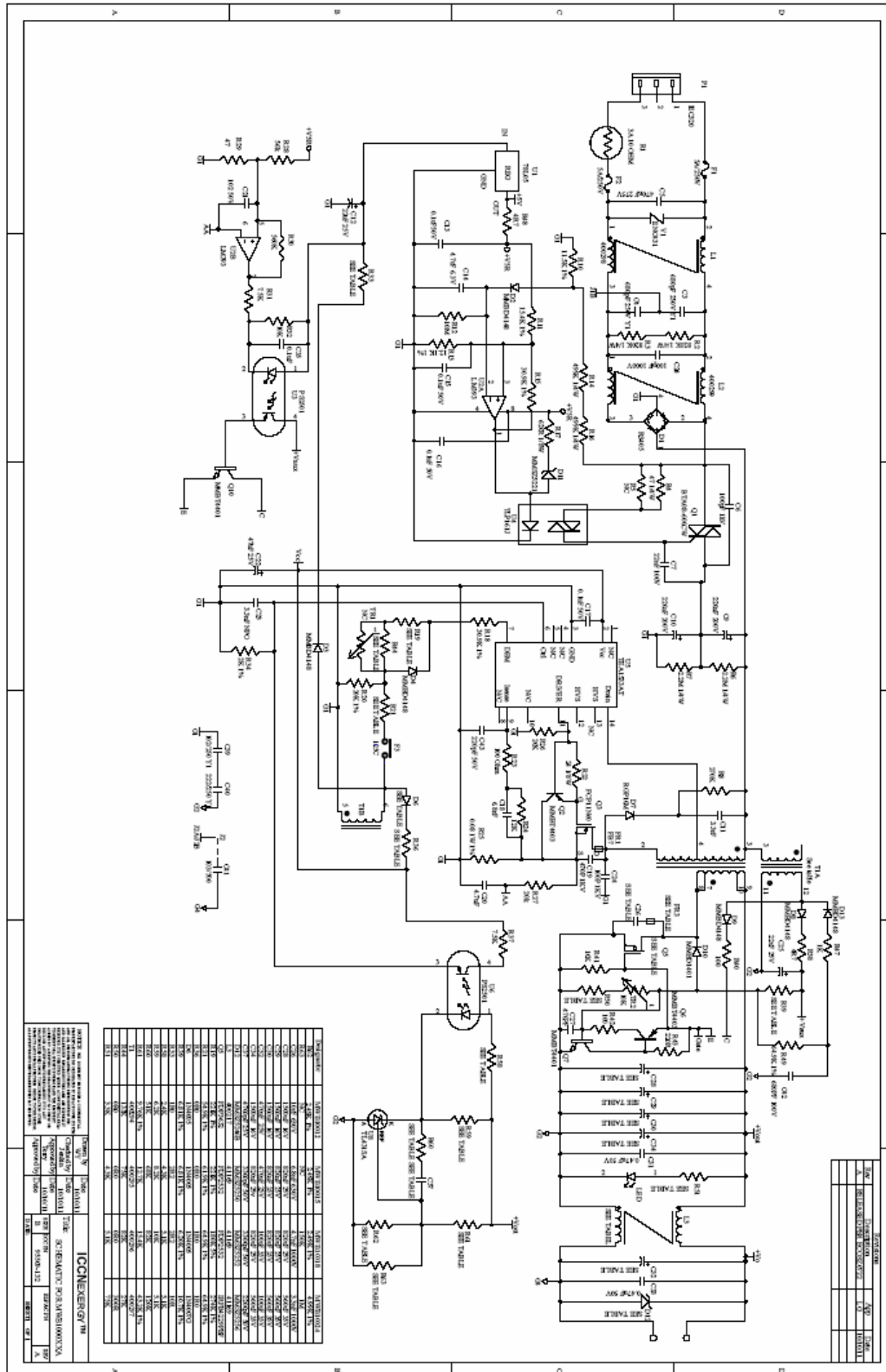
30792801.009

Attachment # 1
Page 6 of 6
Photos

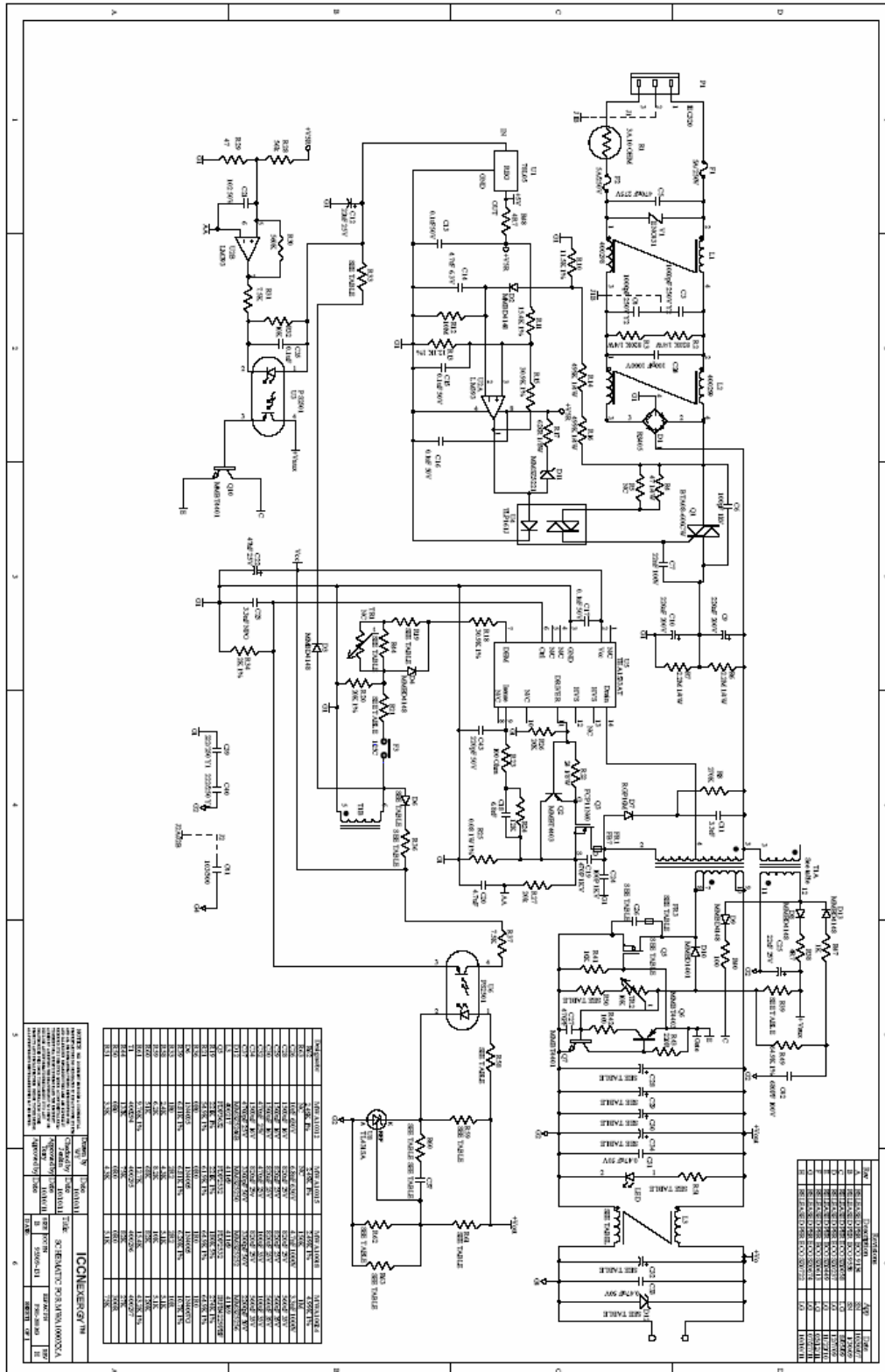
MVA/MVBx0yz



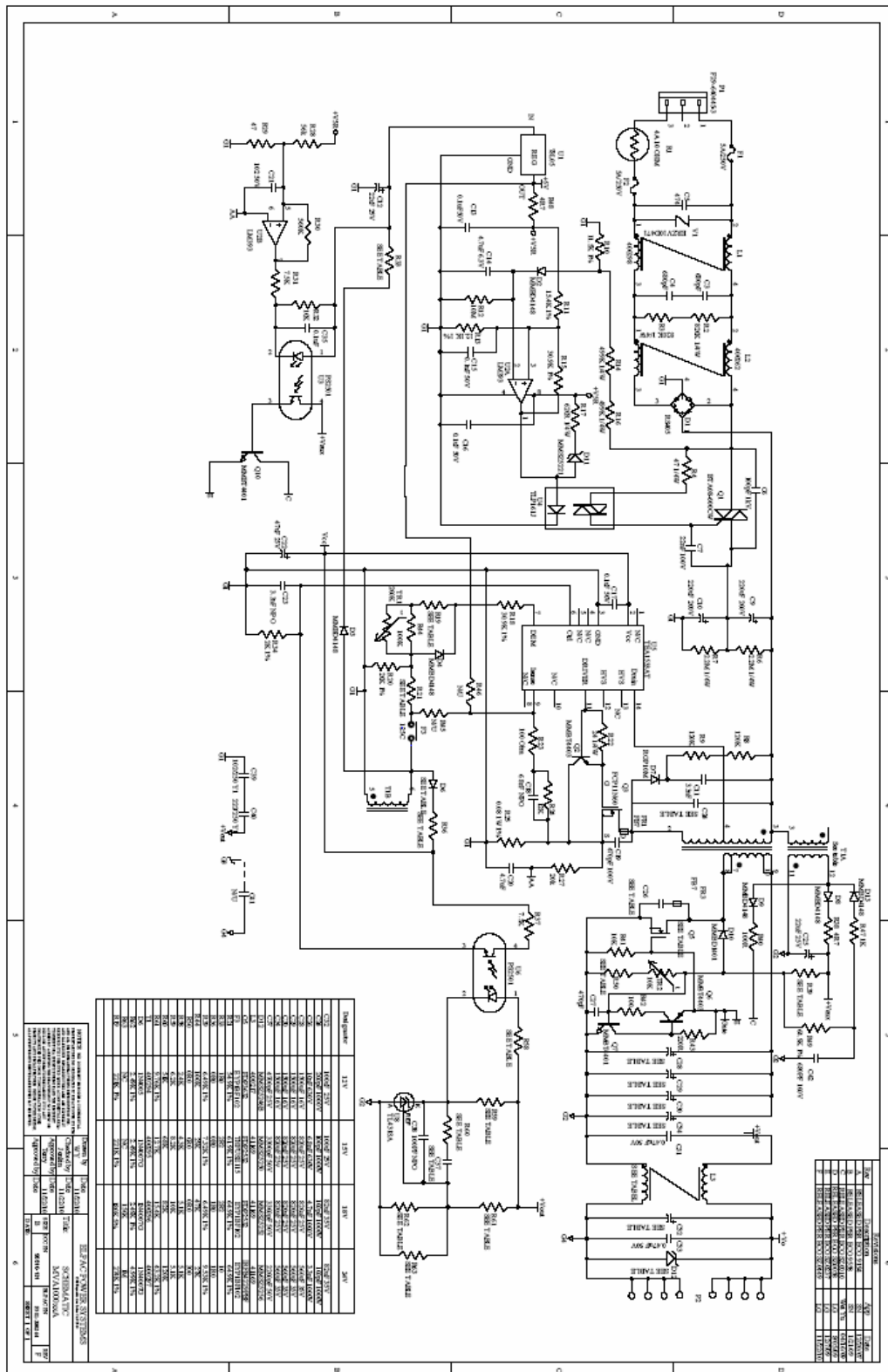
MWBx0yz



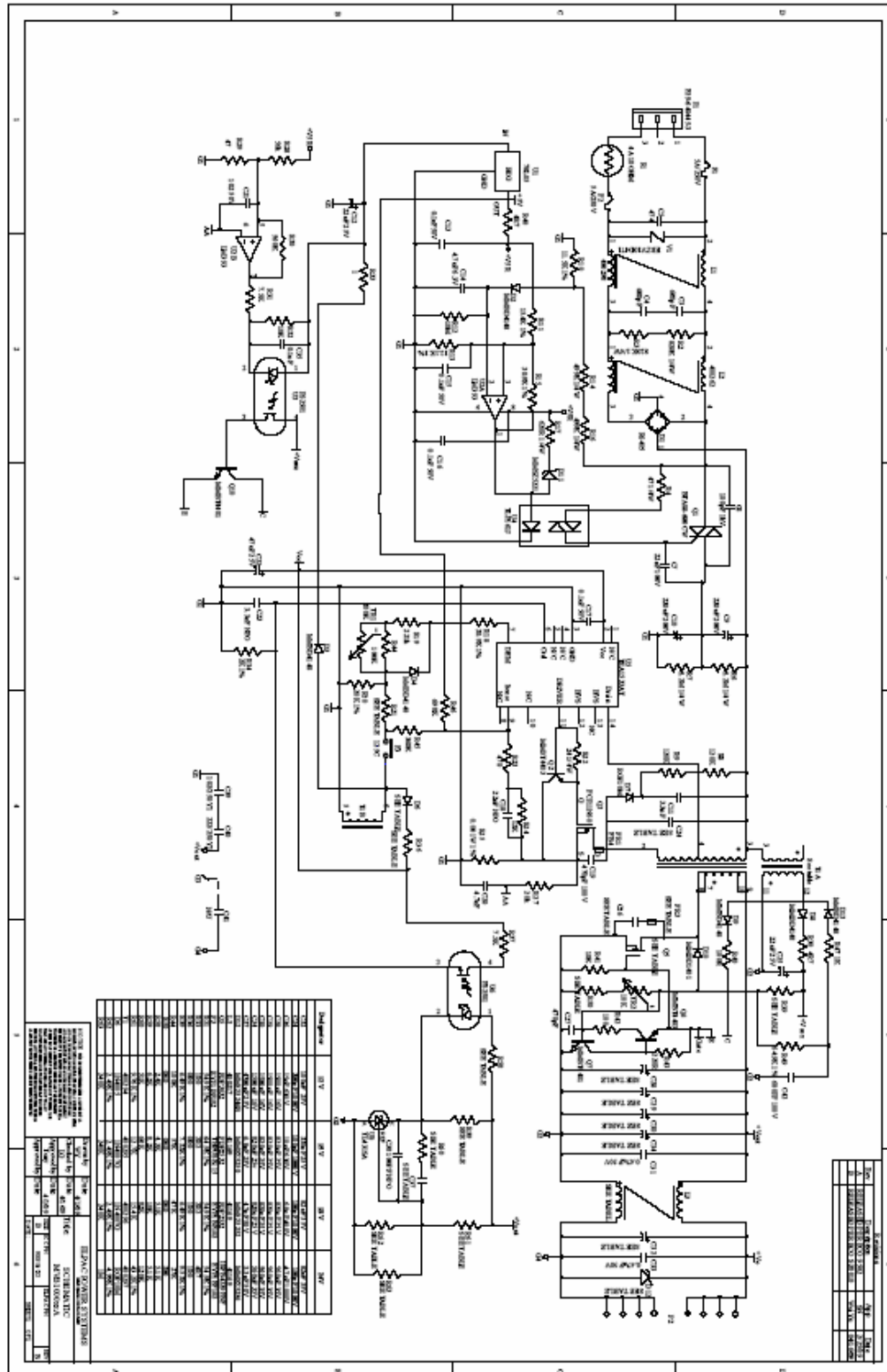
MWx0yz



MVx0yz



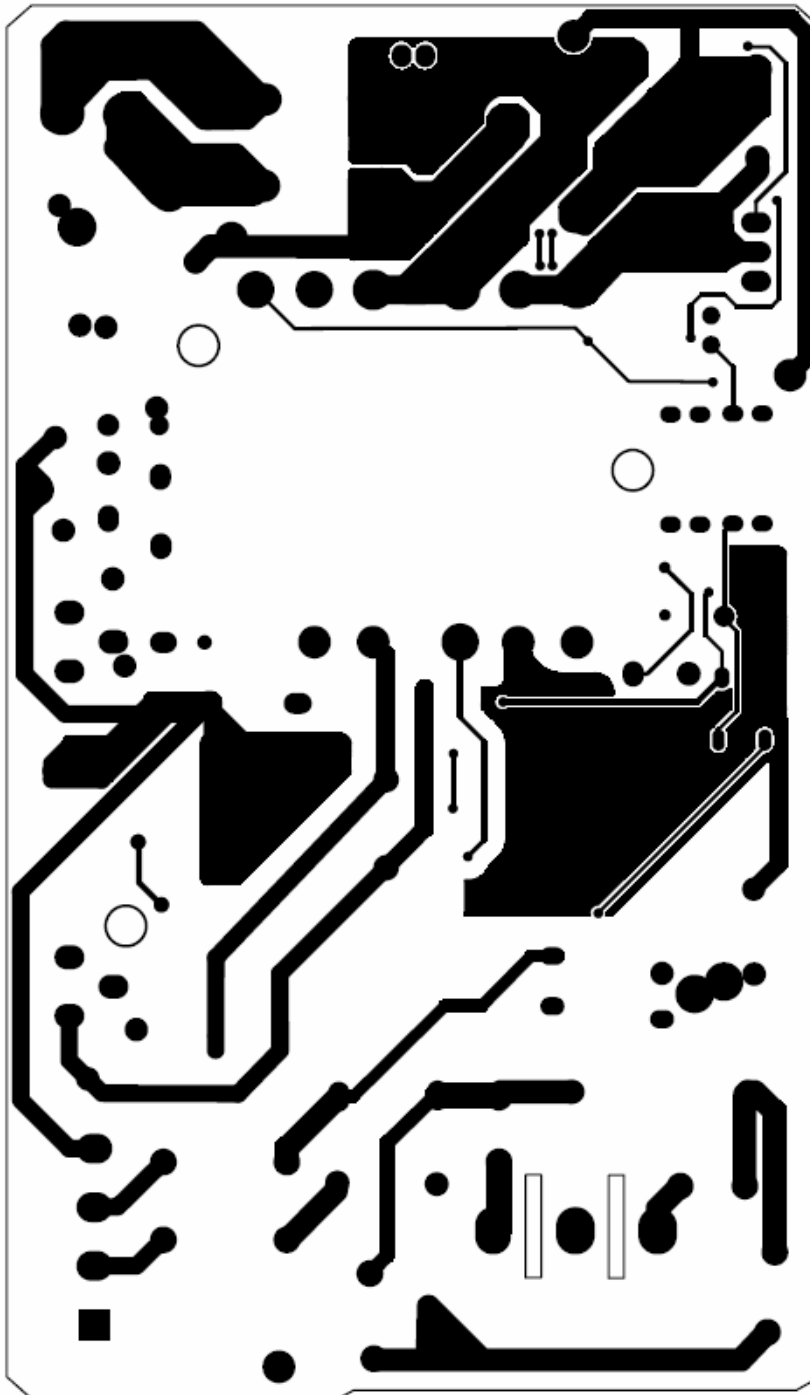
MVBx0yz



30792801.009

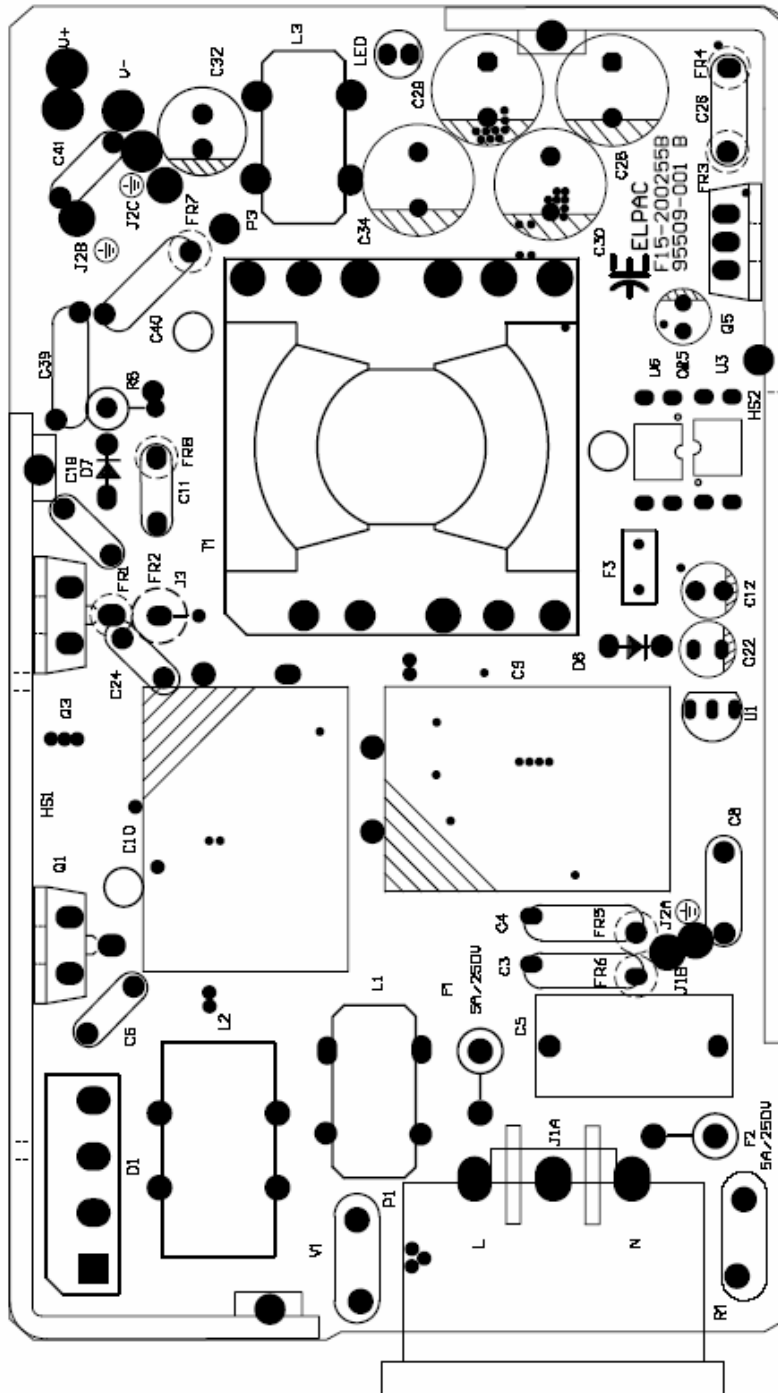
Attachment # 3
Page 1 of 8
PCB Layout

MWA/MWBx0yz



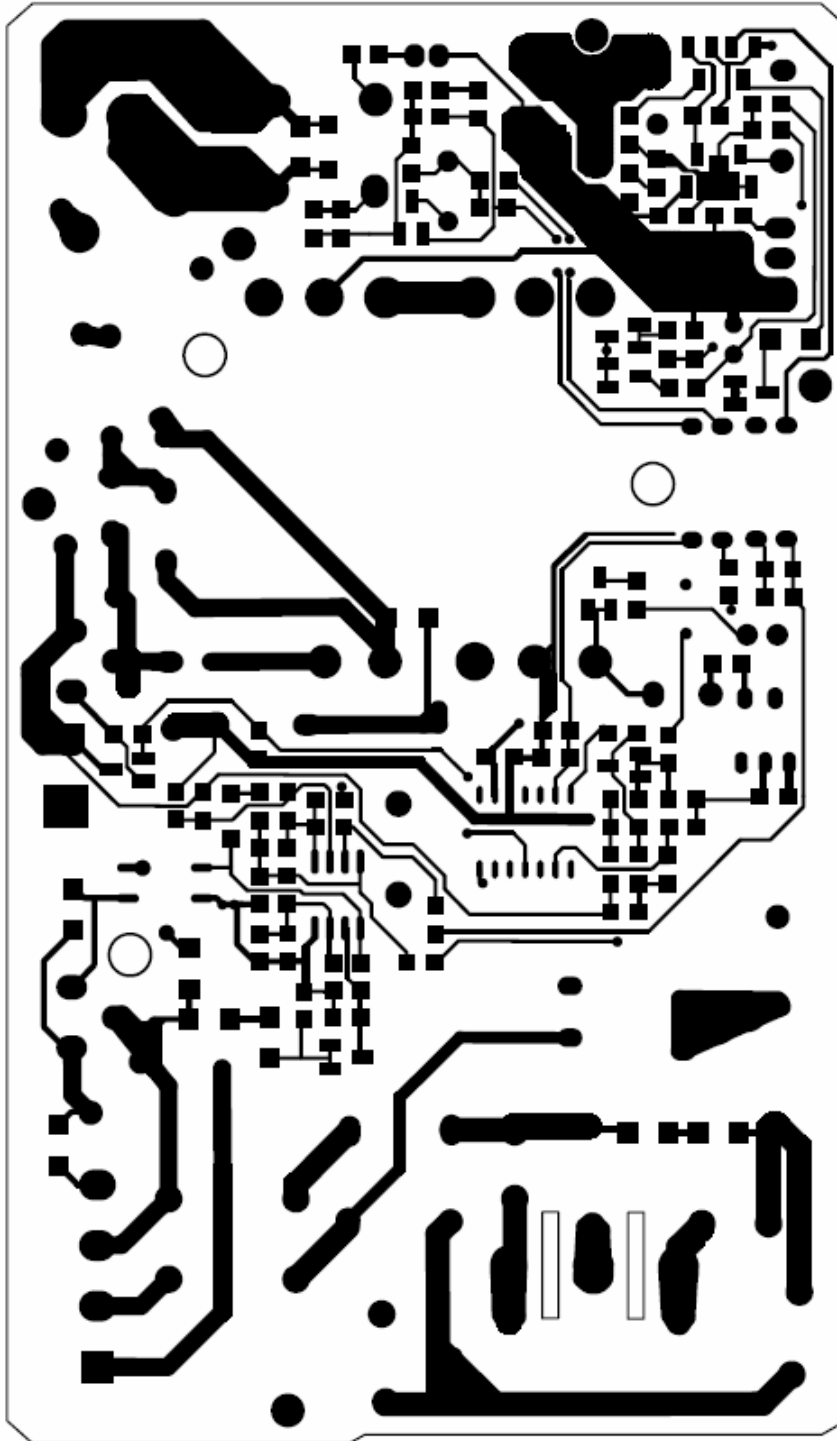
95509-001 Rev B sheet 2 of 5

MWA/MWBx0yz



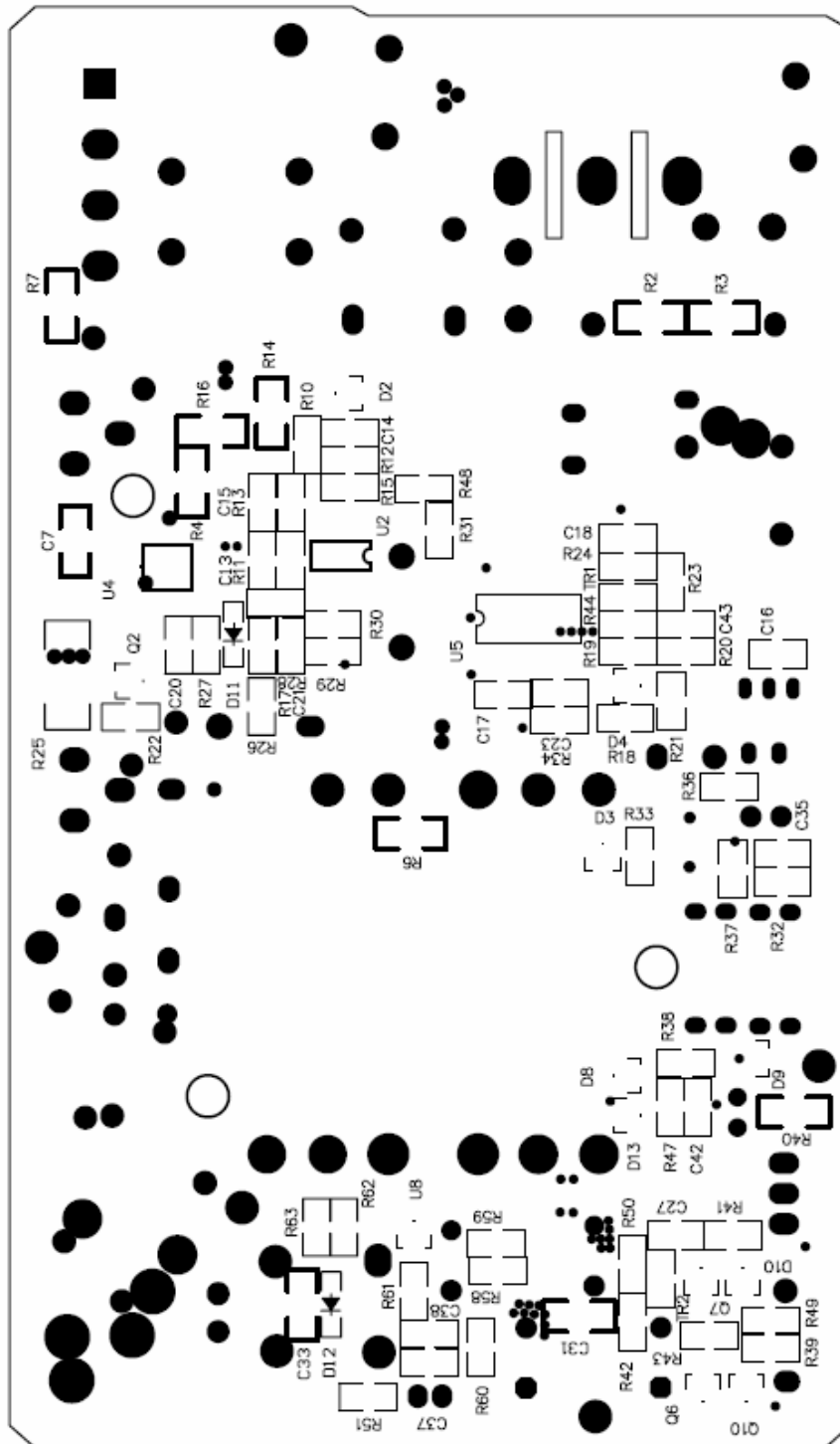
95509-001 Rev B sheet 3 of 5

MWA/MWBx0yz



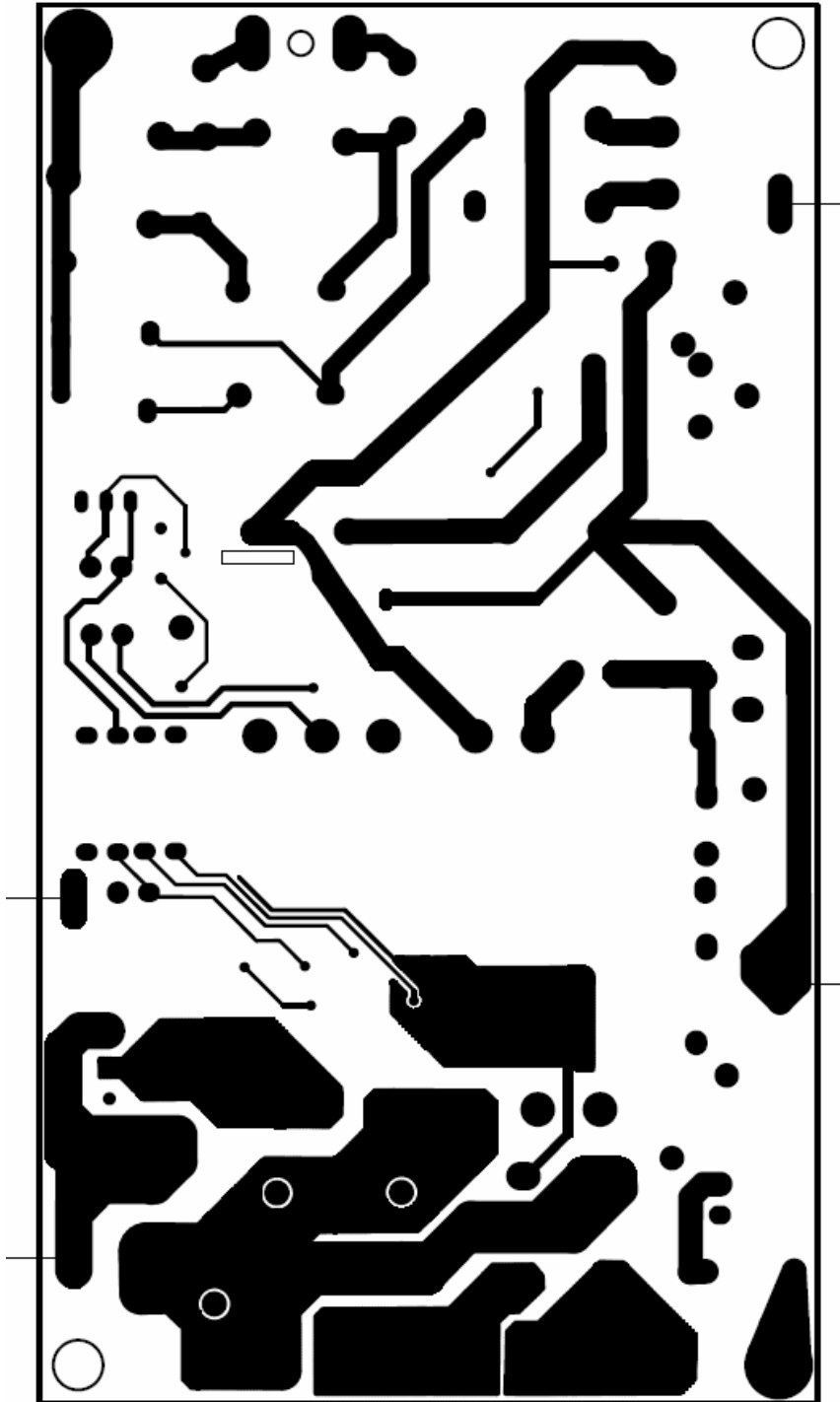
95509-001 Rev B sheet 4 of 5

MWA/MWBx0yz

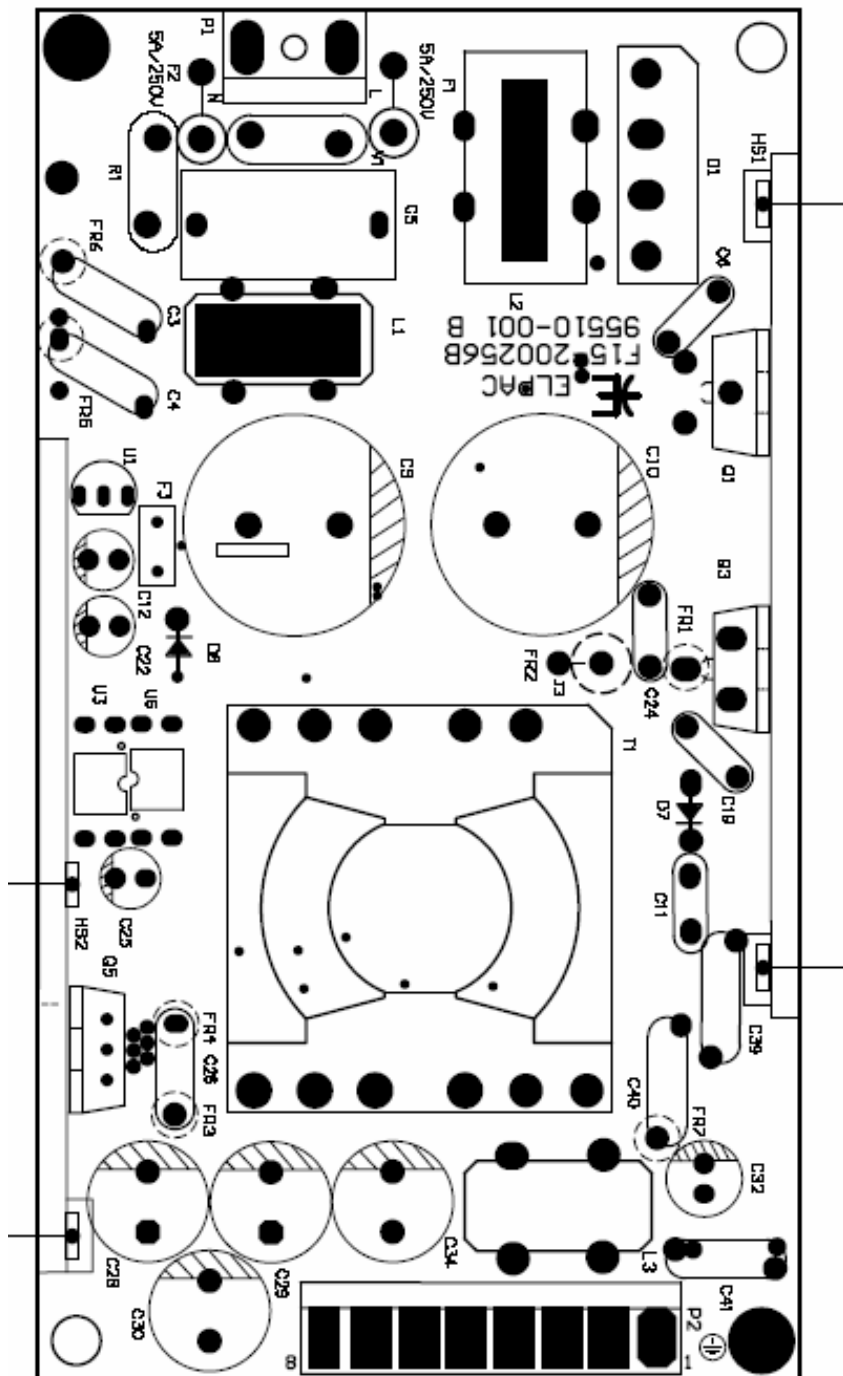


95509-001 Rev B sheet 5 of 5

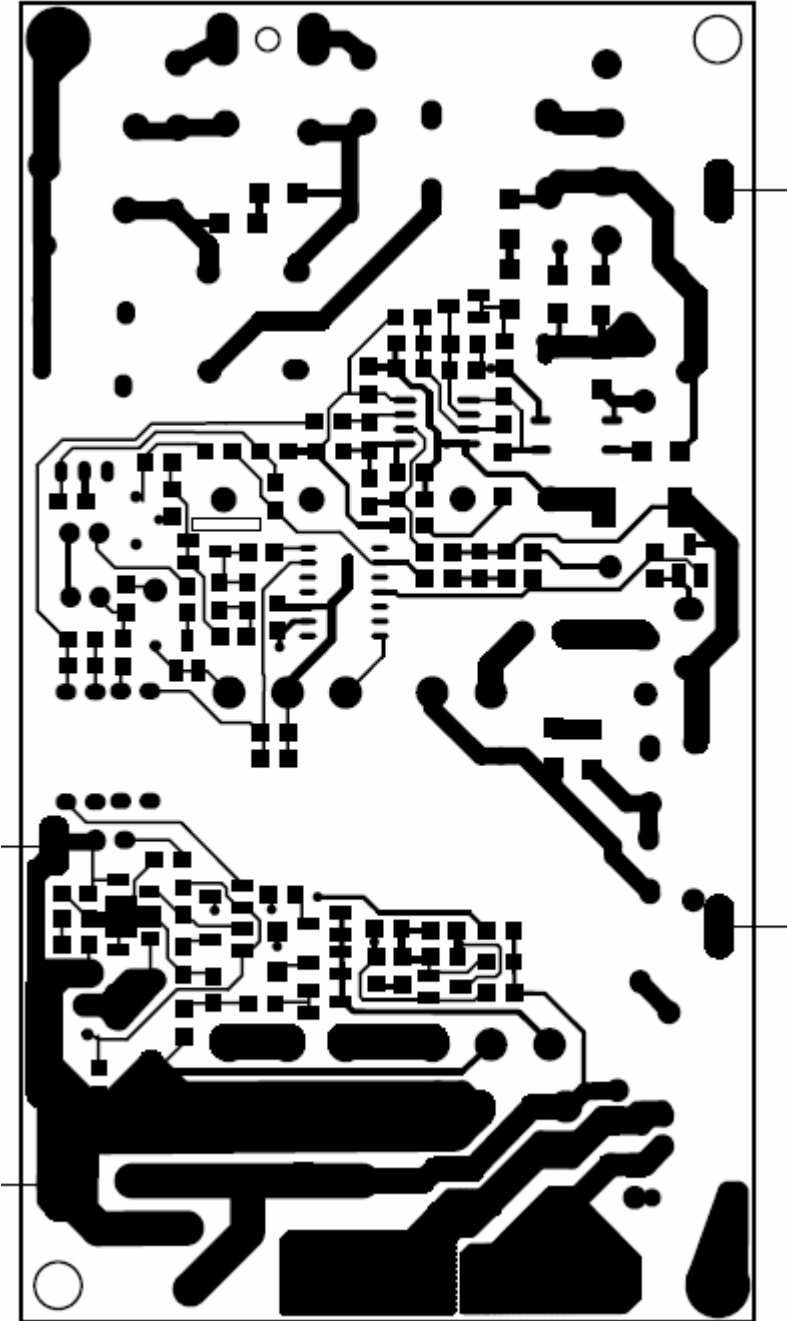
MVA/MVBx0yz



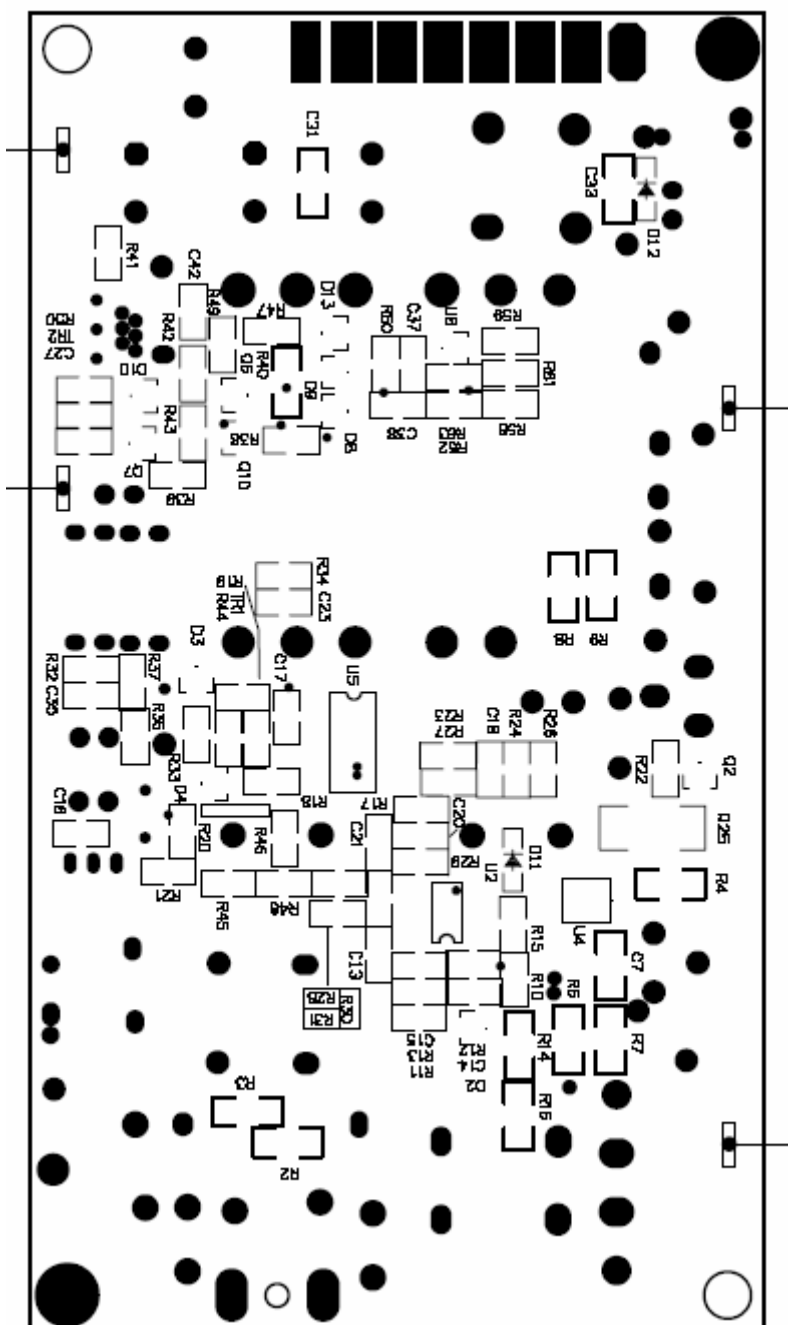
MVA/MVBx0yz

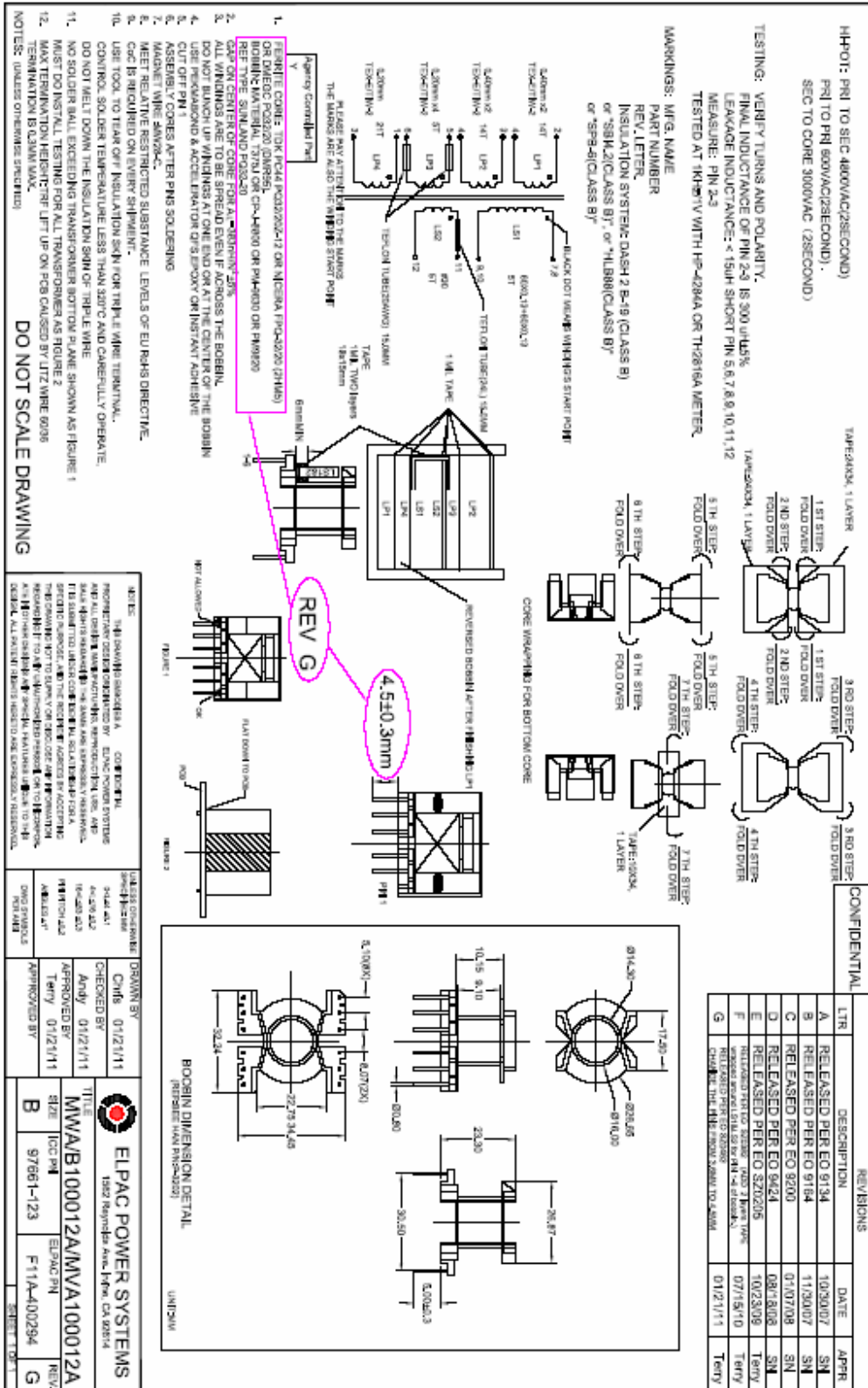


MVA/MVBx0yz

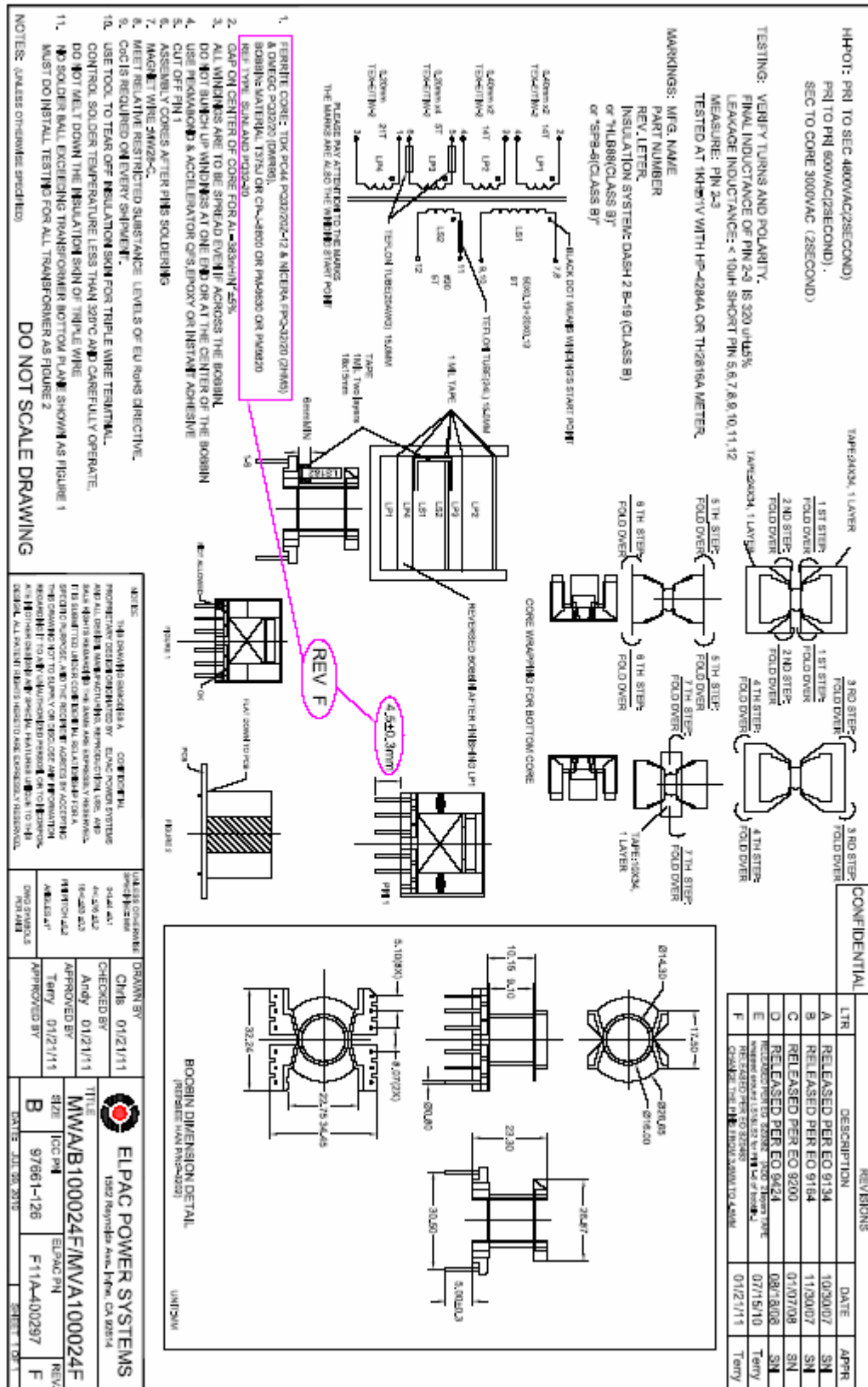


MVA/MVBx0yz

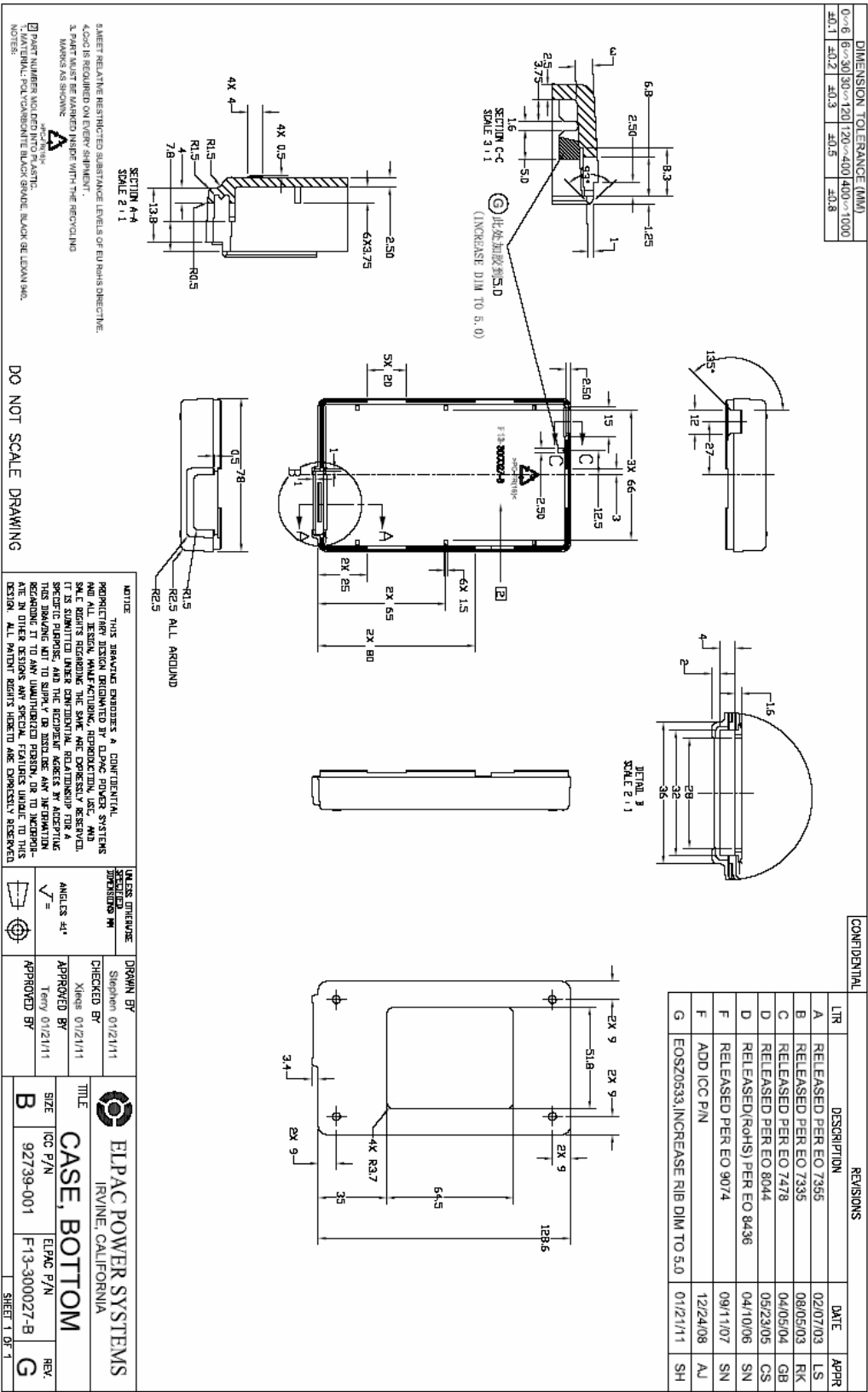




30792801.009

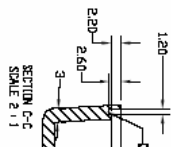
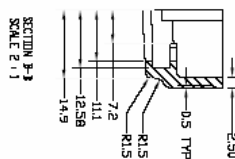
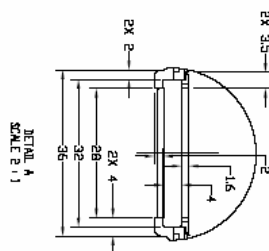
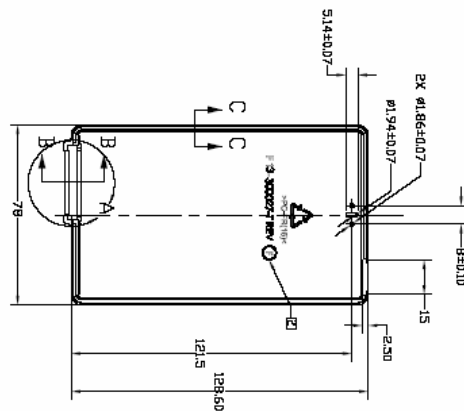
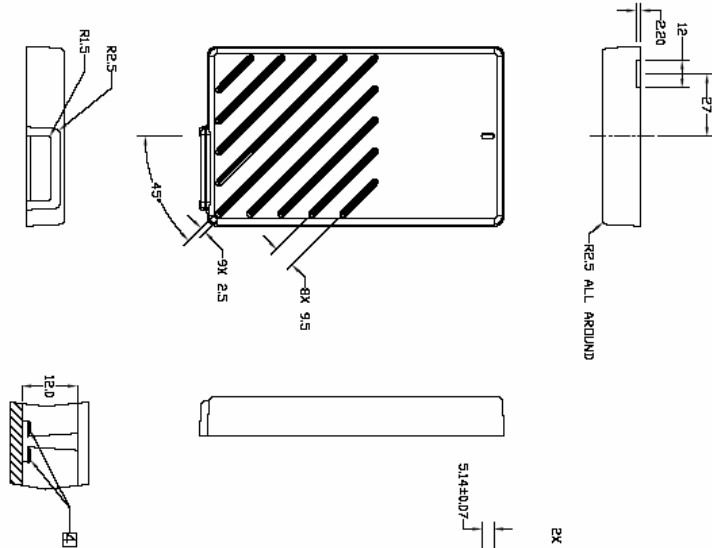


30792801.009



30792801.009

DIMENSION TOLERANCE (MM)				
0~6	6~30	30~120	120~400	400~1000
±0.1	±0.2	±0.3	±0.5	±0.8



REVISIONS			
LTR	DESCRIPTION	DATE	APPR
A	RELEASED PER EO 7215	02/07/03	LS
B	REMOVED PER EO 7335	08/05/03	RK
C	REVISD PER EO 7478	04/05/04	GB
D	REVISED PER EO 8044	05/23/05	CS
D	REVISED (R045) PER EO 8436	05/23/05	CS
F	REVISED PER EO 9074	09/11/07	SN
F	ADD ICC PIN	12/24/08	AJ

7. WELDING OF THE LIGHT PIPE AS SHOWN.
8. PART NUMBER AND REVISION NUMBER MODIFIED IN 1. MATERIAL: POLYCARBONATE BLACK GRADE BLACK GE LEXAN 940.

DO NOT SCALE DRAWING

NOTICE THIS DRAWING EMBODIES A CONFIDENTIAL PROPRIETARY DESIGN RECORDED BY ELAPAC POWER SYSTEMS AND ALL DESIGN, MANUFACTURING, REPRODUCTION, USE, AND SALE RIGHTS REGARDING THE SAME ARE EXPRESSLY RESERVED. IT IS LIMITED TO THE EXCLUSIVE USE OF THE RECIPIENT AND IS TO REMAIN UNDER CONFIDENTIAL RELATIONSHIP FOR A SPECIFIC PURPOSE, AND THE RECIPIENT AGREES BY ACCEPTING THIS DRAWING NOT TO SUPPLY OR DISCLOSE ANY INFORMATION REGARDING IT TO ANY UNAUTHORIZED PERSON, OR TO INCORPORATE IN OTHER DESIGNS ANY SPECIAL FEATURES UNIQUE TO THIS DESIGN. ALL PAYMENT RIGHTS HERETO, AND ALL EXPRESSLY RESERVED

UNLESS OTHERWISE SPECIFIED	ANGLES IN°
TYPE STUDS 44	$\nabla =$
	DRUG SYMBOLS PER ANSI

DRAWN BY	
Stephen	12/24/08
CHECKED BY	
Xlegs	12/24/08
APPROVED BY	
Terry	12/24/08
APPROVED BY	

 ICCNEXERGY™			
TITLE			
CASE TOP FWP80XX & MW65XX			
SIZE	ICG P/N	ELPCG P/N	REV.
B	92739-002	F13-300027-I	F
DATE	SHEET 1 OF 1		

IEC 60601-1 3 rd edition National Differences			
Clause	Requirement + Test	Result - Remark	Verdict

Canada Last modified 10/27/08			
1.1	Scope <i>(Add the following)</i> This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with the <i>Canadian Electrical Code (CEC), Part I, CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32.</i> NOTE 1A: <i>In the IEC 60601 standards series adopted for use in Canada, the Canadian-particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.</i>	Added	N/A
1.3	Collateral standards <i>(Replace the second paragraph and Note 1 with the following)</i> Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard. NOTE 1: <i>When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards</i>	Replaced	N/A
1.4	Particular standards <i>(Replace this clause with the following)</i> A requirement of a Canadian-particular safety standard takes precedence over this standard.	Replaced	Pass
2	Normative references <i>(Replace the first paragraph with the following)</i> The following referenced documents are indispensable for the application of this document. For dated references, the applicable corresponding Canadian adopted IEC standards shall take precedence. For undated references, the latest edition of the referenced document (including any amendments) applies. All Canadian adopted IEC part 2 standards are referenced with the date of publication.	Replaced	Pass

IEC 60601-1 3 rd edition National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	(Add the following) <u>CSA (Canadian Standards Association)</u> B51-03 <i>Boiler, pressure vessel, and pressure piping code</i> C22.1-06 <i>Canadian Electrical Code, Part I</i> CAN/CSA-C22.2 No. 0-M91 (R2006) <i>General requirements — Canadian Electrical Code, Part II</i> C22.2 No. 21-95 (R2004) <i>Cord sets and power supply cords</i> C22.2 No. 42-99 (R2004) <i>General use receptacles, attachment plugs, and similar wiring devices</i> C22.2 No. 49-06 <i>Flexible cords and cables</i> CAN/CSA-E61558-2-1:03 <i>Safety of power transformers, power supply units and similar — Part 2: Particular requirements for separating transformers for general use</i> CAN/CSA-Z32-04 <i>Electrical safety and essential electrical systems in health care facilities</i> <u>Z305 series of Standards:</u> CAN/CSA-Z305.1-92 (R2001) <i>Non-flammable medical gas piping systems</i> CAN/CSA-Z305.6-92 (R2007) <i>Medical oxygen concentrator central supply system for use with nonflammable medical gas piping systems</i> CAN/CSA-Z305.8-03 <i>Medical supply units</i> CAN/CSA-Z305.12-98 (R2004) <i>Guide for the safe storage, handling and use of portable oxygen systems in home, domiciliary and healthcare settings</i>		

