

Test Report issued under the responsibility of:



TEST REPORT IEC 60601-1 Part 1: General requirements for basic safety and essential performance Report Number.: T221-0013/17 Date of issue 2017-03-31 Total number of pages 233 pages Name of Testing Laboratory SIQ Testing and Certification GmbH preparing the Report: Applicant's name : GlobTek, Inc. Address: Corporate Headquarters, 186 Veterans Dr Northvale, NJ 07647, USA Test specification: Standard: IEC 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1 (2012 reprint) Test procedure.....: CB Scheme Non-standard test method : N/A Test Report Form No. : IEC60601 1J PS Test Report Form(s) Originator....: UL(US) Master TRF: 2014-09

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General disclaimer:

The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing CB Testing Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

| Test item description: | Medical Power supply for building-in | | | | | | |
|------------------------|--|---|--|--|--|--|--|
| Trade Mark: | GlobTek, Inc. | | | | | | |
| Manufacturer : | GlobTek, Inc. Corporate Headquarters, 186 Veterans Dr Northvale, NJ 07647, USA | | | | | | |
| Model/Type reference: | GT*91110P240*-****-* series | | | | | | |
| | 1st "*"can be 'M' or '-' or 'H' for market identification and not related to safety | | | | | | |
| | 2nd "*" | denotes the standard rated output voltage designation, which can be "12", "15", "18", "24", "36", "48" or "55" | | | | | |
| | 3rd "*" | can be 'F' which means open frame or 'C' which means perforated enclosure | | | | | |
| | 4th "*" | can be 'A' which means airflow for 240 W load or blank which means no airflow | | | | | |
| | 5th "*" | can be 'W' which means Class II or blank which means Class I | | | | | |
| | 6th "*" | optional, which can be "-0,1" to "-11,9" with interval of 0,1 to denote voltage deviation or blank to indicate no voltage different. The result by subtracting the deviation value from the standard rated output voltage denotes the rated output voltage | | | | | |
| | 7th "*" | can be 'S' or "HIOXXX" or "HOXXX" or "HIXXX". | | | | | |
| | | S = Input header and output header connectors on board | | | | | |
| | | HIOXXX = Input and output wire harness. Where XXX can be from 000 to 500 to indicate harness length (maximum length for input and output harnesses is 500mm). | | | | | |
| | | HOXXX = Input header connector on board and output wire harness. Where XXX can be from 000 to 500 to indicate harness length (maximum harness length for output is 500 mm). | | | | | |
| | | HIXXX = Input wire harness. Output header on board. Where XXX can be from 000 to 500 to indicate harness length (maximum harness length for input is 500mm) | | | | | |
| Ratings: | Input: 100-240 | V~; 50-60 Hz; 4,0 A or 130-320 Vdc; 2,5 A | | | | | |
| | Output: See ne | ext page. | | | | | |