IEC 60601-1 3 rd edition National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	CAN/CSA-Z5359-04 <i>Low pressure hose assemblies for use with medical gases</i> CAN/CSA-Z9170-1-00 (R2005) <i>Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum</i> CAN/CSA-Z9170-2-00 (R2005) <i>Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems</i> CAN/CSA-Z9170-2-00 (R2005) <i>Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems</i> CAN/CSA-Z15002-02 (R2007) <i>Flow-metering devices for connection to terminal units of medical gas pipeline systems</i> ASME International (American Society of Mechanical Engineers) PTC 25-2001 <i>Pressure Relief Devices</i> CGA (Compressed Gas Association) V-1-2005 <i>Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections</i> V-5-2005 <i>Diameter Index Safety System (Non interchangeable Low Pressure Connections for Medical Gas Applications)</i> ISO (International Organization for Standardization) 32:1977 <i>Gas cylinders for medical use — Marking for identification of content</i> 407:2004 <i>Small medical gas cylinders — Pin-index yoke-type valve connections</i>		
3.41	HIGH VOLTAGE <i>(Replace this clause with the following)</i> any voltage above 750 V, 1 050 V peak, as defined in the <i>Canadian Electrical Code (CEC), Part I</i>	Replaced	N/A

IEC 60601-1 3 rd edition National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
4.8 a)	Components of ME EQUIPMENT (Replace Items a) and b) with the following) the applicable safety requirements of a relevant CSA, IEC, or ISO standard; NOTE 1: For the components, it is not necessary to carry out identical or equivalent tests already performed to check compliance with the component standard.	Replaced	Pass
b)	where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied NOTE 2: If there are neither requirements in this standard nor in a CSA, IEC, or ISO standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS.	Replaced	Pass
4.10.2	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS Add the following to the end of the first sentence and shall be in accordance with the <i>Canadian Electrical Code (CEC), Part I, CSA C22.1:</i>	Added	Pass
7.7.1 to 7.7.5	and shall be in accordance with the <i>Canadian Electrical Code (CEC), Part I, CSA C22.1</i> (Add the following to the end of the first sentence of Clauses 7.7.1 to 7.7.5) A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION or insulation shall be identified by either green or green and yellow colour. Colours of neutral and POWER SUPPLY CORD conductors shall be in accordance with the <i>Canadian Electrical Code (CEC), Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49.</i>	Added	Pass
8.7.3	Allowable values (Add the following as the first sentence) Allowable values shall be in accordance with the <i>Canadian Electrical Code (CEC), Part I, CSA C22.1.</i>	Added	Pass
8.11.3.2 a)	POWER SUPPLY CORDS Types (Replace the first paragraph with the following) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be i) if molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21;	Power supply cord not evaluated	N/A

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

IEC 60601-1 3 rd edition National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	NOTE 1A: See CSA C22.2 No. 49 for requirements on the cord types mentioned in Sub-item 2).		
d)	Power supply cords shall meet the requirements of the <i>Canadian Electrical Code, Part I</i> , as applicable.	Power supply cord not evaluated	N/A
	Connecting cords between equipment parts shall meet the requirements of the <i>Canadian Electrical Code, Part I</i> , as applicable.	Power supply cord not evaluated	N/A
8.11.5	Mains fuses and OVER-CURRENT RELEASES (Add the following as the first sentence) Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the <i>Canadian Electrical Code (CEC), Part I, CSA C22.1</i> .	See table 8.10	Pass
9.7.5	Pressure vessels (Add the following) Pressure vessels shall comply with the requirements of CSA B51, as applicable.	No pressure vessels	N/A
9.7.7	Pressure-relief device (Add the following) A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements.	No such pressure-relief device is provided	N/A
15.4.1	Construction of connectors (Add the following item)	No gas cylinders used	N/A
bA)	The point of connection of gas cylinders to EQUIPMENT shall be gas specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on EQUIPMENT shall be i) gas specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1 380 kPa (200 psi); or		
	ii) DISS type complying with CGA V-5 for pressures 1 380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359. NOTE 1A: Users of this standard should consult the CSA Z305 series of standards, CAN/CSA-Z9170-1, CAN/CSA-Z9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke-type valve connections; and ISO 32 for colour coding.	No parts under pressure	N/A

IEC 60601-1 3 rd edition National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
15.4.8	Internal wiring of ME EQUIPMENT <i>(Add the following)</i> Internal wiring of ME EQUIPMENT shall be in accordance with the <i>Canadian Electrical Code (CEC), Part I, CSA C22.1.</i>	Approved wiring used	Pass
16.1	General requirements for the ME SYSTEMS <i>(Replace the third paragraph with the following)</i> An ME SYSTEM shall provide - within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this standard; and - outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA, IEC, or ISO safety standards <i>(Replace the seventh paragraph with the following)</i> - Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with CSA, IEC, or ISO safety standards that are relevant to that equipment	Device is a component power supply, to be evaluated in end use application	N/A
16.9.2.1 c)	MULTIPLE SOCKET OUTLET <i>(Replace the first sentence of Item c) with the following)</i> The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements. <i>(Replace the first dashed sub-item in Item d) with the following)</i> - The separating transformer shall comply with the requirements of CAN/CSA-E61558-2-1 with a rated output not exceeding - 1 kVA for single-phase transformers; and - 5 kVA for polyphase transformers - The separating transformer shall also have a degree of protection not exceeding IPX4.	Device is a component power supply, to be evaluated in end use application	N/A

IEC 60601-1 3 rd edition National Differences			
Clause	Requirement + Test	Result - Remark	Verdict

Switzerland			
Last modified 12/15/2009			
4	Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7, Mercury - Annex 1.7 of SR 814.81 applies for mercury. Switches containing mercury such as thermostats, relays and level controllers are not allowed. Ordinance on chemical hazardous risk reduction SR 814.81, Annex 2.15 Batteries Annex 2.15 of SR 814.81 applies for batteries containing cadmium and mercury. Note: Ordinance relating to environmentally hazardous substances, SR 814.013 of 1986-06-09 is not longer in force and superseded by SR 814.81 of 2009-02-01 (ChemRRV).	Not provided with switches or batteries.	N/A
4	Supply cords of portable electrical appliances having a rated current not exceeding 10 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets: - SEV 6533-2:2009 Plug type 11, L + N, 250V 10A - SEV 6534-2:2009 Plug type 12, L + N + PE, 250V 10A - SEV 6532-2:2009 Plug type 15, 3L + N + PE, 250/400V 10A Supply cords of portable electrical appliances having a rated current not exceeding 16 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets:	Power supply cord not evaluated	N/A

IEC 60601-1 3 rd edition National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	- SEV 5933-2:2009 Plug type 21 L + N, 250 V, 16A - SEV 5934-2:2009 Plug type 23 L + N + PE, 250 V, 16A - SEV 5932-2:2009 Plug type 25 3L + N + PE, 250/400V 16A NOTE 16 A plugs are not often used in Swiss domestic installation system. See TRF template regulatory requirements Switzerland on IECCE Website R.R. TRF templates.		

IEC 60601-1 3 rd edition National Differences			
Clause	Requirement + Test	Result - Remark	Verdict

US Last modified 10/02/08			
4.8	Components of ME EQUIPMENT Replacement: b) where there was no relevant IEC/ISO standard, the relevant US ANSI standard applied: When no relevant US ANSI standard existed, the requirements of this standard applied	IEC 60601-1 is applied when necessary	Pass
4.10.2.	SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS Replacement: Reference to "500 V" replaced with "600 V" in the second and third dashes to agree with the National Electrical Code (NEC) "and the NEC" added after the reference to "IEC 60364-4-41" in the text of the second-to-last dash of this sub-clause to agree with NEC	Rated 240VAC	N/A
8.2	Requirements related to power sources Addition to agree with NEC: The requirement, "ALL FIXED ME EQUIPMENT and PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT"	Not this type of equipment	N/A
8.7.3	Allowable values: Deleted the second sentence and note to sub-clause 8.7.3 d) to read as follows to agree with NFPA 99 which does not permit for allowances larger than the stated values: d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION	Values were not exceeded. See appended table 8.7B	Pass
8.11	MAINS PARTS, components and layout Addition to agree with NEC: The requirement, "Permanently connected ME EQUIPMENT shall have provision for the connection of one of the wiring systems that is in accordance with the NEC" Fixed and stationary X-ray ME EQUIPMENT supplied from a branch circuit rated at 30 A or less, and ME EQUIPMENT not strictly portable but obviously intended to be stationary, considered acceptable when supply connection provided with a length of attached Type S hard service flexible cord, or equivalent: Installation of connecting cords between EQUIPMENT parts comply with NEC, as applicable Cable used as external interconnection between units was: 1) Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord when exposed to abuse, or similar multiple-conductor appliance-wiring material such as computer cable: 2) The cable was as in item 1) above	Not permanently connected equipment	N/A

IEC 60601-1 3 rd edition National Differences			
Clause	Requirement + Test	Result - Remark	Verdict
	when not exposed to abuse, or it was i) Type SPT-2, SP-2, or SPE-2, or equivalent ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material, Or, ii) An assembly of insulated wires each with a nominal insulation thickness of 0.8 mm (1/32 inch) or more, enclosed in acceptable insulating tubing having a nominal wall thickness of 0.8 mm (1/32 inch) or more. Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of pediatric wards, rooms, or areas are listed (e.g., UL Certified) tamper resistant or employ a listed (e.g., UL Certified) tamper resistant cover in accordance with NEC		
8.11.3.2	Addition to agree with NEC: The flexible cord is a type acceptable for the particular application, and it is acceptable for use at a voltage not less than the rated voltage of the appliance and has an ampacity as in NEC, not less than the current rating of the appliance.	Power supply cord not evaluated	N/A

TEST REPORT

IEC 60601-1

Medical electric equipment Part 1: General requirements for safety

Report

Reference No. : **30792801.009 Attachment 7**

Compiled by (+ signature) : Ricardo Felix = See Main Report =

Approved by (+ signature) : Daniel Ruth = See Main Report =

Date of issue : 12//15/2011

Contents : 78 pages

This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator (see below).

Testing laboratory

Name : TÜV Rheinland of North America, Inc.