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| Standard Model Number For Open Frame Version: | <u>Output</u> Voltage* | <u>Minimum</u> Load** | <u>Maximum</u> Load w/o Airflow | Maximum Load with 20CFM Airflow |
|---|--|---|--|---|
| GT(M)91110P24012-FA(W)-S or -HIOXX or -HOXXX or -HOXXX | 12 V=== | 0,2 A | 12,5 A | 20,0 A |
| GT(M)91110P24015-X.X-FA(W)-S or -HIOXX or - HOXXX or -HIXXX | 15 V=== | 0,2 A | 10,0 A | 16,0 A |
| GT(M)91110P24018-X.X-FA(W)-S or -HIOXX or - HOXXX or -HIXXX | 18 V | 0,2 A | 8,33 A | 13,3 A |
| GT(M)91110P24024-X.X-FA(W)-S or -HIOXX or - HOXXX or -HIXXX | 24 V === | 0,1 A | 6,25 A | 10,0 A |
| GT(M)91110P24036-X.X-FA(W)-S or -HIOXX or - HOXXX or –HIXXX | 36 V=== | 0,1 A | 4,17 A | 6,7 A |
| GT(M)91110P24048-X.X-FA(W)-S or -HIOXX or - HOXXX or –HIXXX | 48 V === | 0,1 A | 3,12 A | 5,0 A |
| GT(M)91110P24055-X.X-FA(W)-S or -HIOXX or - HOXXX or –HIXXX | 55 V=== | 0,1 A | 2,72 A | 4,36 A |
| | | | | |
| Standard Model Number For with Perforated Enclosure Version | <u>Output</u> <u>Voltage*</u> | <u>Minimum</u> Load** | <u>Maximum</u> Load w/o Airflow | <u>Maximum</u> Load with 20CFM |
| | | | | Airflow |
| GT(M)91110P24012-CA(W)-S or -HIOXX or -HOXXX or -HIXXX | 12 V== | 0,2 A | 6,7 A | Airflow 16,67 A |
| GT(M)91110P24012-CA(W)-S or -HIOXX or -HOXXX or -HIXXX GT(M)91110P24015-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX | 12 V== 15 V== | 0,2 A 0,2 A | 6,7 A 5,3 A | Airflow 16,67 A 13,38 A |
| GT(M)91110P24012-CA(W)-S or -HIOXX or -HOXXX or -HIXXX GT(M)91110P24015-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX GT(M)91110P24018-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX | 12 V=== 15 V=== 18 V=== | 0,2 A 0,2 A 0,2 A | 6,7 A 5,3 A 4,4 A | Airflow 16,67 A 13,38 A 11,11 A |
| GT(M)91110P24012-CA(W)-S or -HIOXX or -HOXXX or -HIXXX GT(M)91110P24015-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX GT(M)91110P24018-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX GT(M)91110P24024-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX | 12 V== 15 V== 18 V== 24 V== | 0,2 A 0,2 A 0,2 A 0,2 A 0,1 A | 6,7 A 5,3 A 4,4 A 3,3 A | Airflow 16,67 A 13,38 A 11,11 A 8,33 A |
| GT(M)91110P24012-CA(W)-S or -HIOXX or -HOXXX or -HIXXX GT(M)91110P24015-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX GT(M)91110P24018-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX GT(M)91110P24024-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX | 12 V== 15 V== 18 V== 24 V== 36 V== | 0,2 A 0,2 A 0,2 A 0,2 A 0,1 A 0,1 A | 6,7 A 5,3 A 4,4 A 3,3 A 2,2 A | Airflow 16,67 A 13,38 A 11,11 A 8,33 A 5,5 A |
| GT(M)91110P24012-CA(W)-S or -HIOXX or -HOXXX or -HIXXX GT(M)91110P24015-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX GT(M)91110P24018-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX GT(M)91110P24024-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX GT(M)91110P24048-X.X-CA(W)-S or -HIOXX or - HOXXX or -HIXXX | 12 V=== 15 V=== 18 V=== 24 V=== 36 V=== 48 V=== | 0,2 A 0,2 A 0,2 A 0,2 A 0,1 A 0,1 A 0,1 A | 6,7 A 5,3 A 4,4 A 3,3 A 2,2 A 1,7 A | Airflow 16,67 A 13,38 A 11,11 A 8,33 A 5,5 A 4,17 A |

** Output voltage is within regulation range even at no load, but minimal level of audible noise may be heard from the supply.



| Testing procedure and testing location: | | | | | |
|--|--|------------|--|--|--|
| CB Testing Laboratory: | SIQ Testing and Certific | ation GmbH | | | |
| Testing location/ address: | Angerstraße 11, D-86807 Buchloe, Germany | | | | |
| Associated CB Testing Laboratory: | | | | | |
| Testing location/ address: | | | | | |
| Tested by (name + signature): | Alexander Mayr | for bleck | | | |
| Approved by (name + signature): | Janez Vidmar | Jan Nik | | | |
| | 4 | / | | | |
| Testing procedure: TMP/CTF Stage 1: | | | | | |
| Testing location/ address: | | | | | |
| Tested by (name + signature): | | | | | |
| Approved by (name + signature): | | | | | |
| | | | | | |
| Testing procedure: WMT/CTF Stage 2: | | | | | |
| Testing location/ address: | | | | | |
| Tested by (name + signature): | | | | | |
| Witnessed by (name + signature): | | | | | |
| Approved by (name + signature): | | | | | |
| Testing procedure: SMT/CTF Stage 3 or 4: | | | | | |
| Testing location/ address: | | | | | |
| Tested by (name + signature): | | | | | |
| Witnessed by (name + signature): | | | | | |
| Approved by (name + signature): | | | | | |
| Supervised by (name + signature): | | | | | |
| | | | | | |