Address : 1279 Quarry Lane, Ste. A, Pleasanton, CA 94566

Testing location : TÜV Rheinland of North America Inc.
1279 Quarry Lane, Ste. A, Pleasanton, CA 94566

Client

Name : Elpac Electronics Inc.,
Elpac Power Systems, Div of

Address : 17672 Armstrong Ave, Irvine, CA 92614

Test specification

Standard : IEC 60601-1:1988 + A1:1991 + A2:1995

Test procedure : CB-scheme

Procedure deviation : National Differences of Australia, Canada, Denmark, Israel, Korea and
United States

Non-standard test method : N.A.

Test Report Form/blank test report

Test Report Form No. : I601-1_C/97-04

TRF originator. : Underwriters Laboratories Inc.

Master TRF : dated 97-04

Copyright reserved to the bodies participating in the Committee of Certification Bodies (CCB) and/or the
bodies participating in the CENELEC Certification Agreement (CCA).

IEC 60601-1

Test item

Description :  **ELPAC POWER SYSTEMS™** power supply

Trademark :



Model and/or type reference..... : MWAx0yz and MWBx0yz and MVAx0yz and MVBx0yz (x = 050 to 100, y = 12 to 24, z = A – Z or blank, not safety related)

Manufacturer/Factory..... : ICC Electronics (Dongguan) Ltd
3rd Row, Block A, Shang Yuan Road, 2nd Industrial Zone,
Quingxi Town, DongGuan City, Guangdong, China

Rating(s) : Input:
AC 100-240 V, 50/60Hz, 2.3 Amps
Output:
DC 12 to 24 V,
8.3 Amps Max, 100 Watt Max

GENERAL INFORMATION

Test item particulars (see also clause 5):

Classification of installation and use : Unit is a component and dependant on end use device

Supply connection..... : Appliance inlet. Three prong (Class I) on MWAx0yA & MVAx0yA and two prong (Class II) on MWBx0yA & MVBx0yA.

Accessories and detachable parts included in the evaluation : None

Options included : None

Testing

Date of receipt of test item : October 22, 2007 (30792801.001), February 27, 2008 (30792801.003)

Date(s) of performance of test..... : October 23, 2007 to October 26, 2007 (30792801.001), February 27, 2008 (30792801.003)

Test case verdicts

Test case does not apply to the test object..... : N/A

Test item does meet the requirement : Pass

Test item does not meet the requirement : Fail

Abbreviations used in the report:

- normal condition..... N.C. - single fault condition S.F.C.

IEC 60601-1

- operational insulation..... OP	- basic insulation BI
- basic insulation between parts of opposite polarity..... BOP	- supplementary insulation..... SI
- double insulation..... DI	- reinforced insulation..... RI

IEC 60601-1

General remarks

"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IEC 02".

"(see Attachment #)" refers to additional information appended to the report.

"(see appended table)" refers to a table appended to the report.

Throughout this report a point is used as the decimal separator.

The tests results presented in this report relate only to the object tested.

This report shall not be reproduced except in full without the written approval of the testing laboratory.

List of test equipment must be kept on file and available for review.

IEC 60601-1

General product information and considerations

The MWAx0yz series are mains powered, single phase, Class I fully enclosed switch mode power supplies. Mains are connected via a three prong (Class I) AC inlet.

The MWBx0yz series are mains powered, single phase, Class II fully enclosed switch mode power supplies. Mains are connected via a two prong (Class II) AC inlet

The MVAx0yz series are mains powered, single phase, Class I open frame switch mode power supplies. Mains are connected via an AMP type mains connector.

The MVBx0yz series are mains powered, single phase, Class II open frame switch mode power supplies. Mains are connected via an AMP type mains connector.

The x can be any number between and including 050 and 100 and represents the output power. The y can be any number between and including 12 and 24 and represents the output voltage. The z can be A – Z or blank, not safety related.

The units are rated a maximum of 8.3 Amps and all output power is limited to 100 Watts Max.

The MWAx0yA and MVAx0yz can be provided with an earthed output via a jumper or an unearthed output via capacitor C41. Both configurations were considered during this evaluation

MWAx0yz and MWBx0yz and MVAx0yz and MVBx0yz (x = 050 to 100, y = 12 to 24, z = A – Z or blank, not safety related)

Conditions of Acceptability

- a. Models MWAx0yz and MVAx0yz are considered class I devices,
- b. Models MWBx0yz and MVBx0yz are considered class II devices.
- c. Power supply MWAx0yz and MWBx0yz were evaluated for a maximum working temperature (Tmra) of 49°C.
- d. Power supply MVAx0yz and MVBx0yz were evaluated for a maximum working temperature (Tmra) of 60°C.
- e. Models MVAx0yz and MVBx0yz requirements for enclosures (accessibility/protective/fire/mechanical/etc) need to be considered in the end use application.
- f. Models MVAx0yz and MVBx0yz are intended for build in use.
- g. Models MVAx0yz and MVBx0yz: Suitable disconnect to be provided and evaluated in end use application
- h. Models MVAx0yz and MVBx0yz: Additional requirement for separation/spacings to be considered in the end use application
- i. Accompanying document requirements are to be considered and evaluated end use application.
- j. Device is not intended to be used in a permanently connected device
- k. Leakage current shall be considered at end product.
- l. Pollution degree 2 was considered

IEC 60601-1

Attachments

None

Copy of marking plate

See main report

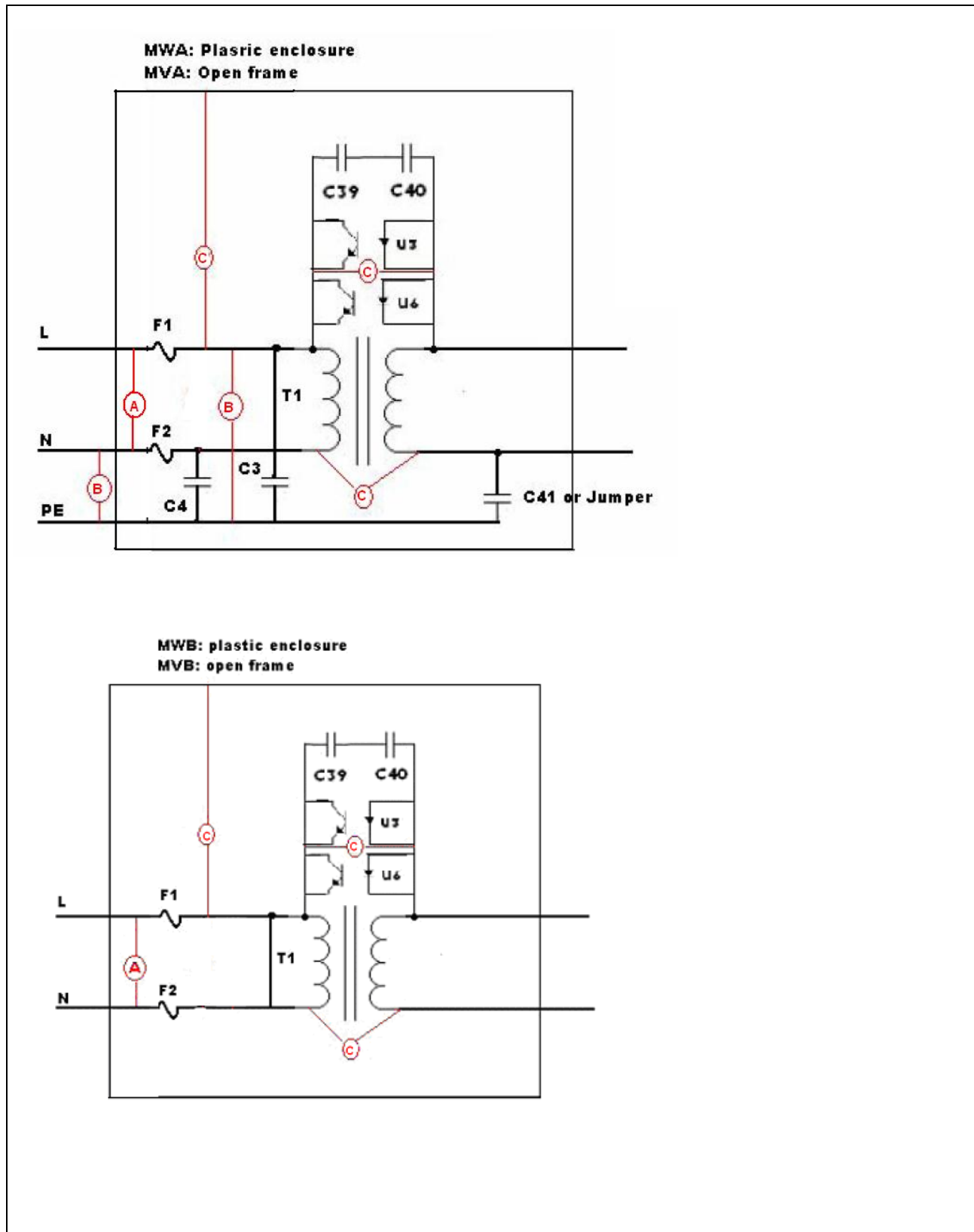
IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict

3.	GENERAL REQUIREMENTS		
3.1	Equipment when transported, stored, installed, operated in normal use and maintained according to the instructions of the manufacturer, causes no safety hazard which could reasonably be foreseen and which is not connected with its intended application in normal condition (N.C.) and in single fault condition (S.F.C.)	The equipment causes no hazards when used according to the manufacturers instruction	Pass
3.4	An alternative means of construction is used to that detailed in this standard and it can be demonstrated that an equivalent degree of safety is obtained	No alternate means of construction used	N/A

5.	CLASSIFICATION		
5.1	Type of protection against electric shock		
	Class I equipment	MWAX0yz and MVAX0yz are Class I device	Pass
	Class II equipment	MWBX0yz and MVBX0yz are Class II device	Pass
	Internally powered equipment	Not an Internally powered equipment	N/A
5.2	Degree of protection against electric shock	See below	N/A
	Type B applied part	No applied parts provided	N/A
	Type BF applied part	No applied parts provided	N/A
	Type CF applied part	No applied parts provided	N/A
	Not classified, no applied parts		Pass
5.3	Classification according to the degree of protection against ingress of water as detailed in the current edition of IEC 529 (see 6.1.1)	Not provided with a degree of protection against water (IPX0) Ordinary equipment	Pass
5.4	Methods of sterilization or disinfection	None required	N/A
5.5	Equipment not suitable for use in the presence of flammable mixtures	Not suitable for use in presence of flammable mixture	Pass
	Category AP equipment	Equipment is not AP category equipment	N/A
	Category APG equipment	Equipment is not APG category equipment	N/A
5.6	Mode of operation:		

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	continuous operation	Intended for continuous operation	Pass
	short-time operation, specified operation; period .. :		N/A
	intermittent operation, specified operation; rest period :		N/A
	continuous operation with short-time, stated permissible loading time :		N/A
	continuous operation with intermittent, stated permissible loading/rest time :		N/A
	Table: insulation diagram		Pass
	Protection against electric shock - Block diagram of system		
INSULATION DIAGRAM			

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



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

Table: to insulation diagram							Pass
area	insulation type: operational/basic/ supplementary /double/reinforced	reference voltage (V)	required creepage (mm)	required clearance (mm)	measured creepage (mm)	measured clearance (mm)	remarks
A	Basic Opposite Polarity	250	3.0	1.6	13.2	13.2	MWAx0yz/ MWBx0yz: Line to Neutral before fuse
A	Basic Opposite Polarity	250	3.0	1.6	8.7	8.7	MVAx0yz/ MVBx0yz: Line to Neutral before fuse
B	Basic	250	4.0	2.5	4.6	4.0	MWAx0yz: PE trace to Line trace
B	Basic	250	4.0	2.5	9.2	9.2	MVAx0yz: PE trace to Line trace
C	DI/RI	378	12.0	7.0	13.0	13.0	MWAx0yz/ MWBx0yz:T1 pin2 to pin 7/8
C	DI/RI	378	12.0	7.0	17.0	17.0	MVAx0yz/ MVBx0yz: T1 pin2 to pin 7/8

INSULATION DIAGRAM CONVENTIONS

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:

1. All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
2. Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional.
3. Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
4. Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.
5. Blocks containing the letter "Z" indicate protective impedance.
6. Operational Insulation (OP) - indicates insulation that may be required for function of the equipment, but is not required or relied on for compliance with requirements of Cl. 17., 20. and 57.

*

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
6.	IDENTIFICATION, MARKING AND DOCUMENTS		Pass
6.1	Marking on the outside of equipment or equipment parts		Pass
	c) Markings of the specific power supply are affixed	No specific power supply	N/A
	d) If marking is not practicable due to size or nature of enclosure, information is included in accompanying documents	Marking provided	N/A
	e) Name and/or trademark of the manufacturer or supplier	Marked with manufacturers trade name "Elpac Power Systems"	Pass
	f) Model or type reference	MWAx0yz, MWBx0yz, MVAx0yz and MVBx0yz (x = 050 to 100, y = 12 to 24, z = A – Z or blank, not safety related)	Pass
	g) Rated supply voltages or voltage range(s)	Marked 100-240 V~	Pass
	Number of phases	Single phase, Marking not required	N/A
	Type of current	See above	Pass
	h) Rated frequency or rated frequency range(s) (Hz)	Marked 50/60 Hz	Pass
	j) Rated power input (VA, W or A)	Marked 2.3 A	Pass
	k) Power output of auxiliary mains socket-outlets	No auxiliary Mains	N/A
	l) Class II symbol	MWBx0yz and MVBx0yz are Class II device	Pass
	Symbol for degree of protection against ingress of water provided	No water protection provided	N/A
	Symbol for protection against electric shock	Marking not required	N/A
	If equipment has more than one applied part with different degrees of protection, the relevant symbols are clearly marked on such applied parts, or on or near relevant outlets		N/A
	Symbol for protection of defibrillation-proof applied parts	Not provided with a defibrillation-proof applied part	N/A
	Symbol 14 from Table DI for defibrillation-proof with protection partly in patient cable		N/A
	m) Mode of operation (if no marking, suitable for continuous operation	Continuous operation, no marking required	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	n) Types and rating of external accessible fuses ... :	No operator accessible fuses, however, fuses are marked appropriately (F1 and F2)	N/A
	p) Ratings of external output	Marked 012 to 024 Vdc, 8.3 Amps max	Pass
	q) Symbol for physiological effect(s):		
	attention, consult accompanying documents	Equipment does not produce physiological effects	N/A
	non-ionizing radiation, or symbols as adopted by ISO or IEC 417	None produced	N/A
	r) Anaesthetic-proof symbol: AP or APG	Not of category AP or APG	N/A
	s) Dangerous voltage symbol	No parts with a voltage over 1000VAC or over 1500 VDC or 1500 V peak value	N/A
	t) Special cooling requirements	No special requirements	N/A
	u) Limited mechanical stability	Refer to Clause 24	N/A
	v) Protective packing requirement(s)	No special Measures regarding (Un)Packing, transportation, or storage	N/A
	Marking(s) for unpacking safety hazard(s)	No safety hazards	N/A
	Equipment or accessories supplied sterile, marked as sterile	Parts are not supplied as sterile	N/A
	y) Potential equalization terminal	No such terminal provided	N/A
	Functional earth terminal	Functional earthing marking provided	Pass
	z) Removable protective means	No such removable protective means	N/A
	Durability of marking test	See appended table 6.1	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
6.2	Marking on the inside of equipment or equipment parts		Pass
	a) Nominal voltage of permanently installed equipment	Device is an enclosed power supply and will not be used in permanently installed equipment	N/A
	b) Maximum power loading for heating elements or holders for heating lamps	No heating elements	N/A
	c) Dangerous voltage symbol	No high voltage accessible parts	N/A
	d) Type of battery and mode of insertion	No Batteries in the unit	N/A
	Marking referring to accompanying documents used for battery not intended to be changed by the operator		N/A
	e) Fuses accessible with a tool identified either by type and rating or by a reference to diagram	Fuses are not accessible with the aid of a tool	N/A
	f) Protective earth terminal	MWBx0yz and MVBx0yz are class II device MWAx0yz and MVAx0yz, marking provided.	Pass
	g) Functional earth terminal	Marking provided.	Pass
	h) Supply neutral conductor in permanently installed equipment (N)	Device is a component power supply Intended to be used internal to devices that are not permanently installed	N/A
	j) Markings required in 6.2 f), h), k) ,and l) remain visible after connection and are not affixed to parts which have to be removed	Refer to 6.2 f), h), k) and l).	Pass
	Markings comply with IEC 445	See above	Pass
	k) For permanently connected devices the supply connections are clearly marked adjacent to the terminals (or in accompanying documents for small equipment)	Device is a built in power supply intended to be used internal to devices that are not permanently installed	N/A
	l) Statement for suitable wiring materials at temperatures over 75 deg C	Not provided with a terminal box or wiring compartment	N/A
	n) Capacitors and/or circuit parts are marked as required in Cl. 15. c)	None	N/A
6.3	Marking of controls and instruments		N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	a) Mains switch clearly identified	Device is a component power supply and not provided with controls or instruments, requirements for Marking of controls and instruments to be evaluated in end use application	N/A
	ON and OFF positions marked according to Symbols 15 and 16 of Table D1 or indicated by an adjacent indicator light	See above	N/A
	b) Indications of different positions of control devices and switches	See above	N/A
	c) Indication of the direction in which the magnitude of the function changes, or an indicting device	See above	N/A
	f) The functions of operator controls and indicators are identified	See above	N/A
	g) Numeric indications of parameters are in SI units except for units listed in A2	See above	N/A
6.4	Symbols		Pass
	Symbols used comply with Appendix D or IEC 417 and/or IEC 878 or ISO publications (if applicable)	Symbols used comply with Annex D	Pass
6.5	Colours of insulation of conductors		Pass
	a) Protective earth conductor has green/yellow insulation	To be evaluated in end use product	N/A
	b) All insulations of internal protective earth conductors are green/yellow at least at their terminations	MWAx0yz: Green and Yellow protective bonding conductor provided internal to the device. MVAx0yz: No internal conductors provided in power supply MWBx0yz and MVBx0yz are class II device	Pass
	c) Only protective or functional earthing, or potential equalization conductors are green/yellow	MWAx0yz: Green and Yellow protective bonding conductor provided internal to the device. MVAx0yz: No internal conductors provided in power supply MWBx0yz and MVBx0yz are class II device	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	d) Colour of neutral conductor	To be evaluated in end use product	N/A
	e) Colours of phase conductors	To be evaluated in end use product	N/A
	Compliance with IEC 227 and IEC 245	See above	N/A
	f) Additional protective earthing in multi-conductor, cords are marked green/yellow at the ends of the additional conductors	To be evaluated in end use product	N/A
6.6	Medical gas cylinders and connections		N/A
	a) In accordance with ISO/R 32	No gas cylinders	N/A
	b) Identification of connection point		N/A
6.7	Indicator lights and push-buttons		N/A
	a) Red indicator lights used exclusively to indicate a warning of danger and/or a need for urgent action	Red indicator light not used	N/A
	Yellow used to indicate caution or attention required	Yellow indicator light not used	N/A
	Green used to indicate ready for action	Green indicator light not used	N/A
	b) Colour red used only for push-buttons by which a function is interrupted in case of emergency	Not provided with push buttons	N/A
6.8	Accompanying documents		N/A
6.8.1	Equipment is accompanied by documents containing at least instructions for use, a technical description and an address to which the user can refer	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	Classifications specified in Cl. 5. are included in both the instructions for use and the technical description	See above	N/A
	Markings specified in 6.1 included in the accompanying documents if they have not been permanently affixed to equipment	See above	N/A
	Warning statements and the explanation of warning symbols provided in the accompanying documents	See above	N/A
6.8.2	Instructions for use		N/A
	a) General information provided in instructions for use:		N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	- state the function and intended application of the equipment	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	- include an explanation of: the function of controls, displays and signals	See above	N/A
	- the sequence of operation	See above	N/A
	- the connection and disconnection of detachable parts and accessories	See above	N/A
	- the replacement of material which is consumed during operation	See above	N/A
	- information regarding potential electromagnetic or other interference and advice regarding avoidance	See above	N/A
	- include: indications of recognized accessories, detachable parts and materials, if the use of other parts or materials can degrade minimum safety	See above	N/A
	- instructions concerning cleaning, preventive inspection and maintenance to be performed including the frequency of such maintenance	See above	N/A
	General information provided in instructions:		N/A
	- information for the safe performance or routine maintenance	Instructions for use are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	- parts on which preventive inspection and maintenance shall be performed by other persons including the periods to be applied	See above	N/A
	- explanation of figures, symbols, warning statements and abbreviations on the equipment	See above	N/A
	c) Signal output or signal input parts intended only for connection to specified equipment described	See above	N/A
	d) Details about acceptable cleaning, disinfection or sterilization methods included	See above	N/A
	e) Warning statement for mains operated equipment with additional power source	See above	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	f) A warning to remove primary batteries if equipment is not likely to be used for some time	See above	N/A
	g) Instructions to ensure safe use and adequate maintenance of rechargeable batteries	See above	N/A
	h) Identification of specified external power supplies or battery chargers necessary to ensure compliance with the requirements of IEC 601-1	See above	N/A
	j) Identification of any risks associated with the disposal of waste products, residues, etc.	See above	N/A
	Advice in minimizing these risks	See above	N/A
6.8.3	Technical description		N/A
	a) All characteristics essential for safe operation provided	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	b) Required type and rating of fuses utilized in the mains supply circuit external to permanently installed equipment	See above	N/A
	Instructions for replacement of interchangeable and/or detachable parts which are subject to deterioration during normal use	See above	N/A
	c) Instructions or reference information for repair of equipment parts designated by the manufacturer as repairable provided	See above	N/A
	d) Environmental conditions for transport and storage specified in accompanying documents and marked on packaging	See above	N/A
7.	POWER INPUT		Pass
	Power input measurements	Refer to appended table 7	Pass
10.	ENVIRONMENTAL CONDITIONS		Pass
10.1	Equipment is capable while packed for transport or storage of being exposed to the conditions stated by the manufacturer	-35°C to 65 °C	Pass
10.2.2	a) Rated voltage not exceeding 250 V for hand-held equipment	Not Handheld equipment	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	Rated voltage not exceeding 250 V d.c. or single-phase a.c. or 500 V polyphase a.c. for equipment up to 4 kVA	Unit does not exceed 250V	Pass
	Rated voltage not exceeding 500 V for all other equipment	Rated 100-240 VAC	N/A
	Rated input frequency not more than 1 kHz	50/60 Hz	Pass
	b) Internal replaceable electric power source specified	No internal source	N/A

14.	REQUIREMENTS RELATED TO CLASSIFICATION		Pass
14.4	a) Class I and Class II equipment in addition to basic insulation provided with an additional protection	MWAX0yz and MVAX0yz are Class I device provided with with basic insulation, protective earthing and reinforced insulation, primary fused. MWBX0yz and MVBX0yz are Class II device provided with reinforced insulation, primary fused	Pass
	b) Equipment supplied from external d.c. source of reverse polarity results in no safety hazard	Not powered from an external dc power source	N/A
14.5	b) Internally powered equipment complies with requirements for Class I or Class II equipment while connected to supply mains, and with requirements for internally powered equipment when not connected	Not internally powered equipment	N/A
14.6	c) Applied parts intended for direct cardiac application are of type CF	Not intended for cardiac application.	N/A

15.	LIMITATION OF VOLTAGE AND/OR ENERGY		Pass
	b) Voltage measured one sec after disconnection of the mains plug does not exceed 60 V	See appended table 15.1	Pass
	c) For live parts accessible after equipment has been de-energized the residual voltage does not exceed 60 V nor residual energy exceeds 2 mJ	No such parts	N/A
	Marking provided for manual discharging	No manual discharge	N/A

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

16.	ENCLOSURES AND PROTECTIVE COVERS		Pass
	a) Equipment enclosed to protect against contact with live parts, and with parts which can become live (finger, pin, hook test)	MWAx0yz and MWBx0yz are fully enclosed devices MVAx0yz and MVBx0yz models are a component power supply. Not provided with enclosure, requirements for enclosures and protective covers to be evaluated in end use application	Pass
	Insertion or removal of lamps: protection against contact with live parts provided	No lamps	N/A
	b) Opening in a top cover so positioned that accessibility of live parts by a test rod is prevented	Device enclosure does not have openings	N/A
	c) Conductive parts accessible after the removal of handles, knobs, levers:		N/A
	- have a resistance of not more than 0,2 ohms	No such conductive parts	N/A
	- separated from live parts by one of the means described in Cl. 17. g)	See above	N/A
	d) Parts with voltage exceeding 25 V a.c. or 60 V d.c. which cannot be disconnected by external mains switch or plug protected against contact	MWAx0yz and MWBx0yz: All parts are disconnected from the supply by the appliance coupler, which is accessible at all times. MVAx0yz and MVBx0yz series requires a suitable disconnect to be provided and evaluated in end use application	Pass
	e) Removable enclosures protecting against contact with live parts	See below	Pass
	Removal possible only with the aid of a tool	MWAx0yz and MWBx0yz enclosures cannot be removed, enclosures are sealed with ultra-sonic welding MVAx0yz and MVBx0yz series are not provided with enclosure, Device is a component power supply, Suitable enclosure to be provided and evaluated in end use application	Pass
	Use of automatic device making parts not live when the enclosure is opened or removed	See above	N/A
	Exception 16 e) applied to the following parts :	No exception	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	f) Openings for the adjustment of controls using a tool. The tool not able to touch basic insulation or any live parts	No user accessible pre-set controls	N/A

17.	SEPARATION		N/A
	a) Separation method of the applied part from live parts:		N/A
	1) basic insulation: applied part earthed	Not provided with applied parts	N/A
	2) by protectively earthed conductive part (e.g. screen)	See above	N/A
	3) by separate earthed intermediate circuit limiting leakage current to applied part in event of insulation failure	See above	N/A
	4) by double or reinforced insulation	See above	N/A
	5) by protective impedances limiting current to applied part	See above	N/A
	Additional leakage current test in single fault conditions	See above	N/A
	c) There is no conductive connection between applied parts and accessible conductive parts, which are not protectively earthed	Not provided with applied parts	N/A
	d) Supplementary insulation between hand-held flexible shafts and motor shafts (Class I)	Not such device	N/A
	g) Separation method of accessible parts other than applied parts from live parts:		Pass
	1) basic insulation: accessible part earthed	Separation method for models MVAx0yz and MVBx0yz to be evaluated in end use product	N/A
	2) by protectively earthed conductive part (e.g. screen)	Not provided	N/A
	3) by separate earthed intermediate circuit limiting leakage current to enclosure in event of insulation failure	Not provided	N/A
	4) by double or reinforced insulation	MWAx0yz and MWBx0yz models provided with polymeric enclosure which meets reinforced insulation requirements	Pass
	5) by protective impedances limiting current to accessible part	Not provided	N/A
	Additional leakage current test in single fault conditions	See above	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	h) Arrangements used to isolate defibrillation-proof applied parts so designed that:		
	- no hazardous electrical energies appear during a discharge of a cardiac defibrillator	Not provided with Defibrillator proof applied parts	N/A
	- after exposure to the defibrillation voltage, the equipment continues to perform its intended function	See above	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
18.	PROTECTIVE EARTHING, FUNCTIONAL EARTHING AND POTENTIAL EQUALIZATION		Pass
	a) Accessible parts of Class I equipment separated from live parts by basic insulation connected to the protective earth terminal	MWAx0yz, output connector are protected from live parts by basic insulation MVAx0yz: Device is a component power supply requirements to be evaluated in end use product MWBx0yz and MVBx0yz are class II device	Pass
	b) Protective earth terminals suitable for connection to the protective earth conductor	MWAx0yz, suitable protective terminal provided, refer to cause 58. MVAx0yz: Device provided with an eyelet for connection to the protective earth via a screw, additional requirements to be considered in the end use device MWBx0yz and MVBx0yz are class II device	Pass
	e) Potential equalization conductor:	No Potential equalization terminal	N/A
	- readily accessible	See above	N/A
	- accidental disconnection prevented in normal use	See above	N/A
	- conductor detachable without the use of a tool	See above	N/A
	- power supply cord does not incorporate a potential equalization conductor	See above	N/A
	- connection means marked with Symbol 9, Table DI	See above	N/A
	f) For equipment without power supply cord, impedance between protective earth terminal and accessible metal part $< 0,1 \Omega$	MVAx0yz tested at 40 Amps from PE eyelet and PE trace at C4	Pass
	For equipment with an appliance inlet, impedance between protective earth contact and any accessible metal part $< 0,1 \Omega$	MWAx0yz tested at 40 Amps from AC inlet protective earth pin to J2B solder pad. MVAx0yz: Device provided with an eyelet for connection to the protective earth via a screw. MWBx0yz and MVBx0yz are Class II device	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	For equipment with a non-detachable power supply cord, impedance between protective earth pin in mains plug and accessible metal part < 0,2 Ω	MVAx0yz and MVBx0yz: Not provided with a non-detachable power cord MWAx0yz and MWBx0yz: Provided with an appliance inlet	N/A
	g) If the impedance of protective earth connections other than in Cl. 18. F) exceeds 0,1 Ω , the allowable value of the enclosure leakage current is not exceeded in single fault condition	MWAx0yz and MVAx0yz do not exceed 0.1 Ω MWBx0yz and MVBx0yz are class II device	N/A
	k) Functional earth terminal not used to provide protective earthing	No functional earth provided	N/A
	l) Class II equipment with isolated internal screens		N/A
	- insulation of screens and all internal wiring connected to them is double insulation or reinforced insulation	MWBx0yz and MVBx0yz not provided with internal screens. MWAx0yz and MVAx0yz are class I device	N/A
	- functional earth terminal clearly marked	See above	N/A
	- explanation of functional earth terminal provided in the accompanying documents	See above	N/A
19.	CONTINUOUS LEAKAGE CURRENTS AND PATIENT AUXILIARY CURRENTS		Pass
19.1	b) Leakage currents	Refer to appended table 19	Pass
	Earth leakage current	Refer to appended table 19	Pass
	Enclosure leakage current	Refer to appended table 19	Pass
	Patient leakage current	Not provided with applied parts	N/A
	Patient auxiliary current	Not provided with applied parts	N/A
20.	DIELECTRIC STRENGTH AT OPERATING TEMPERATURE		Pass
	Overall compliance with Cl. 20.	Refer to appended table 20	Pass
21.	MECHANICAL STRENGTH		Pass
	a) Sufficient rigidity of enclosure tested by: force of 45 N	45 N steady force performed on model series MWAx0yz and MWBx0yz	Pass
	b) Sufficient strength of an enclosure tested by: impact hammer	0.5 J impact performed on model series MWAx0yz and MWBx0yz	Pass
	c) Portable equipment carrying handles or grips withstand the requirements of the loading test	Not provided with carrying handles	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
21.3	No damage to parts of patient support and/or immobilization system after the loading test	No such parts	N/A
21.5	Hand-held equipment or equipment parts are safe after drop test	Not a hand held device	N/A
21.6	Portable and mobile equipment is able to withstand rough handling	Refer to appended table 21	Pass
22.	MOVING PARTS		N/A
22.2	a) Moving parts of a transportable equipment are provided with guards which form an integral part of the equipment	Not provided with Moving parts	N/A
	b) Moving parts of a stationary equipment are provided with similar guards as above, unless it is evident that equivalent protection is separately provided during installation	Not provided with Moving parts	N/A
22.3	Cords (ropes), chains and bands are provided with guides to prevent them from running off or from jumping out of their guiding devices	Not provided with Moving parts	N/A
	Guides or other safeguards are removable only with a tool	Not provided with Moving parts	N/A
22.4	Dangerous movements of equipment parts, which may cause physical injury to the patient, are possible only by the continuous activation of the control by the operator	Not provided with Moving parts	N/A
22.6	Parts of equipment subject to mechanical wear are accessible for inspection	Not provided with Moving parts	N/A
22.7	Means provided for emergency switching of an electrically produced mechanical movement which could cause a safety hazard	Not provided with Moving parts	N/A
	The means for emergency switching is readily identifiable and accessible and does not introduce a further safety hazard	Not provided with Moving parts	N/A
	Devices for emergency stopping able to break the full load current of the relevant circuit, taken into account possible stalled motor currents	Not provided with Moving parts	N/A
	Means for stopping of movements operate as a result of one single action	Not provided with Moving parts	N/A
23.	SURFACES, CORNERS AND EDGES		Pass
	Rough surfaces, sharp corners and edges which may cause injury or damage avoided or covered	Rounded corners and smooth edges	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
24.	STABILITY IN NORMAL USE (see appended table)		Pass
24.1	Equipment does not overbalance during normal use when tilted through an angle of 10°	MWAx0yz and MWBx0yz series: Refer to appended table 24 MVAx0yz and MVBx0yz series: Stability to be evaluated in end use product	Pass
24.3	Equipment overbalances when tilted through an angle of 10°:		N/A
	- does not overbalance when tilted through an angle of 5° in any position excluding transport	See 24.1	N/A
	- carry a warning notice stating that transport should only be undertaken in a certain position	See above	N/A
	- in the position specified for transport does not overbalance when tilted to an angle of 10°	See above	N/A
24.6	a) Equipment or its parts with a mass of more than 20 kg is provided with:		N/A
	- suitable handling devices (grips etc.), or	Weighs less than 20kg	N/A
	- instructions for lifting and handling during assembly	No instructions required	N/A
	b) On portable equipment with a mass of more than 20 kg carrying handle(s) is (are) so situated that equipment may be carried by 2 or more persons	Not more than 20 kg	N/A
25.	EXPELLED PARTS		Pass
25.1	Protective means are provided where expelled parts of the equipment could be a hazard	MWAx0yz and MWBx0yz series: No expelled parts MVAx0yz and MVBx0yz series: Suitable enclosure to be provided and evaluated in end use product	Pass
25.2	Display vacuum tubes with a face dimension exceeding 16 cm are provided with adequate protection against implosion	No display vacuum tubes	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
28.	SUSPENDED MASSES		N/A
28.3	Suspension system with safety device:		N/A
	Safety device provided where the integrity of a suspension depends on parts which may have hidden defects, or on parts having safety factors not complying with 28.4	No suspended masses.	N/A
	Safety device has safety factors complying with 28.4.2	See above	N/A
	Clear indication to the operator that the safety device has been activated after failure of suspension means	See above	N/A
28.4	Suspension systems of metal without safety devices:		N/A
	1) the total load does not exceed the safe working load	No suspended masses.	N/A
	2) safety factors not less than 4 where it is unlikely that supporting characteristics will be impaired	See above	N/A
	3) safety factors not less than 8 where impairment is expected	See above	N/A
	4) safety factors multiplied by 1,5 for metal having an elongation at break of less than 5%	See above	N/A
	5) sheaves, sprockets, bandwheels and guides so constructed that the safety factors shall be maintained till replacement	See above	N/A
29.	X-RADIATION		N/A
29.2	Equipment not intended to produce X-radiation produces an exposure $\leq 130 \text{ nC/kg}$ (0,5 mR)	Equipment produces no X-radiation	N/A
36.	ELECTROMAGNETIC COMPATIBILITY		Pass
	Equipment complies with IEC 601-1-2`	EMC report provided	Pass
37.	COMMON REQUIREMENTS FOR CATEGORY AP AND CATEGORY APG EQUIPMENT		N/A
	Requirements for category AP and APG equipment (Cl. 37. - 41.)	Equipment is not a AP or APG equipment	N/A

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

42.	EXCESSIVE TEMPERATURES		Pass
42.1	Equipment does not attain temperatures exceeding the values given in Table Xa over the range of ambient temperatures specified in 10.2.1	Refer to appended table 42	Pass
42.2	Equipment does not attain temperatures exceeding the values given in Table Xb at 25 °C ambient	Refer to appended table 42	Pass
42.3	Applied parts not intended to supply heat have surface temperatures not exceeding 41 °C	Refer to appended table 42	Pass
42.5	Guards to prevent contact with hot surfaces removable only with a tool	No such guards present	N/A

43.	FIRE PREVENTION		Pass
	Strength and rigidity necessary to avoid a fire hazard	MWAx0yz and MWBx0yz series: Equipment is provided with suitable enclosure MVAx0yz and MVBx0yz: Equipment not provided with a complete enclosure. Will need to be evaluated in final product.	Pass

44.	OVERFLOW, SPILLAGE, LEAKAGE, HUMIDITY, INGRESS OF LIQUIDS, CLEANING, STERILIZATION, DISINFECTION (see appended table)		Pass
44.2	If equipment contains a liquid reservoir:		N/A
	- the equipment is electrically safe after 15% overfill steadily over a period of 1 min	No use of liquid containers or liquids in normal operation, However end use product to be evaluate	N/A
	- transportable equipment is electrically safe after additionally having been tilted through an angle of 15 deg in the least favourable direction(s) (if necessary with refilling)	See above	N/A
44.3	Electrical properties of the equipment do not change in connection of spillage test (200 ml of water)	See above	N/A
44.4	Liquid which might escape in a single fault condition does not wet parts which may cause a safety hazard	See above	N/A
44.5	Equipment sufficiently protected against the effects of humidity	Refer to appended table 44	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
44.6	Enclosures designed to give a protection against harmful ingress of water classified according to IEC Publication 529	Not designed for protection against ingest of liquids. End use to be evaluated	N/A
44.7	Equipment capable of withstanding cleaning, sterilization or disinfection without deterioration of safety provisions	Cleaning, sterilization and disinfection not required. However end use to be evaluated	N/A
45.	PRESSURE VESSELS AND PARTS SUBJECT TO PRESSURE		N/A
45.2	Pressure vessel with pressure volume greater than 200 kPa x l and pressure greater than 50 kPa withstand the hydraulic test pressure	Not provided with a pressure vessel or regulator	N/A
45.3	The maximum pressure does not exceed the maximum permissible working pressure for individual parts	See above	N/A
45.7	Unless excessive pressure cannot occur, pressure-relief device provided	See above	N/A
	a) Pressure-relief device connected as close as possible to the pressure vessel	See above	N/A
	b) Readily accessible for inspection	See above	N/A
	c) Not capable of being adjusted or rendered inoperative without a tool	See above	N/A
	d) Discharge opening so located that the released material is not directed towards any person	See above	N/A
	e) Discharge opening so located that operation will not deposit material which may cause a safety hazard	See above	N/A
	f) Adequate discharge capacity to ensure that pressure does not exceed the maximum permissible working pressure	See above	N/A
	g) No shut-off valve between the pressure-relief device and the parts intended to be protected	See above	N/A
	h) Minimum number of cycles of operation is 100 000	See above	N/A
48.	BIOCOMPATIBILITY		N/A
	Parts of equipment and accessories intended to come into contact with biological tissues, cells or body fluids are evaluated in accordance with ISO 10993-1	No parts of the equipment or accessories are intended to come into contact with biological tissue, cells or body fluids	N/A

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

49.	INTERRUPTION OF THE POWER SUPPLY		Pass
49.1	Thermal cut-outs and over-current releases with automatic resetting not used if they may give a safety hazard	Not provided with self resetting devices	N/A
49.2	Interruption and restoration of the power supply shall not result in a safety hazard other than interruption of its intended function	No hazard observed, End use to be evaluated	Pass
49.3	Means are provided for removal of mechanical constraints on a patient in case of a supply mains failure	No mechanical constraints on a patient by the unit	N/A

51.	PROTECTION AGAINST HAZARDOUS OUTPUT		N/A
51.4	Equipment providing both low-intensity and high-intensity outputs provided with means minimizing the possibility of a high-intensity output being selected accidentally	No hazardous outputs	N/A

52.	ABNORMAL OPERATION AND FAULT CONDITIONS		Pass
52.1	Equipment is so designed and manufactured that even in single fault condition no safety hazard as described under 52.4 exists (see 3.1 and Cl. 13.)	Equipment is designed to prevent safety hazards in case of single fault condition. End use application to be considered	Pass
	The safety of equipment incorporating programmable electronic systems is checked by applying IEC 601-1-4	No programmable electronic system	N/A
52.5.2	Failure of thermostat presents no safety hazard	No thermostats	N/A
52.5.3	Short-circuiting of either constituent part of double insulation presents no safety hazard	Refer to appended table 52	Pass
52.5.5	Impairment of cooling: temperatures not exceeding 1,7 times the values of Cl. 42. minus 17,5 °C	No cooling required	N/A
52.5.6	Locking of moving parts presents no safety hazard	No such moving parts present in the device	N/A
52.5.7	Interruption and short-circuiting of motor capacitors presents no safety hazard	Equipment has no motor capacitors	N/A
52.5.8	Duration of motors locked rotor test in compliance with 52.5.8	No motors used	N/A
52.5.9	Failure of one component at a time presents no safety hazard	Refer to appended table 52	Pass
52.5.10	Overload of heating elements presents no safety hazard	Equipment is not provided with heating elements	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	f) Motors intended to be remotely controlled, automatically controlled, or liable to be operated continuously provided with running overload protection	No motors in the unit	N/A
	h) Equipment with three-phase motors can safely operate with one phase disconnected	No three-phase motors	N/A
56.	COMPONENTS AND GENERAL ASSEMBLY		Pass
	List of critical components	Refer to appended table 56	Pass
56.1	b) Ratings of components not in conflict with the conditions of use in equipment	The components are used according to there rating.	Pass
	Ratings of mains components are identified	All components in the mains parts are marked or otherwise identified regarding their ratings	Pass
	d) Components, movements of which could result in a safety hazard mounted securely	Components are secured. No parts capable of unintended movement	Pass
	f) Conductors and connectors are secured and/or insulated to prevent accidental detachment resulting in a safety hazard	Conductors are connectors are adequately secured and insulated. Accidental detachment does not result in a safety hazards.	Pass
56.3	a) Connectors provide separation required by Cl. 17. g)	Refer to Clause 17g	Pass
	Plugs for connection of patient circuit leads can not be connected to other outlets on the same equipment	Not provided with patient circuit leads	N/A
	Medical gas connections not interchangeable	Equipment has no medical gas connections	N/A
	b) Accessible metal parts cannot become live when detachable interconnection cord between different parts of equipment is loosened or broken	None provided	Pass
	c) Leads with conductive connection to a patient are constructed such that no conductive connection remote from the patient can contact earth or hazardous voltages	Not provided with patient connections	N/A
56.4	Connections of capacitors		Pass
	Not connected between live parts and non-protectively earthed accessible parts	No such capacitors	N/A
	If connected between mains part and protectively earthed metal parts, comply with IEC 384-14	Certified Y2 capacitors provided, Refer to list of Critical components	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	Enclosure of capacitors connected to mains part and providing only basic insulation is not secured to non-protectively earthed metal parts	No such capacitors	N/A
	Capacitors or other spark-suppression devices are not connected between the contacts of thermal cut-outs	None provided	N/A
56.5	Protective devices which cause disconnection from the supply mains by producing a short-circuit not provided in equipment	No such devices used	N/A
56.6	Temperature and overload control devices		Pass
	a) Thermal cut-outs which have to be reset by a soldering not fitted in equipment	No such thermal cut-outs	N/A
	Thermal safety devices provided where necessary to prevent operating temperatures exceeding the limits	Thermal fuses provided. Attached to HS2 above C12 and C22	Pass
	Independent non-self-resetting thermal cut-out provided where a failure of a thermostat could constitute a safety hazard	Not provided with thermostat	N/A
	Audible warning provided where the loss of function caused by operation of a thermal cut-out presents a safety hazard	Operation of thermal fuse does not present a safety hazard, additional consideration to be evaluated in the end use device.	N/A
	Self-resetting thermal cut-outs and self-resetting over-current releases operated 200 times	Not self-resetting	N/A
	Non-self-resetting over-current releases operated 10 times	Approved fuses provided	Pass
	b) Thermostats with varying temperature settings clearly indicated	Not provided with varying temperature settings	N/A
	Operating temperature of cut-outs is clearly indicated	Not provided with thermal cut-outs	N/A
56.7	Batteries		N/A
	a) Battery compartments are:		N/A
	- adequately ventilated	No batteries	N/A
	- accidentally short-circuiting is prevented	See above	N/A
	b) Incorrect polarity of connection prevented	See above	N/A
56.8	Indicators, unless indication is provided by other means (from the normal operation position), indicator lights are used (colour see 6.7)		N/A
	- to indicate that equipment is energized	See sub-clause 6.3.a	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	- to indicate the operation of non-luminous heaters if a safety hazard could result	No heaters	N/A
	- to indicate when output exists if a safety hazard could result	See Sub-clause 6.7	N/A
	- charging mode indicator is provided	No charging mode	N/A
56.10	Actuating parts of controls	No actuating parts of controls	N/A
	b) Actuating parts are adequately secured to prevent them from working loose during normal use	See above	N/A
	Controls are secured to prevent the movement relative to scale marking (safety related only)	See above	N/A
	Detachable indicating devices are prevented from incorrect connection without the use of a tool	See above	N/A
	c) Stops are provided on rotating controls:		N/A
	- to prevent an unexpected change from maximum to minimum or vice versa where this could produce a safety hazard	No use of rotating or moveable parts of control	N/A
	- to prevent damage to wiring	See above	N/A
56.11	Cord-connected hand-held and foot-operated control devices		N/A
	a) Contain voltages not exceeding 25 V a.c. or 60 V d.c. and isolated from the mains part by Cl. 17. g)	Not handheld or foot operated	N/A
	b) Hand-held devices comply with the requirement and test of 21.5	See above	N/A
	Foot-operated control devices designed to support the weight of an adult human being	See above	N/A
	c) Devices shall not change their setting when inadvertently placed	See above	N/A
	d) Foot-operated control devices are at least IPX1	See above	N/A
	For surgical use, electrical switching parts are IPX8	See above	N/A
	e) Adequate strain relief at the cord entry provided	See above	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
57.	MAINS PARTS, COMPONENTS AND LAYOUT		Pass
57.1	Isolation from supply mains		Pass
	a) Equipment provides means to isolate its circuits electrically from the supply mains on all poles simultaneously	MWAX0yz and MWBX0yz series: All poles isolated simultaneously MVAx0yz and MVBx0yz series Suitable disconnect device to be provided and evaluated in the end use application	Pass
	Means for isolation incorporated in equipment or, if external, specified in the accompanying documents	MWAX0yz and MWBX0yz series: Means for isolation incorporated in the equipment MVAx0yz and MVBx0yz series: to be evaluated in end use application	Pass
	d) Switches used to comply with 57.1 a) comply with the creepage distances and air clearances as specified in IEC 328	No Mains switch	N/A
	f) Mains switches not incorporated in a power supply cord	Not provided with switch	N/A
	h) Appliance couplers and flexible cords with mains plugs provide compliance with 57.1 a)	MWAX0yz and MWBX0yz: appliance Inlet provided	Pass
	m) Fuses and semiconductor devices are not used as isolating devices	None provided.	Pass
57.2	Mains connectors and appliance inlets		Pass
	e) Auxiliary mains socket-outlets on non-permanently installed equipment of a type that cannot accept a mains plug	No auxiliary mains outlets	N/A
	g) Unless functional earth needs to be provided, Class I appliance inlet is not used in Class II equipment	MWBx0yA provided with two prong, class II, inlet. MWAX0yA is class I device	Pass
57.3	Power supply cords		N/A
	a) Not more than one connection to a particular supply mains	To be evaluated in end use product	N/A
	If alternative supply allowed, no safety hazards when more than one connection is made simultaneously	See above	N/A
	The mains plug has only one power supply cord	See above	N/A
	Non-permanently connected equipment provided with power supply cord or appliance inlet	See above	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	b) Power supply cords sufficiently robust to comply with the requirements of IEC 227, designation 53 and IEC 245, designation 53	See above	N/A
	Polyvinyl chloride insulated power supply cords not used for equipment having external metal parts with a temperature exceeding 75 degC	See above	N/A
	c) Nominal cross-sectional area of conductors of power supply cords not less than in Table XV	See above	N/A
	d) Stranded conductors not soldered if fixed by any clamping means	See above	N/A
57.4	Connection of power supply cords		
	a) Cord anchorages:		N/A
	Equipment provided with power supply cords has cord anchorages such that the conductors are relieved from strain, including twisting	MWAx0yz and MWBx0yz series: Provided with an appliance inlet MVAx0yz and MVBx0yz series: Device is a component power supply provided with an Amp type mains connection. Additional consideration and requirements for mains terminal devices are to be evaluated in end use application	N/A
	Tying the cord into a knot or tying the ends with string not used	See above	N/A
	Cord anchorages made of insulating material or metal insulated from unearthed accessible metal parts by supplementary insulation	See above	N/A
	Cord anchorages made of metal provided with an insulating lining	See above	N/A
	Clamping screws do not bear directly on the cord insulation	See above	N/A
	Screws associated with cable replacement are not used to secure other components	See above	N/A
	Conductors of the power supply cord so arranged that the protective earth conductor is not subject to strain as long as the phase conductors are in contact with their terminals	See above	N/A
	b) Power supply cord protected against excessive bending	See above	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	c) Adequate space inside equipment to allow the supply cable conductors to be introduced and connected	See above	N/A
57.5	Mains terminal devices and wiring of mains part		Pass
	a) Mains connected equipment other than those with a detachable supply cord is provided with mains terminals, where connections are made with screws, nuts or equally effective methods	MWAX0yz and MWBX0yz series: Provided with an appliance inlet MVAx0yz and MVBx0yz series: Device is a component power supply provided with an Amp type mains connection. Additional consideration and requirements for mains terminal devices are to be evaluated in end use application	Pass
	If a conductor breaks away, barriers are provided such that creepage distances and air clearances cannot be reduced	To be considered in the end use device	N/A
	Screws and nuts which clamp external conductors shall not serve to fix any other component	No such devices provided	N/A
	b) Terminals closely grouped with any protective earth terminal	No such terminal devices	N/A
	Mains terminal devices accessible only with use of a tool	See above	N/A
	Mains terminal devices located or shielded so that, should a wire of a stranded conductor escape when the conductors are fitted, there is no risk of accidental contact	See above	N/A
	c) Internal wiring not subjected to stress when the means for clamping the conductors are tightened or loosened		N/A
	d) Cord terminals shall not require special preparation of the conductor	No special preparation required	N/A
57.6	Mains fuses and over-current releases		Pass
	Fuses or over-current releases provided accordingly for Class I and Class II	Fuse provide in the line and neutral conductor	Pass
	Current rating of mains fuses and over-current releases such that they reliably carry the normal operating current	Fuse rated 5.0 Amps	Pass
	Protective earth conductor not fused	Fuse not provided in protective earth conductor	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	Neutral conductor not fused for permanently installed equipment	Device is a component power supply and will not be installed in permanently installed equipment	N/A
57.8	Wiring of mains part		Pass
	a) Individual conductors in the mains part with insulation not at least electrically equivalent to that of the individual conductors of flexible supply cords complying with IEC 227 or IEC 245, treated as bare conductor	So such wiring in mains part	N/A
	b) Cross-sectional area of conductors up to protective device not less than the minimum required for the power supply	See above	N/A
	Cross-sectional area of other wiring and the sizes of tracks on printed wiring circuits are sufficient to prevent any fire hazard	Track on PWB's provide suitable cross-sectional areas	Pass
57.9	Mains supply transformers		Pass
57.9.1	Overheating		Pass
	External to the transformer protective devices connected in such a way that failure of any component cannot render the protective devices inoperative	Failure of any component other than wiring interposed between the protective devices and the transformer does not render the protective devices inoperative.	Pass
	a) Short-circuit of secondary windings not caused excessive temperature	Short circuiting of secondary windings did not create a hazard	Pass
	b) Overload of secondary windings not caused excessive temperature	Overloading secondary winding did not create a hazard	Pass
57.9.2	The dielectric strength of the electrical insulation of a mains supply transformer such that it passes tests	No breakdown occurred	Pass
57.9.4	Construction		Pass
	a) Separation of primary and secondary windings:		Pass
	- separate bobbins or formers	Primary winding provided with triple insulation	N/A
	- one bobbin with insulating partition	Primary winding provided with triple insulation	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	- one bobbin with concentric windings and having copper screen with a thickness of not less than 0,13 mm	Primary winding provided with triple insulation	N/A
	- concentrically wound on one bobbin with windings separated by double insulation	Primary winding provided with triple insulation	Pass
	c) Means provided to prevent displacement of end turns	Means provided	Pass
	d) Insulated overlap of not less than 3 mm if a protective earth screen has only one turn	No protective earthed screen used	N/A
	e) Insulation between the primary and secondary winding in transformers with double insulation:		Pass
	- 1 insulation layer having a thickness of at least 1 mm	See below	N/A
	- at least 2 insulation layers with a total thickness of at least 0,3 mm	See below	N/A
	- 3 layers provided that each combination of 2 layers can withstand the dielectric strength test for reinforced insulation	Primary winding provided with triple insulation	Pass
	g) Exit of the wires of toroidal transformers provided with double sleeving complying with requirements for double insulation and having a total thickness at least 0,3 mm extending at least 20 mm outside the winding	Not provided with toroidal transformers	N/A
57.10	Creepage distances and air clearances		Pass
	a) Values: compliance with at least the values of Table XVI	MWAX0yz and MWBX0yz series: Complies with the values of table XVI. MVAx0yz and MVBx0yz series: Complies with the values of table XVI where applicable, however end use application to be considered (see table for insulation diagram)	Pass
	Creepage distances for slot insulation of motors are at least 50% of the specified values	No motors	N/A
	b) Minimum creepage distances and air clearances in the mains part between parts of opposite polarity not required if short-circuiting does not produce a safety hazard	Short circuiting of opposite polarity does not produce a safety hazard due to the protective fusing	N/A
	c) Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts	No such applied parts	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
58.	PROTECTIVE EARTHING - TERMINALS AND CONNECTIONS		Pass
58.1	Clamping means of the protective earth terminal	MWAx0yz series: Provided with an appliance inlet MVAx0yz: Device is a built in power supply provided with an eyelet for connection to the protective earth via a screw Additional consideration and requirements for connection of power supply cords are to be evaluated in end use application MWBx0yz and MVBx0yz are class II devices. Protective earth terminal not provided.	Pass
	Not be able to loosen without the aid of a tool	MWAx0yz: Provided with an appliance inlet MVAx0yz: To be evaluated in end use application MWBx0yz and MVBx0yz are class II devices. Protective earth terminal not provided.	Pass
	Screws for internal earth connections are covered or protected against loosening from outside	MVAx0yz: To be evaluated in end use application	N/A
58.7	Earth pin of the appliance inlet regarded as the protective earth terminal	MWAx0yz: Appliance earth pin is considered protective earth MVAx0yz: Device is a built in power supply provided with an eyelet for connection to the protective earth via a screw MWBx0yz and MVBx0yz are class II devices. Protective earth terminal not provided.	Pass
58.8	The protective earth terminal is not used for the mechanical connection or the fixing of any component not related to earthing	MWAx0yz and MVAx0yz: Terminal not used for any purpose other than earthing	Pass
58.9	Where the protective earth connections are made via a plug or socket device the protective earth connection is made before and interrupted after the supply connections during connection and interrupting	MWAx0yz: The appliance inlet makes first and breaks last. Protective earthing connection is not accessible to the operator	Pass
59.	CONSTRUCTION AND LAYOUT		Pass
59.1	Internal wiring		

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	a) Cables and wiring protected against contact with a moving part	Not provided with moving parts	N/A
	Wiring having basic insulation only protected by additional fixed sleeving	None provided	N/A
	Components are not likely to be damaged in the normal assembly or replacement of covers	MWAX0yA and MWBX0yA series: Provided with ultra-sonic welded covers	Pass
	b) Movable leads are not bent around a radius of less than five times the outer diameter of the lead	No movable leads	N/A
	c) Insulating sleeving adequately secured	None provided	N/A
	If the sheath of a flexible cable or cord is used as supplementary insulation it complies with requirements of IEC 227 and IEC 245 and dielectric strength test	Not used	N/A
	Conductors subjected to temperatures exceeding 70 deg C, have an insulation of heat-resistant material	No such conductors subjected to temperatures exceeding 70 deg C	Pass
	d) Aluminium wires of less than 16 mm ² cross-section not used	No use of aluminum	N/A
	f) Connecting cords between equipment parts considered as belonging to the equipment	No such connecting cords	N/A
59.2	Insulation		Pass
	b) Mechanical strength and resistance to heat and fires retained by all types of insulation	Characteristics of insulation are retained	Pass
	c) Insulation not likely to be impaired by deposition of dirt or dust resulting from wear of parts	Insulation is not likely to be impaired	Pass
	Parts of rubber resistant to ageing	No such parts	N/A
59.3	Excessive current and voltage protection		N/A
	Internal electrical power source provided with device for protection against fire hazard	No internally electrical power sources	N/A
	Fuse elements replaceable without opening the enclosure fully enclosed in a fuseholder	None provided	N/A
	Protective devices between an isolated applied part and the body of the equipment do not operate below 500 V r.m.s.	No such protective parts	N/A
59.4	Oil containers		N/A
	Oil containers adequately sealed	No oil containers	N/A
	Container design shall allow for the expansion of the oil		N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	Oil containers in mobile equipment sealed to prevent the loss of oil during transport		N/A
	Partially sealed oil-filled equipment or equipment parts provided with means for checking the oil level		N/A

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

National Differences

AU

6.1.g)	Insert the following sub-clause between the first and second dashes: For low voltage equipment rated at 200 V or more, a voltage marking (which may be part of a voltage range) of not less than 230V. Supply frequency ratings which include 60 Hz must also include 50 Hz.	Rated 100-240 V~, 50/60 Hz	Pass
6.6	Replace the existing text of Item a) with the following: a) Identification of the content of gas cylinders used in medical practice as part of electrical EQUIPMENT shall be in accordance with AS 1944, (see also Sub-clause 56.3a).	Replaced, However no gas cylinders provided	N/A
28.2	Replace the existing text with the following: Support (a) Ceiling-supported EQUIPMENT EQUIPMENT shall comply with the following requirements:	Replaced, However no suspended masses	N/A
	(i) EQUIPMENT shall be fitted with an anticrash device or have suspension cables duplicated and independently anchored.		N/A
	(ii) Motorized drives shall be designed to prevent the driven part from becoming hazardous in the event of a power failure.		N/A
	(iii) Carriages, brakes and supports shall be designed such that any single failure will not constitute a hazard to the PATIENT.		N/A
	(iv) Effective means shall be incorporated to prevent carriages running off supporting rails.		N/A
	(v) Effective means shall be incorporated to facilitate adequate inspection of cables and anchorages.		N/A
	(vi) Proximity or pressure switches may be used to minimize hazards.		N/A
	(vii) Ceiling-supported EQUIPMENT or parts thereof connected by electrical supply cables shall be provided with stops (e.g. for limitation of rotation or linear movement) to restrict movement in a manner which avoids any undue strain on the wiring termination or damage to the wiring.		N/A
	(b) Floor and floor-to-ceiling supported (including mobile) EQUIPMENT EQUIPMENT shall comply with the following		N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	requirements:		
	(i) Anticrash devices shall be fitted to cable, chains, etc.		N/A
	(ii) Means shall be incorporated to facilitate adequate inspection of cables and anchorages.		N/A
	(iii) Cross-arms or pivots shall be fitted with adequate stops, locknuts, grub screws or similar devices to prevent supported masses being dislodged.		N/A
42.3	Item 2) Add the following prior to the first dash: For this clause only, low voltage equipment rated at greater than 200 V is regarded as having a maximum rated voltage of 230 V.	Added, Refer to appended table 42	Pass
Table XII	In second row, first dash, after 'if impedance protected,' add 'maximum value'.	Added	Added
56.3a)	Replace the text in the 3rd dash by the following: Medical gas connections on EQUIPMENT shall, if operating at positive pressures greater than 50 kPa in NORMAL USE comply with AS 2472, AS 2473 or AS 2896, as appropriate.	Replaced, However not provided with medical gas connection	N/A
57.2a)	Replace 'not used' with: Supply plugs -- Provision for inspection Where a supply flexible cord is fitted with a rewirable plug of a type complying with the requirements of AS 3112 for 3-pin plugs, the plug shall be clear-backed to facilitate inspection of the core colours and the condition of the terminations.	Replaced, However not provided with rewirable plugs	N/A

CA

6	Where written safety warnings appear as equipment markings, they should appear in French and English.	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
6.6	The point of connection of gas cylinders to equipment is gas specific The point of connection of gas cylinders to equipment is non-interchangeable The point of connection of gas cylinders to equipment is identified	Not provided with connection to gas cylinders	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
56.3a)	Medical gas inlet connectors on equipment are gas specific Medical gas inlet connectors on equipment are non-interchangeable Medical gas inlet connectors on equipment are DISS type complying with CGA V-5 Medical gas inlet connectors on equipment are configured to permit the supply from assemblies complying with CAN/CSA –Z305.2.	Not provided with medical gas cylinders or connections	N/A
56.6a)	Where consequential loss of function caused by operation of a thermal cut-out presents a safety hazard, both visible and audible warnings provided.	Not provided with thermal cutouts.	N/A
57.2g)	Mains plug of non-permanents installed equipment: - if molded on type – hospital grade complying with CSA C22.2, No. 21 Mains plug of non-permanent installed equipment: - hospital grade disassembly type complying with CSA C22.2, No. 42 Mains plug of non-permanent installed equipment: - if Class II equipment – polarized hospital grade CSA configuration 1-15P	Device is a component power supply, end use to be considered	N/A
57.3b)	Detachable power supply cord is unlikely to be detached accidentally. Detachable power supply cord impedance of earth contacts presents no safety hazard. Detachable power supply cord: possibility of replacement by a cord which could make equipment hazards minimized. Detachable power supply cord complies with CSA C22.2 No. 21. Detachable power supply cord not smaller than No. 18 AWG Detachable power supply cord minimum serviceability of type SJ for mobile equipment or Type SV for other.	Device is a component power supply, end use to be considered	N/A
57.9	Switching power supplies conform to CSA Electrical Bulletin 1402C.	Considered	Pass
58.2	Protective earth connections comply with CSA C22.2 No. 04` (Does the protective earth circuit withstand a current double the rating of the overcurrent protective device.)	MWAx0yA. See table 18 for details	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
59.1	Connecting cables comply with Canadian Electrical Code, Part I.	Not provided with internal wiring	Pass
60	Creepage distances or clearances of at least 4 mm are maintained between defibrillation-proof applied parts and other parts.	Not provided with defibrillation-proof parts	N/A

DK

For plugs and socket outlets the National Standard SB 107-2-D1 3rd ed. applies.			
	For Class I equipment: Plugs: DK 2-1a, DK 2-1a with flat phase pin or DK 2-5a	Approved medical grade power cord will be provided by end use manufacturer or end use manufacturer's distributor	N/A
	For Class I equipment: Socket outlets: DK 1-3a	Not provided with socket outlets	N/A
	For Class II equipment: Plugs: DKA 2-1a, DKA 2-1b, C1b, C5, C6 or according to EN 50075	Class I device	N/A

IL

4.7	A. Equipment that is to be connected to the mains, shall be intended for one of the following voltages and frequencies: Nominal frequency of 50Hz. Nominal voltage of 230V for portable and hand-held equipment. Nominal voltage 230V, for one phase equipment with input power not exceeding 4kVA. Nominal voltage 400V, for multiphase equipment.	Rated 100-240 VAC 50/60 Hz	Pass
	B. It is allowed to connect to the mains other equipment, with the following ratings: One phase equipment, for the range of 220 to 240 Volts. Multiphase equipment, for the range of 380 to 440 Volts. The equipment shall comply with all the requirements of the standard, while being connected to the above mentioned mains frequencies and voltages, as if it was marked for 50Hz and 230 or 400 Volts.	See above	Pass
36	Change clause 36. - EMC – to: The equipment shall comply with the	EMC report provided	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	requirements of SI 1011 part 1.2 (IEC 60601-1-2).		

KR

	Supply Voltage Rating: National supply voltages are 110V, 220V and 380V.	Rated 100-240 VAC	Pass
	Frequency: Only appliances having supply frequency of 60 Hz or a frequency range including 60 Hz are accepted.	Rated 50/60 Hz	Pass
	Instruction: Instruction manuals and appliance markings related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC 60417.	Accompanying documents are not provided with component power supply. Accompanying document requirements have not been evaluated. To be determined in end use application.	N/A
	Plug: Plugs for the connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300).	MWAX0yA and MWBX0yA series : Power supply cord for this country is not provided at this time, Approved medical grade power cord will be provided by end use manufacturer or end use manufacturer's distributor	N/A
6.1j)	Equipment for one or several rated voltage or frequency ranges, the rated input for 220V, 60Hz or if applicable for 110V, 60Hz shall be separately marked.	Rated 100-240 VAC, 50/60 Hz	Pass
6.1s)	HIGH VOLTAGE TERMINAL DEVICES on the outside of equipment which are accessible without the use of a tool shall be marked with the symbol "dangerous voltage" (Appendix D, Table DII, Symbol 6) and with Korean language.	Not provided with high voltage terminal devices	N/A
6.2c)	The presence of HIGH VOLTAGE PARTS shall be marked with symbol "dangerous voltage" (Appendix D, Table DII, Symbol 6) and with Korean language.	Not provided with High voltage accessible parts	N/A
6.8.1	Language of accompanying documents shall be included Korean.	Accompanying documents are not provided with component power supply. Accompanying document	N/A

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
		requirements have not been evaluated. To be determined in end use application.	

US

Deviations based on requirements of the US National Electrical Code NEC, ANSI/NFPA 70 and Federal Regulations			
2.4.1, 2.10.100, 2.10.101c) 10.2.2	High voltage X-Ray installations Long Time and Momentary ratings definitions Clause 6, 6.2 and product markings shall agree with the NEC.	Not an x-ray device	N/A
6.2l)	Replace 75°C with 60°C.	Replaced, However not permanently connected	N/A
14, 18	The class of high voltage parts of equipment shall be in accordance with the provisions of NEC.	Considered	Pass
57	All equipment installations are required to be in accordance with NEC.	Considered	Pass
57.2	"Hospital Grade" or "Hospital Only" mains plugs required on cord connected equipment marking/ instructions regarding grounding reliability is to be provided.	MWAX0yA and MWBX0yA series: Power supply cord for this country is not provided at this time, Approved medical grade power cord will be provided by end use manufacturer or end use manufacturer's distributor	N/A
	Radiographic control disconnect mains plugs shall be acceptable for a current not less than 50 per cent of the maximum input current measured. Except for X-Ray equipment mains plugs shall be rated no less than 125 percent of the rated current of the equipment.		N/A
	Where polarized mains plugs are used in edison base lampholders and any single pole protective device shall be connected in the ungrounded side of the line, except if it is in addition to the one in the ungrounded side.		N/A
57.3, 59.1	Power supply cords and internal wiring including interconnection cords between equipment shall meet the requirements of NEC. A detachable power supply cord for non-permanently installed equipment shall be unlikely to become detached accidentally, unless it can be shown that detachment will not constitute a safety hazard.	Power supply cord for this country is not provided at this time. Approved medical grade power cord will be provided by end use manufacturer or end use manufacturer's distributor. MWAX0yA Internal wiring (protective earthing) is approved.	Pass
Deviations based on requirements other than the US National Electrical Code NEC, ANSI/NFPA 70			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
1.1, Section 5	Safety hazards resulting from intended physiological function of and ionizing radiation resulting from equipment covered by this standard are not considered. Such equipment is subject to US FDA requirements and US Federal Radiation Standards (21CFR Part 1020) promulgated under the Radiation Control for Health and Safety Act of 1968.	Information	Pass
2.12.100, 2.12.101, 19	In addition to the requirements in the base standard, equipment shall comply with ANSI/AAMI Safety Current Limits (SCL) and ANSI/NFPA 99 Health Care Facilities Standards. X-ray equipment need only comply with the Clause 19 requirements in UL 2601-1.	No X-ray	N/A
3.100, 3.100.1, 3.101, 3.101.1, 3.101.2 3.102, 57.5	In addition to compliance with this standard, primary connected components, printed wiring boards, lithium batteries, optical isolators, wiring and tubing, and cathode ray tubes exceeding 5 inches maximum dimensions shall meet US nationally recognized standards, such as ANSI/UL standards or internationally harmonized component standards. Components shall be used in accordance with their intended use and in consideration of their inherent limitations.	Approved components provided	Pass
6	"CAUTION", "WARNING" or "DANGER" markings shall be in contrasting color to the background. The signal word letters shall be minimum 2.8 mm high, all others minimum 1.6 mm high. A "WARNING" statement is required for ionizing radiation producing equipment.	Not provided with such markings	N/A
22, 28	In addition to the requirements and the basic standard, equipment shall be found to be in compliance with the Standard for X-Ray equipment, ANSI/UL 187, 5th edition, Sections 31 and 34 with respect to the movement control and supported masses.	No a X-Ray device	N/A
42	In addition, to the basic requirements in this standard, insulating systems operating at greater than Class 105°C limits during normal use and normal condition shall comply with the requirements of the Standard for Systems of Insulating Materials – General (UL 1446).	Considered, See appended test data table 42	Pass
55	The flaking or peeling of a conductive coating is not to contribute to safety hazard. External combustible materials having a surface area of more than 4.74 square meters shall have controlled flame spread characteristics.	Conductive coating not provided	N/A
	Polymetric enclosures and covers shall be considered for flammability characteristics and be resistant to mold stress relief and impact/drop safety hazards consistent with their use.	See list of critical components	Pass

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
56.3	The likelihood of a patient connected lead or part being misused so as to introduce a safety hazard shall be investigated.	Not provided with patient connected leads	N/A
58.2	PROTECTIVE EARTHING Connections shall be made mechanically secure as well as being soldered.	MWBx0yz and MVBx0yz are class II device. Protective earth terminal not provided. MWAx0yA series: AC inlet is soldered .	Pass
400	For equipment which uses oxygen or recommends use with oxygen, special safety hazards associated with use of oxygen should be addressed in accordance with Clause 400. These requirements are based on oxygen-related requirements from IEC 601-2-19, particular requirements for the safety of baby incubators.	Does not use oxygen	N/A
600	A separate power unit employing a separable connector for supplying the equipment shall be packaged with the equipment or be referenced to by the marking on the equipment. Direct plug-in units shall comply with the mechanical assembly, enclosure, input connections, accessibility of live parts, grounding, marking and performance requirements in the Standard for Class 2 Power Units, UL 1310.	Device is a component power supply, requirements to be evaluated in the end use application, not provided with internal wiring	N/A

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

6.1	TABLE: marking durability		Pass
marking tested			remarks
Ratings label			Pass
Supplementary information: - Webber Marking System Ultraplate II and 3M Marking System 7815 tested on enclosures made with Lexan 500, Lexan 945 and Lexan 940 material (MWAx0yz and MWBx0yz models) Webber Marking System Ultraplate II and 3M Marking System 7815 tested on heat sinks (MVAx0yz and MVBx0yz models)			

7.	TABLE: power input					Pass
Operating condition		Voltage (V)	Frequency (Hz)	Current (A)	Power (W)	Remarks
Model MWA100012z						
12Vdc@8.3A		90	50	2.146	113.84	
12Vdc@8.3A		100	50	1.964	112.89	
12Vdc@8.3A		115	50	1.582	111.56	
12Vdc@8.3A		230	50	1.010	110.14	
12Vdc@8.3A		240	50	0.981	110.03	
12Vdc@8.3A		264	50	0.919	109.88	
12Vdc@8.3A		90	60	2.182	115.05	
12Vdc@8.3A		100	60	1.985	114.20	
12Vdc@8.3A		115	60	1.757	112.91	
12Vdc@8.3A		230	60	1.024	110.23	
12Vdc@8.3A		240	60	0.984	110.15	
12Vdc@8.3A		264	60	0.917	109.82	
Model MWA100024z						
24Vdc@4.2A		90	50	2.128	113.03	
24Vdc@4.2A		100	50	1.810	111.58	
24Vdc@4.2A		115	50	1.583	110.75	
24Vdc@4.2A		230	50	1.010	108.70	
24Vdc@4.2A		240	50	0.981	108.55	
24Vdc@4.2A		264	50	0.921	108.43	
24Vdc@4.2A		90	60	2.142	112.89	

IEC 60601-1						
Clause	Requirement - Test			Result - Remark		Verdict
24Vdc@4.2A	100	60	1.941	111.80		
24Vdc@4.2A	115	60	1.539	111.36		
24Vdc@4.2A	230	60	1.008	108.93		
24Vdc@4.2A	240	60	0.977	108.81		
24Vdc@4.2A	264	60	0.915	108.36		
Model MWB100012z						
12Vdc@8.3A	90	50	2.146	113.84		
12Vdc@8.3A	100	50	1.964	112.89		
12Vdc@8.3A	115	50	1.582	111.56		
12Vdc@8.3A	230	50	1.010	110.14		
12Vdc@8.3A	240	50	0.981	110.03		
12Vdc@8.3A	264	50	0.919	109.88		
12Vdc@8.3A	90	60	2.182	115.05		
12Vdc@8.3A	100	60	1.985	114.20		
12Vdc@8.3A	115	60	1.757	112.91		
12Vdc@8.3A	230	60	1.024	110.23		
12Vdc@8.3A	240	60	0.984	110.15		
12Vdc@8.3A	264	60	0.917	109.82		
Model MWB100024z						
24Vdc@4.2A	90	50	2.128	113.03		
24Vdc@4.2A	100	50	1.810	111.58		
24Vdc@4.2A	115	50	1.583	110.75		
24Vdc@4.2A	230	50	1.010	108.70		
24Vdc@4.2A	240	50	0.981	108.55		
24Vdc@4.2A	264	50	0.921	108.43		
24Vdc@4.2A	90	60	2.142	112.89		
24Vdc@4.2A	100	60	1.941	111.80		
24Vdc@4.2A	115	60	1.539	111.36		
24Vdc@4.2A	230	60	1.008	108.93		
24Vdc@4.2A	240	60	0.977	108.81		
24Vdc@4.2A	264	60	0.915	108.36		
Supplementary information:						

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

15. b)	TABLE: residual voltage in attachment plugs										Pass	
voltage measured between:		measurements (V)									remarks	
		1	2	3	4	5	6	7	8	9		10
Line and Neutral		24	22	25	26	23	24	24	23	22	22	Test A
Line and Neutral		22	22	26	24	23	24	24	26	25	24	Test B
Line and Neutral		26	22	22	24	25	22	26	22	26	25	Test C
Line to Ground		2	1	1	2	2	4	2	4	1	4	Test C
Neutral to Ground		6	2	3	3	6	6	3	2	2	5	Test C
Line and Neutral		22	22	24	22	26	26	24	23	22	24	Test D
Line to Ground		4	4	2	1	4	3	3	4	4	1	Test D
Neutral to Ground		4	2	2	3	2	4	1	2	3	2	Test D
Supplementary information:												
Test A: Testing performed on MWB100012z												
Test B: Testing performed on MWB100024z												
Test C: Testing performed on MWA100012z												
Test D: Testing performed on MWA100024z												
15. c)	TABLE: residual voltage or energy in capacitors										N/A	
capacitor and its location		residual voltage (V)		time after disconnection (s)		capacitance value (mF)		residual energy (mJ)		Remarks		
Supplementary information: No such parts												

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

17. h1)	TABLE: defibrillation-proof applied parts				N/A
Test Condition: Fig. 50 or 51	Accessible part of measurement:	Applied part with test voltage	Test voltage polarity	Measured voltage between Y1 and Y2 (mV)	Remarks
Supplementary information: No Such parts					

17. h2)	TABLE: defibrillation-proof recovery time				N/A
Applied part with test voltage	Test voltage polarity	Recovery time from accompanying documents (s)	Measured recovery time (s)	Remarks	
Supplementary information: No Such parts					

18.	TABLE: protective earthing				Pass
Test location		Test current (A)	Measured voltage (V)	Resistance (Ω)	Remarks
MVAx0yz: impedance between earth pin in the APPLIANCE INLET and J2B solder pad		40	0.28	.007 Ω	Tested for 2 minutes
MVAx0yz: impedance between PE eyelet and PE trace at C4		40	.020	.005	Tested for 2 minutes
Supplementary information:					

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

19.	TABLE: leakage current				Pass
type of leakage current and test condition (including single faults)	supply voltage (VAC)	supply frequency (Hz)	measured max. value (uA)	Remarks	
ER –B, NC (S1=1, S5=1)	264	60	185	MWA/MVA100012z floating output	
ER –B, NC (S1=1, S5=0)	264	60	185	MWA/MVA100012z floating output	
ER –B, SFC (S1=0, S5=1)	264	60	350	MWA/MVA100012z floating output	
ER –B, SFC (S1=0, S5=0)	264	60	349	MWA/MVA100012z floating output	
ER –A, NC (S1=1, S5=1)	264	60	185	MWA/MVA100012z floating output	
ER –A, NC (S1=1, S5=0)	264	60	186	MWA/MVA100012z floating output	
ER –A, SFC (S1=0, S5=1)	264	60	350	MWA/MVA100012z floating output	
ER –A, SFC (S1=0, S5=0)	264	60	349	MWA/MVA100012z floating output	
ER –B, NC (S1=1, S5=1)	264	60	187	MWA/MVA100012z floating output	
ER –B, NC (S1=1, S5=0)	264	60	186	MWA/MVA100012z floating output	
ER –B, SFC (S1=0, S5=1)	264	60	358	MWA/MVA100012z floating output	
ER –B, SFC (S1=0, S5=0)	264	60	358	MWA/MVA100012z floating output	
ER –A, NC (S1=1, S5=1)	264	60	188	MWA/MVA100012z floating output	
ER –A, NC (S1=1, S5=0)	264	60	187	MWA/MVA100012z floating output	
ER –A, SFC (S1=0, S5=1)	264	60	358	MWA/MVA100012z floating output	
ER –A, SFC (S1=0, S5=0)	264	60	358	MWA/MVA100012z floating output	
ER –B, NC (S1=1, S5=1)	264	60	181	MWA/MVA100024z floating output	
ER –B, NC (S1=1, S5=0)	264	60	180	MWA/MVA100024z floating output	
ER –B, SFC (S1=0, S5=1)	264	60	348	MWA/MVA100024z floating output	
ER –B, SFC (S1=0, S5=0)	264	60	348	MWA/MVA100024z floating output	
ER –A, NC (S1=1, S5=1)	264	60	180	MWA/MVA100024z floating output	
ER –A, NC (S1=1, S5=0)	264	60	180	MWA/MVA100024z floating output	

IEC 60601-1				
Clause	Requirement - Test	Result - Remark		Verdict
ER –A, SFC (S1=0, S5=1)	264	60	348	MWA/MVA100024z floating output
ER –A, SFC (S1=0, S5=0)	264	60	348	MWA/MVA100024z floating output
ER –B, NC (S1=1, S5=1)	264	60	188	MWA/MVA100024z grounded output
ER –B, NC (S1=1, S5=0)	264	60	188	MWA/MVA100024z grounded output
ER –B, SFC (S1=0, S5=1)	264	60	355	MWA/MVA100024z grounded output
ER –B, SFC (S1=0, S5=0)	264	60	354	MWA/MVA100024z grounded output
ER –A, NC (S1=1, S5=1)	264	60	188	MWA/MVA100024z grounded output
ER –A, NC (S1=1, S5=0)	264	60	188	MWA/MVA100024z grounded output
ER –A, SFC (S1=0, S5=1)	264	60	355	MWA/MVA100024z grounded output
ER –A, SFC (S1=0, S5=0)	264	60	355	MWA/MVA100024z grounded output
EN –B, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100012z floating output
EN –B, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100012z floating output
EN –B, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100012z floating output
EN –B, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100012z floating output
EN –B, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100012z floating output
EN –B, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100012z floating output
EN –A, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100012z floating output
EN –A, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100012z floating output
EN –A, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100012z floating output
EN –A, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100012z floating output
EN –A, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100012z floating output
EN –A, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100012z floating output
EN –B, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100012z grounded output
EN –B, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100012z grounded output

IEC 60601-1				
Clause	Requirement - Test	Result - Remark		Verdict
EN –B, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100012z grounded output
EN –B, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100012z grounded output
EN –B, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100012z grounded output
EN –B, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100012z grounded output
EN –A, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100012z grounded output
EN –A, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100012z grounded output
EN –A, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100012z grounded output
EN –A, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100012z grounded output
EN –A, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100012z grounded output
EN –A, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100012z grounded output
EN –B, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100024z floating output
EN –B, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100024z floating output
EN –B, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100024z floating output
EN –B, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100024z floating output
EN –B, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100024z floating output
EN –B, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100024z floating output
EN –A, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100024z floating output
EN –A, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100024z floating output
EN –A, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100024z floating output
EN –A, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100024z floating output
EN –A, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100024z floating output
EN –A, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100024z floating output
EN –B, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100024z grounded output
EN –B, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100024z grounded output

IEC 60601-1				
Clause	Requirement - Test	Result - Remark		Verdict
EN –B, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100024z grounded output
EN –B, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100024z grounded output
EN –B, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100024z grounded output
EN –B, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100024z grounded output
EN –A, NC (S1=1, S5=1, S7=1)	264	60	3	MWA/MWB100024z grounded output
EN –A, NC (S1=1, S5=0, S7=1)	264	60	3	MWA/MWB100024z grounded output
EN –A, SFC (S1=0, S5=1, S7=1)	264	60	4	MWA/MWB100024z grounded output
EN –A, SFC (S1=0, S5=0, S7=1)	264	60	4	MWA/MWB100024z grounded output
EN –A, SFC (S1=1, S5=1, S7=0)	264	60	7	MWA/MWB100024z grounded output
EN –A, SFC (S1=1, S5=0, S7=0)	264	60	7	MWA/MWB100024z grounded output
Abbreviations used:				
ER	- Earth leakage current	MD	- Measuring device	
EN	- Enclosure leakage current	A	- After humidity conditioning	
P	- Patient leakage current	B	- Before humidity conditioning	
PM	- Patient leakage current with mains on the the applied parts	1	- Switch closed or set to normal polarity	
PA	- Patient auxiliary current	0	- Switch open or set to reversed polarity	
Fig. 15 - refers to Fig. 15 in IEC 601-1		NC	- Normal condition	
		SFC	- Single fault condition	

20.	TABLE: dielectric strength				Pass
Insulation under test (area from insulation diagram)	Insulation type: (OP-operational / BI-basic / SI-supplementary / DI-double / RI-reinforced)	Reference voltage (V)	Test voltage (V)	Remarks	
Primary to PE: MWAx0yz and MVAx0yz	Basic insulation	256 VAC	1512 VAC	No breakdown	
Primary to secondary: MWAx0yz and MWBx0yz and MVAx0yz and MVBx0yz	Reinforced insulation	276 VAC	4104 VAC	No breakdown	
Primary to enclosure: MWAx0yz and MWBx0yz	Reinforced insulation	276 VAC	4104 VAC	No breakdown	
Supplementary information:					
Test conducted after temperature test, abnormal test and humidity preconditioning					

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

21.	TABLE: mechanical strength		Pass
Part under test		Test (impact, drop, force, handle, rough handling, mobile)	Remarks
Polymeric enclosure parts on model MWAx012z		45 N steady force	No hazards result. No access to internal live parts.
Polymeric enclosure parts on model MWAx012z		0.5 J impact	No hazards result. No access to internal live parts.
Model MWAx012z		1 m drop	No hazards result. No access to internal live parts.
Model MWAx012z		5 cm rough handling	No hazards result. No access to internal live parts.
Supplementary information: Test performed on MWAx0yz and MWBx0yz series, MVAx0yz and MVBx0yz series are open frame power supplies, end use to be considered			
Test performed on enclosures made of Lexan 940, Lexan 945 and Lexan 500 material			

24.	TABLE: stability		N/A
Part under test		Test condition	Remarks
Supplementary information: - Stability to be evaluated in the end use device			

29.	TABLE: X-radiation			N/A
Part under test		Test condition	Measured radiation (mR)	Remarks
Supplementary information: - Equipment produces no X-Radiation				

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
42.	TABLE: normal temperature		Pass
	Supply voltage	90 V ac, 60 Hz	-
	Ambient temperature °C	29°C	-
	Test condition	MWA100012z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		86.7	100
T1 Winding		93.8	100
C10 between L2 and C10		79.5	85
C9		75.8	85
L2 winding		90.6	100
L1 winding		89.5	100
L3 winding		79.6	100
C34 facing T1		82.6	85
C32 between C32 and L3		71.0	85
PWB under R1		93.6	110
PWB under Q5		93.7	110
PWB under R8		84.8	110
HS2 next to Q5		79.4	--
Enclosure outside above T1		64.6	66
		V in = 90 Vac @ 60 Hz P in = 113.42 W I in = 1.930 A V out = 11.81 Vdc I out = 8.3 A	
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Max allowable temperature linear calculated for 49°C operating temperature Duration: 4 hours			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
42.	TABLE: normal temperature		Pass
	Supply voltage	264 V ac, 50 Hz	-
	Ambient temperature °C	26°C	-
	Test condition	MWA100012z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		76.4	97
T1 Winding		84.0	97
C10 between L2 and C10		60.3	82
C9		61.1	82
L2 winding		56.9	97
L1 winding		56.4	97
L3 winding		71.5	97
C34 facing T1		73.4	82
C32 between C32 and L3		62.9	82
PWB under R1		61.3	107
PWB under Q5		85.1	107
PWB under R8		68.5	107
HS2 next to Q5		71.0	--
Enclosure outside above T1		56.1	63
		V in = 264 Vac @ 50 Hz P in = 108.97 W I in = 0.618 A V out = 11.81 Vdc I out = 8.3 A	
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Max allowable temperature linear calculated for 49°C operating temperature Duration: 3.5 hours			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
42.	TABLE: normal temperature		Pass
	Supply voltage	90 V ac, 60 Hz	-
	Ambient temperature °C	27°C	-
	Test condition	MWA100024z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		69.8	98
T1 Winding		73.9	98
C10 between L2 and C10		67.2	83
C9		64.0	83
L2 winding		77.6	98
L1 winding		75.3	98
L3 winding		65.9	98
C34 facing T1		71.1	83
C32 between C32 and L3		59.1	83
PWB under R1		91.2	108
PWB under Q5		77.5	108
PWB under R8		75.3	108
HS2 next to Q5		70.0	--
Enclosure outside above T1		58.9	64
		V in = 90 Vac @ 60 Hz P in = 112.24 W I in = 1.963 A V out = 24.84 Vdc I out = 4.2 A	
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Max allowable temperature linear calculated for 49°C operating temperature Duration: 4 hours			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
42.	TABLE: normal temperature		Pass
	Supply voltage	264 V ac, 50 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWA100024z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		62.2	96
T1 Winding		66.9	96
C10 between L2 and C10		52.0	81
C9		52.5	81
L2 winding		51.4	96
L1 winding		50.3	96
L3 winding		59.1	96
C34 facing T1		63.6	81
C32 between C32 and L3		52.2	81
PWB under R1		59.7	106
PWB under Q5		70.6	106
PWB under R8		64.1	106
HS2 next to Q5		62.7	--
Enclosure outside above T1		51.3	62
		V in = 264 Vac @ 50 Hz P in = 108.6 W I in = 0.607 A V out = 23.84 Vdc I out = 4.2 A	
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Max allowable temperature linear calculated for 49°C operating temperature Duration: 3.5hours			

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

42.	TABLE: normal temperature		Pass
	Supply voltage	90 V ac, 60 Hz	-
	Ambient temperature °C	24°C	-
	Test condition	MVA100012z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		76.0	84
T1 Winding		81.2	84
C10 between L2 and C10		56.1	69
C9		59.2	69
L2 winding		59.4	84
L1 winding		64.6	84
L3 winding		48.0	84
C34 facing T1		61.0	69
C32 between C32 and L3		44.7	69
PWB under R1		47.6	94
PWB under Q5		62.0	94
PWB under R8		69.3	94
HS2 next to Q5		56.4	--
V in = 90 Vac @ 60 Hz P in = 115.61 W I in = 2.010 A V out = 12.04 Vdc I out = 8.3 A			
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Max allowable temperature linear calculated for 60°C operating temperature Duration: 3 hours			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
42.	TABLE: normal temperature		Pass
	Supply voltage	264 V ac, 50 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MVA100012z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		77.0	85
T1 Winding		82.5	85
C10 between L2 and C10		48.9	70
C9		52.2	70
L2 winding		44.8	85
L1 winding		49.2	85
L3 winding		49.4	85
C34 facing T1		61.9	70
C32 between C32 and L3		45.9	70
PWB under R1		42.0	95
PWB under Q5		62.9	95
PWB under R8		64.9	95
HS2 next to Q5		57.0	--
		V in = 264 Vac @ 50 Hz P in = 110.4 W I in = 0.868 A V out = 12.03 Vdc I out = 8.3 A	
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Max allowable temperature linear calculated for 60°C operating temperature Duration: 2.5 hours			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
42.	TABLE: normal temperature		Pass
	Supply voltage	90 V ac, 60 Hz	-
	Ambient temperature °C	27°C	-
	Test condition	MVA100024z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		71.1	87
T1 Winding		75.7	87
C10 between L2 and C10		58.4	72
C9		56.4	72
L2 winding		61.8	87
L1 winding		65.0	87
L3 winding		47.5	87
C34 facing T1		49.9	72
C32 between C32 and L3		37.9	72
PWB under R1		60.4	97
PWB under Q5		62.8	97
PWB under R8		65.3	97
HS2 next to Q5		57.1	--
		V in = 90 Vac @ 60 Hz P in = 113.48 W I in = 1.997 A V out = 24.07 Vdc I out = 4.2 A	
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Max allowable temperature linear calculated for 60°C operating temperature Duration: 3 hours			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
42.	TABLE: normal temperature		Pass
	Supply voltage	264 V ac, 50 Hz	-
	Ambient temperature °C	26°C	-
	Test condition	MVA100024z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		72.5	86
T1 Winding		76.7	86
C10 between L2 and C10		50.1	71
C9		48.1	71
L2 winding		45.5	86
L1 winding		48.9	86
L3 winding		48.1	86
C34 facing T1		51.6	71
C32 between C32 and L3		38.4	71
PWB under R1		49.0	96
PWB under Q5		63.9	96
PWB under R8		62.2	96
HS2 next to Q5		57.7	--
		V in = 264 Vac @ 50 Hz P in = 108.4 W I in = 0.873 A V out = 24.07 Vdc I out = 4.2 A	
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Max allowable temperature linear calculated for 60°C operating temperature Duration: 2.5hours			

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

44.	TABLE: overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection		Pass
Test type and condition		Part under test	Remarks
44.5 Humidity, Preconditioning test at 25°C, 93%, 48h performed		Complete device	Pass
Supplementary information: -Testing performed on MWA100012z, MWA100024z, MWB100012z, MWB100024z, MVA100012z, MVA100024z, MVB100012z and MVB100024z			

45.	TABLE: hydrostatic pressure and pressure-relief device cycling test		N/A
Test type and condition		Part under test	Test pressure
Supplementary information: - No part subjected to pressure			

52.	TABLE: abnormal operation		Pass
Test type, condition and clause reference		Observed results	Remarks
MWA100012z D3 Short D to G		Unit shut down within 1 sec no hazardous observed. F1 and F2 opened. Fuse F1 and F2 tested in unit: Littelfuse series 392, Belfuse series RST, Walter series 2010, Walter series FAP5, Conquer series PBU, Conquer series PGU and Sunfuse series 5QP5 Before: After Vin: 264V~ 264V~ Freq: 60Hz 60Hz Pin: 109.1 W 0W I in: 0.621 A 0 A Vout: 11.86 Vdc 0 Vdc Iout: 8.3 A 0A	NB, NC, NT

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
MWB100024z Q3 Short D to S	Unit shut down within 1 sec no hazardous observed. F1 and F2 opened. Fuse F1 and F2 tested in unit: Littelfuse series 392, Belfuse series RST, Walter series 2010, Walter series FAP5, Conquer series PBU, Conquer series PGU and Sunfuse series 5QP5 Before: After Vin: 264V~ 264V~ Freq: 60Hz 60Hz Pin: 108.59 W 0W I in: 0.612 A 0 A Vout: 23.86 Vdc 0 Vdc Iout: 4.2 A 0A	NB, NC, NT	
MWB100024z Q3 Short G to S	Unit shut down within 1 sec no hazardous observed. Recovers when short removed Before: After Vin: 264V~ 264V~ Freq: 60Hz 60Hz Pin: 45.70 W 0W I in: 0.303 A 0 A Vout: 23.9 Vdc 0 Vdc Iout: 1.67 A 0A	NB, NC, NT	
MWA100024z D1 Short AC to AC	Unit shut down within 1 sec no hazardous observed. F1 and F2 opened. Fuse F1 and F2 tested in unit: Littelfuse series 392, Belfuse series RST, Walter series 2010, Walter series FAP5, Conquer series PBU, Conquer series PGU and Sunfuse series 5QP5 Before: After Vin: 264V~ 264V~ Freq: 60Hz 60Hz Pin: 108.57 W 0W I in: 0.608 A 0 A Vout: 23.9 Vdc 0 Vdc Iout: 4.2A 0A	NB, NC, NT	

IEC 60601-1				
Clause	Requirement - Test	Result - Remark		Verdict
MWA100024z D1 Short + to AC	Unit shut down within 1 sec no hazardous observed. F1 and F2 opened. Fuse F1 and F2 tested in unit: Littelfuse series 392, Belfuse series RST, Walter series 2010, Walter series FAP5, Conquer series PBU, Conquer series PGU and Sunfuse series 5QP5 Before: After Vin: 264V~ 264V~ Freq: 60Hz 60Hz Pin: 108.67 W 0W I in: 0.611 A 0 A Vout: 23.9 Vdc 0 Vdc Iout: 4.2A 0A			NB, NC, NT
MWA100012z C9 Short	Input power and current increased, F1 and F2 opened after 5 seconds. no hazardous observed. F1 and F2 opened. Fuse F1 and F2 tested in unit: Littelfuse series 392, Belfuse series RST, Walter series 2010, Walter series FAP5, Conquer series PBU, Conquer series PGU and Sunfuse series 5QP5 Before: 0-5secs. 5secs Vin: 264V~ 264V~ 264V~ Freq: 60Hz 60Hz 60Hz Pin: 109.1 W 140W 0W I in: 0.621 A 0.715 A 0A Vout: 11.85 Vdc 11.85 Vdc 0Vdc Iout: 8.3A 8.3A 0A			NB, NC, NT
MWB100024z C10 Short	Input power and current increased, F1 and F2 opened after 5 seconds. no hazardous observed. F1 and F2 opened. Fuse F1 and F2 tested in unit: Littelfuse series 392, Belfuse series RST, Walter series 2010, Walter series FAP5, Conquer series PBU, Conquer series PGU and Sunfuse series 5QP5 Before: 0-5secs. 5secs Vin: 264V~ 264V~ 264V~ Freq: 60Hz 60Hz 60Hz Pin: 109.1 W 134W 0W I in: 0.621 A 0.699A 0A Vout: 11.85 Vdc 11.85 Vdc 0Vdc Iout: 8.3A 8.3A 0A			NB, NC, NT
Output overload MWA100012z	Refer to table 52 A			NB, NC, NT
Output overload MWA100024z	Refer to table 52 B			NB, NC, NT
Short output of Model MWA100012z	Refer to table 52 C			NB, NC, NT
Short output of Model MWA100024z	Refer to table 52 D			NB, NC, NT

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
MWB100024z U3 Short pin 1 and 2	Refer to table 52 E		NB, NC, NT
MWB100012z U2 Short pin 3 and 4	Refer to table 52 F		NB, NC, NT
MWB100024z U3 Open pin 3	Refer to table 52 G		NB, NC, NT
MWB100024z U6 Short pin 1 and 2	Refer to table 52 H		NB, NC, NT
MWB100024z U6 Short pin 3 and 4	Refer to table 52 I		NB, NC, NT
MWB100012Az U6 Open pin 3	Refer to table 52 J		NB, NC, NT
Supplementary information: For single fault condition according to clause 52.5.1 refer to table 57.9.1b) NB: No breakdown. NC: Cheesecloth remained intact. NT: Tissue paper remained intact.			

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

52 A.	TABLE: abnormal temperature - Output overload MWA100012z		Pass
	Supply voltage	264 V ac, 60 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWA100012z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		95.6	175
T1 Winding		107.0	175
		Before	After
V in =		264 Vac @ 60 Hz	264 Vac @ 60 Hz
P in =		109.68 W	143.9 W
I in =		0.606 A	0.841 A
V out =		11.83 Vdc	11.63 Vdc
I out =		8.3 A	10.7 A
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Duration: 4 Hours			

52 B.	TABLE: abnormal temperature - Output overload MWA100024z		Pass
	Supply voltage	264 V ac, 60 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWA100024z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		83.3	175
T1 Winding		91.9	175
		Before	After
V in =		264 Vac @ 60 Hz	264 Vac @ 60 Hz
P in =		108.4 W	152.0 W
I in =		0.0.616 A	0.815 A
V out =		23.91 Vdc	23.65 Vdc
I out =		4.2 A	5.8 A
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Duration: 4 Hours			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
52 C.	TABLE: normal temperature - Short output of Model MWA100012z		Pass
	Supply voltage	264 V ac, 60 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWA100012z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		54.2	175
T1 Winding		58.3	175
		Before	After
V in =		264 Vac @ 60 Hz	264 Vac @ 60 Hz
P in =		110.05 W	Pulsing 0.025 to 35.2W
I in =		0.607 A	Pulsing 0.025 to 0.12A
V out =		11.87 Vdc	0 Vdc
I out =		8.3 A	0 A
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Duration: 3 Hours			

52 D.	TABLE: abnormal temperature - Short output of Model MWA100024z		Pass
	Supply voltage	264 V ac, 60 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWA100024z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		41.8	175
T1 Winding		44.3	175
		Before	After
V in =		264 Vac @ 60 Hz	264 Vac @ 60 Hz
P in =		109.26 W	Pulsing 0.63 to 19.1W
I in =		0.618 A	Pulsing 0.024 to 0.132A
V out =		23.92 Vdc	0 Vdc
I out =		4.2 A	0 A
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Duration: 3 Hours			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
52 E.	TABLE: abnormal temperature – MWB100024z U3 Short pin 1 and 2		Pass
	Supply voltage	264 V ac, 60 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWB100024z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		79.0	175
T1 Winding		80.5	175
		Before	After
V in =		264 Vac @ 60 Hz	264 Vac @ 60 Hz
P in =		109.9 W	113.4 W
I in =		0.683 A	0.752A
V out =		23.86 Vdc	24.79 Vdc
I out =		4.2 A	4.2 A
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Duration: 1.5 Hrs			

52 F.	TABLE: abnormal temperature – MWB100012z U3 Short pin 3 and 4		Pass
	Supply voltage	264 V ac, 60 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWB100012z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		36.8	175
T1 Winding		37.0	175
		Before	After
V in =		264 Vac @ 60 Hz	264 Vac @ 60 Hz
P in =		109.8 W	pulsing 5 to 23 W
I in =		0.671 A	pulsing 0.03 to 0.3 A
V out =		11.88 Vdc	0 Vdc
I out =		8.3 A	0 A
			Recovers when short is removed.
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Duration: 1.5 Hrs Min			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
52 G.	TABLE: abnormal temperature – MWB100024z U3 Open pin 3		Pass
	Supply voltage	264 V ac, 60 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWB100024z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		53.5	175
T1 Winding		55.1	175
		Before	After
V in =		264 Vac @ 60 Hz	264 Vac @ 60 Hz
P in =		110.6 W	pulsing 14 to 57 W
I in =		0.668 A	pulsing 0.2 to 0.43 A
V out =		23.82 Vdc	pulsing 1.4 to 2.3 Vdc
I out =		4.2 A	pulsing 0.7 to 2.5 A
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Duration: 1.5 Hrs			

52 H.	TABLE: abnormal temperature – MWB100024z U6 short pin 1 and 2		Pass
	Supply voltage	264 V ac, 60 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWB100024z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		45.2	175
T1 Winding		45.5	175
		Before	After
V in =		264 Vac @ 60 Hz	264 Vac @ 60 Hz
P in =		110.3 W	0.73 W
I in =		0.665 A	0.035 A
V out =		23.93 Vdc	0 Vdc
I out =		4.2 A	0 A
			Recovers when short is removed
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Duration: 1.5 Hrs			

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
52 I.	TABLE: abnormal temperature – MWB100024z U6 short pin 3 and 4		Pass
	Supply voltage	264 V ac, 60 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWB100024z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		45.2	175
T1 Winding		45.5	175
V in = P in = I in = V out = I out =		Before 264 Vac @ 60 Hz 110.6 W 0.668 A 23.03 Vdc 4.2 A	After 264 Vac @ 60 Hz Pulsing 15 to 27 W Pulsing 0.4 to 0.5 A Pulsing 1.2 to 2.5 Vdc Pulsing 1.0 to 2.6 A Recovers when short is removed
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Duration: 2 Hrs			

52 J.	TABLE: abnormal temperature – MWB100012z U6 Open pin 3		Pass
	Supply voltage	264 V ac, 60 Hz	-
	Ambient temperature °C	25°C	-
	Test condition	MWB100012z	-
Measuring location		Measured Temperature (°C)	Allowed max. temperature T (°C)
T1 Core		94.1	175
T1 Winding		102.2	175
V in = P in = I in = V out = I out =		Before 264 Vac @ 60 Hz 112.3 W 0.672 A 11.69 Vdc 8.3 A	After 264 Vac @ 60 Hz 117.8 W 0.706 A 11.59 Vdc 8.3 A
Supplementary information: Thermo coupler method applied. Test condition: refer to Input test data Duration: 1.5 Hrs			

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

56.10	TABLE: actuating parts and controls		N/A
Part under test		Torque applied	Remarks
Supplementary information: - No Actuating parts			

56.11 b)	TABLE: foot-operated control devices loading		N/A
Part under test		Observed results	Remarks
Supplementary information: - No a foot operated device			

57.4	TABLE: cord anchorages					N/A
Cord under test		Mass of equipment	Pull	Torque	Remarks	Verdict
Supplementary information: - Provided with appliance inlet						

57.4 b)	TABLE: cord bending			N/A
Cord under test		Test mass	Measured curvature	Remarks
Supplementary information: - Provided with appliance inlet				

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

57.9.1 a)	TABLE: transformers short-circuit					Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Remarks
		Primary	Secondary	Ambient		
Primary MWB100012 z	F1 and F2	50.0 2.5 Hours After Short	53.9 2.5 Hours After Short	26	2.5 Hours	Before: Vin: 264V~ Freq: 60Hz Pin: 109.57 W I in: 0.608 A Vout: 12.0 Vdc Iout: 8.3 A After Vin: 264V~ Freq: 60Hz Pin: Pulsing 0.92 to 21.96W I in: Pulsing 0.02 to 0.156A Vout: 0 Vdc Iout: 0 A Temperatures were stabilized after 2.5 Hours
Primary MWB100024 z	F1 and F2	41.8 2.5 Hours After Short	44.0 2.5 Hours After Short	26	2.5 Hours	Before: Vin: 264V~ Freq: 60Hz Pin: 110.0 W I in: 0.620 A Vout: 24.17 Vdc Iout: 4.2 A After Vin: 264V~ Freq: 60Hz Pin: Pulsing 0.05 tp 12.5W I in: Pulsing 0.01 to 0.049A Vout: 0 Vdc Iout: 0 A Temperatures were stabilized after 2.5 Hours
Supplementary information:						
NB: No breakdown. NC: Cheesecloth remained intact. NT: Tissue paper remained intact						

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

57.9.1 b)	TABLE: overload						Pass
Winding under test	Protection	Measured temperatures (°C)			Test duration	Test current or thermal cut-out temp.	Remarks
T1 Core	T1 Wind	Ambient					
Secondary MWB100012 z	F1 and F2	94.9	107.5	28	2.5 Hours	5.01A	NB, NC, NT
Secondary MWB100024 z	F1 and F2	77.7	85.5	28	2.5 Hours	2.0A	NB, NC, NT
Supplementary information:							
NB: No breakdown. NC: Cheesecloth remained intact. NT: Tissue paper remained intact.							

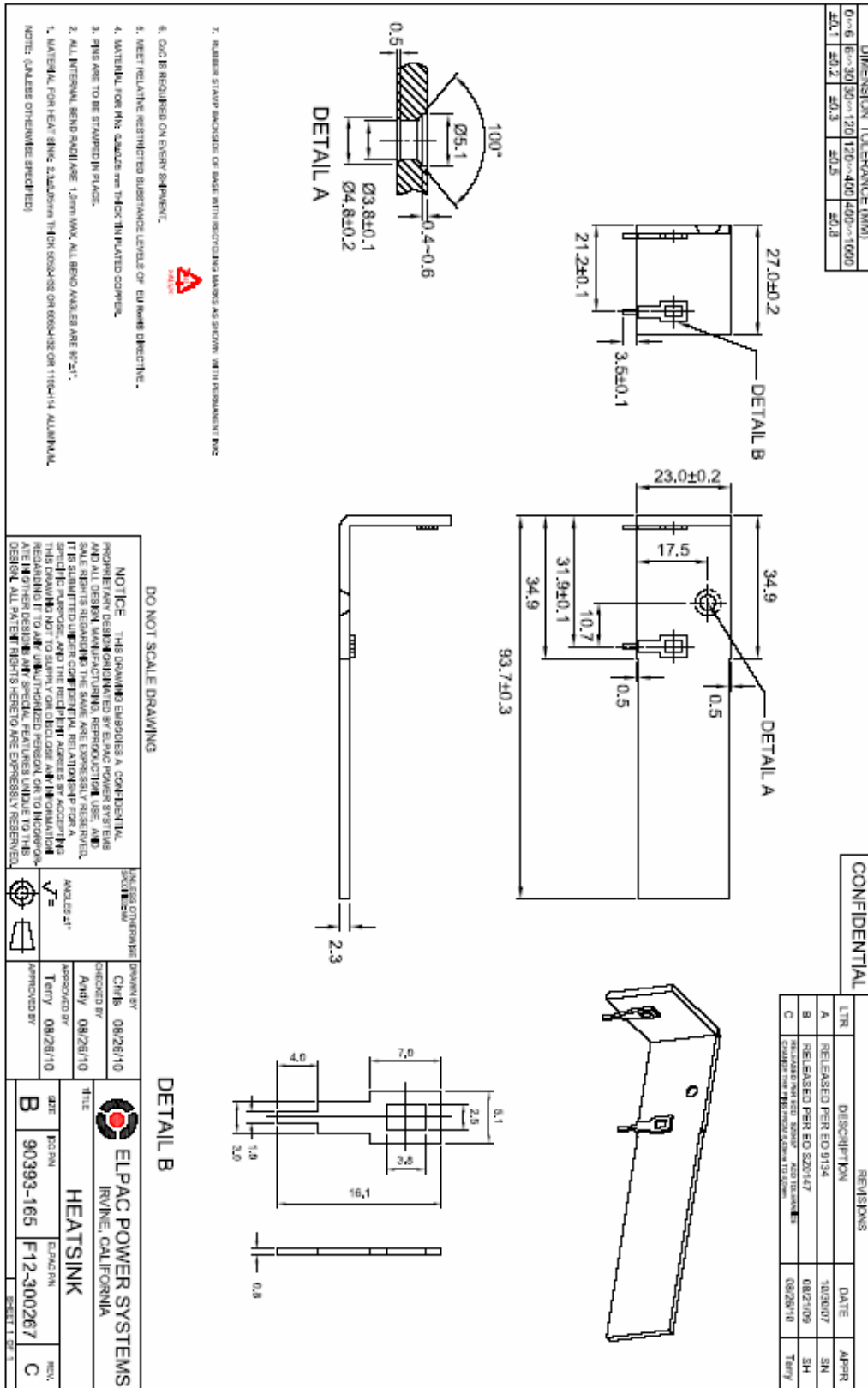
57.9.2	TABLE: transformer dielectric strength				Pass
Transformer under test	Test voltage applied to	Test voltage	Test frequency	Remarks	
Mains transformer	Primary to secondary	1200 VAC	300 Hz	NB	
Supplementary information: - NB: No breakdown					

IEC 60601-1			
Clause	Requirement - Test	Result - Remark	Verdict
	TABLE: additional tests		Pass
Clause	Test type and condition	Remarks and observed results	
59.2	Ball Pressure Test –	Bobbin; Chang Chu Plastic, T375J. Test temp 125 deg C Impression diameter: 0.45mm	Pass
59.2	Ball Pressure Test –	Bobbin; Chang Chu Plastic, T357. Test temp 125 deg C Impression diameter: 0.46mm	Pass
59.2	Ball Pressure Test –	Bobbin; Chang Chu Plastic, T375HF. Test temp 125 deg C Impression diameter: 0.44mm	Pass
59.2	Ball Pressure Test – ChangChun Plastic Co. Type T375J	Test temp 125 deg C impression diameter: 0.45mm	Pass
59.2	Ball Pressure Test – Hitachi Chemical Type CP-J-8800	Test temp 125 deg C impression diameter: 0.45mm	Pass
59.2	Ball Pressure Test – Sumitomo Bakelite Co. Type PM-9630	Test temp 125 deg C impression diameter: 0.45mm	Pass
59.2	Ball Pressure Test – Sumitomo Bakelite Co. Type PM-9820	Test temp 125 deg C impression diameter: 0.45mm	Pass
59.2	Ball Pressure Test – Sumitomo Bakelite Co. Type PM-9720	Test temp 125 deg C impression diameter: 0.45mm	Pass
59.2	Ball Pressure Test – Sumitomo Bakelite Co. Type PM-9750	Test temp 125 deg C impression diameter: 0.45mm	Pass
59.2	Ball Pressure Test – Sumitomo Bakelite Co. Type PM-9850	Test temp 125 deg C impression diameter: 0.45mm	Pass
59.2	Ball Pressure Test – Sumitomo Bakelite Co. Type PM-9870	Test temp 125 deg C impression diameter: 0.45mm	Pass
59.2	Ball Pressure Test – ChangChun Plastic Co. Type T357	Test temp 125 deg C impression diameter: 0.45mm	Pass
59.2	Ball Pressure Test – ChangChun Plastic Co. Type T375HF	Test temp 125 deg C impression diameter: 0.45mm	Pass
Supplementary information:			

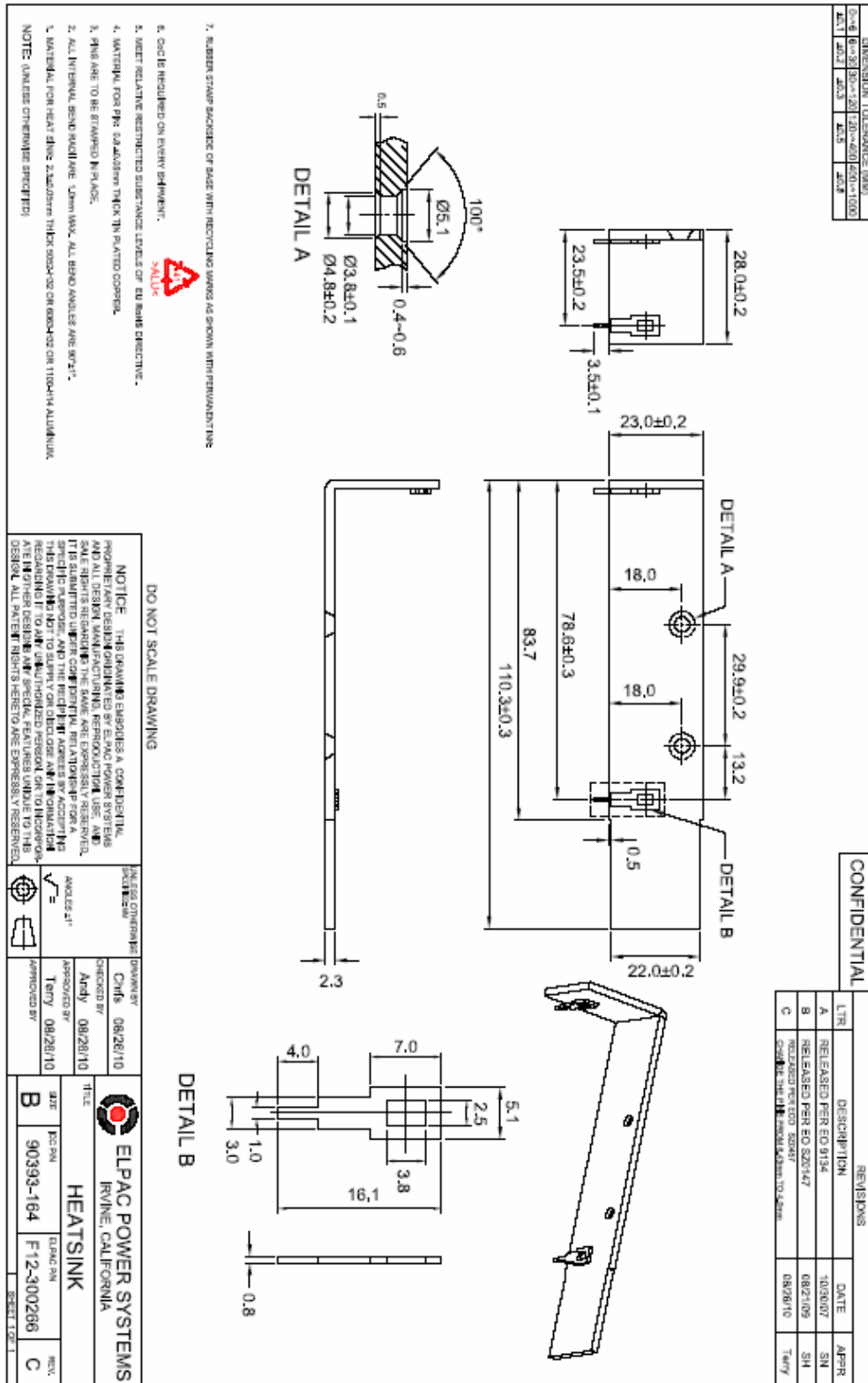
END OF TEST REPORT

30792801.009

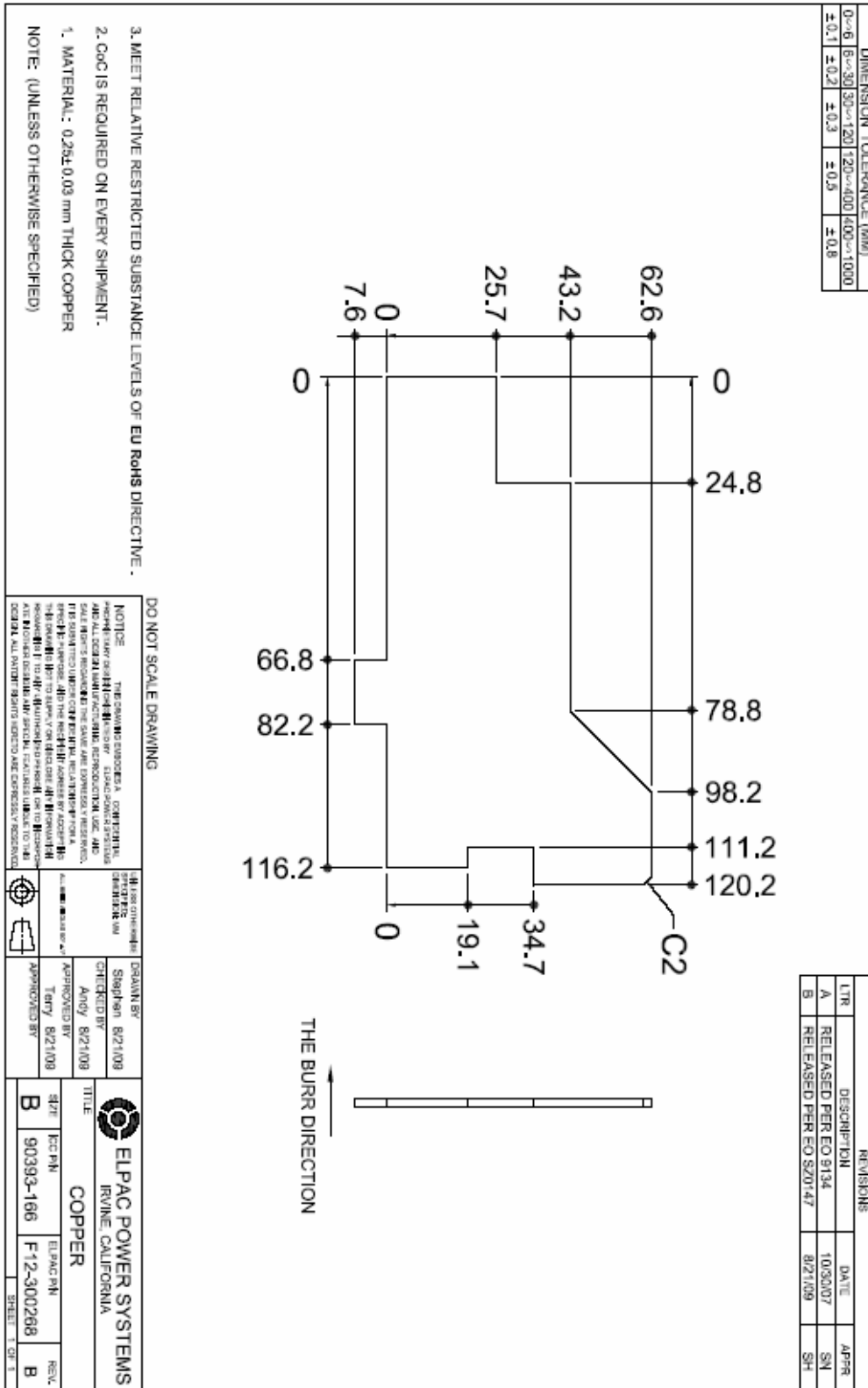
MWA/MWBx0yz



MWA/MWBx0yz



MWA/MWBx0yz



30792801.009

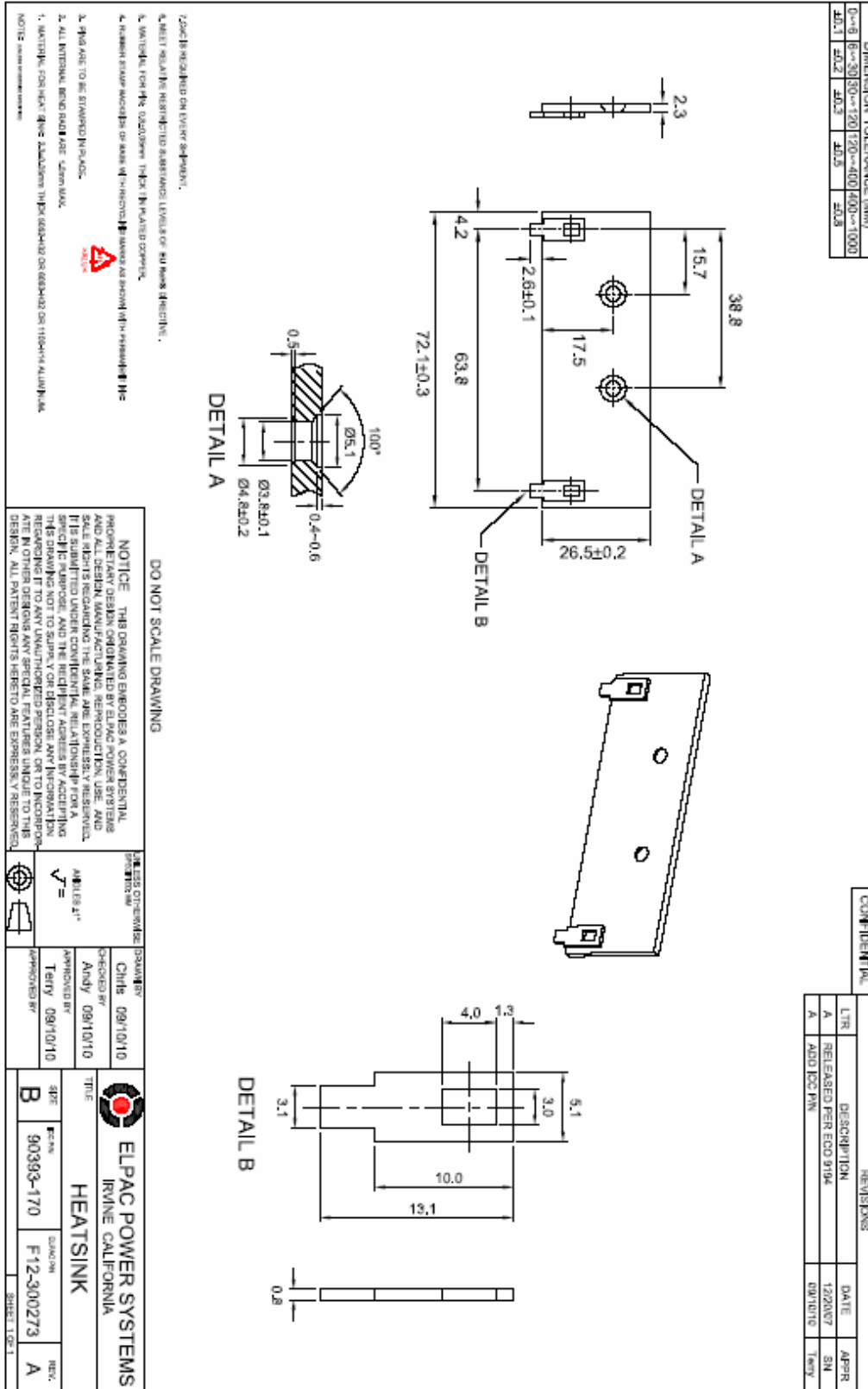
Attachment # 8

Page 4 of 5

Heat Sink and Copper Shield Drawings



MVA/MVBx0yz



30792801.009

Attachment # 8

Page 5 of 5

Heat Sink and Copper Shield Drawings

MVA/MVBx0yz