List of Attachments (including a total number of pages in each attachment): 1. Test Report (171 pages) 2. National Differences to IEC 60601-1: 2005 + AM1: 2012 – Enclosure No. 1 (10 pages) Photo documentation – Enclosure No. 2 (7 pages) 4. Schematics, layouts and transformer drawings - Enclosure No. 3 (43 pages) Summary of testing Tests performed (name of test and test clause): **Testing location:** 4.11 Power Input Initial report p to report Rev. No. 1.0 5.7 Humidity treatment SIQ Ljubljana, Tržaška c. 2, 7.1.3 Durability of marking SI-1000 Ljubljana, Slovenia 8.4.3 ME equipment intended to be connected to a power source by a plug 8.5.4 Working voltage Measurement Report Rev. No. 2.0 8.6.4 Impedance and current- carrying capability of protective earth SIQ Testing and Certification connections GmbH, 8.7.4.5 Earth Leakage Current Angerstarße 11, D-86807 Buchloe, Germany 8.7.4.6 Touch Current 8.8.3 Dielectric Strength test of solid insulation materials with safety functions 8.9.4 Measurement of creepage distances and air clearances 11.1 Excessive temperatures in ME EQUIPMENT 13.2 Single Fault conditions 15.5.1.2 Transformer short circuit 15.5.1.3 Transformer overload 15.5.2 Transformer dielectric strength after humidity preconditioning of 5.7 Evaluation of voltage limiting components in SELV circuits Summary of compliance with National Differences List of countries addressed: Austria**, Canada*, France*, Slovenia*, Sweden**, Switzerland*, Turkey*, United Kingdom**, USA* as listed in online CB-Bulletin. * National differences according to IEC 60601-1: 2005 declared. ** EU group differences The product fulfils the requirements of EN 60601-1: 2006 + A1: 2013 + A12: 2014



















| GENERAL INFORMATION | |
|--|---|
| Test item particulars (see also Clause 6): | |
| Classification of installation and use | EUT is intended for building-in. |
| Device type (component/sub-assembly/ equipment/ system): | Component (power supply unit intended for building-in). |
| Intended use (Including type of patient, application location) : | EUT is intended to provide power to medical devices with isolation grade MOOP |
| Mode of operation: | Continuous |
| Supply connection | Not directly connected to the mains. EUT is intended for building-in. |
| Accessories and detachable parts included: | No accessories and detachable parts included |
| Other options include: | No other options included |
| Testing | |
| Date of receipt of test item(s): | 2010-06-30 2017-03-24 Rev. No. 2.0 |
| Dates tests performed: | From 2010-06-30 to 2010-12-15 2017-03-27 Rev. No. 2.0 |
| 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 (collateral standards only) |
| - test object does not meet the requirement: | Fail (F) |
| Abbreviations used in the report: | |
| - normal condition N.C. | - single fault condition: S.F.C. |
| - means of Operator protection | - 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 \boxtimes comma / \square point is used as the decimal separator.

This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3rd edition + AM1. The Risk Management was excluded from the investigation; this shall be clearly identified in this report and on the accompanying CB Test Certificate.

Additional test data and/or information may be provided in the attachments to this report.

| Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012 | | | | | | | | |
|---|---|--|--|--|--|--|--|--|
| The application for obtaining a CB Test Certificate | ⊠ Yes | | | | | | | |
| 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 | ☐ Not applicable | | | | | | | |
| When differences exist; they shall be identified in th | ne General product information section. | | | | | | | |
| Name and address of factory (ies): | GlobTek, Inc. Corporate Headquarters, 186 Veterans Dr Northvale, NJ 07647, USA | | | | | | | |
| | Globtek (Suzhou) Co. Ltd. Building 4, # 76, Jin Ling East Rd., Suzhou Park, Suzhou, Jiangsu CN-215021, China | | | | | | | |
| General product information: | | | | | | | | |
| Model Differences: | | | | | | | | |
| The power supply is a switch mode power supply for b active power factor correction. Factory configurable ou have built in EMI filter, there is also remote output sen | ouilding in. The unit has universal input (AC or DC) with utput is from 12 V to 55 V in 0,1 V increments. The unit sing options. | | | | | | | |
| Unit is provided as open frame power supply or as pove supply unit can be provided with or without PE (Protect | wer supply unit with performed enclosure. Power tive Earthing). | | | | | | | |
| Perforated enclosure with PE: Bottom metal plate is co separated from primary circuit by basic insulation. Fas protective earthing. PCB is connected to metal bottom secondary side). Primary screws provide protective ea | onnected to protective earthing. Bottom metal plate is ton blade terminal used for connection of the plate by four screws (2 on primary side and 2 on orthing of the bottom metal plate. Additional insulation | | | | | | | |

Perforated enclosure without PE: The following capacitors shall be removed from the equipment (CY1, CY2, CY3, CY4, CY5, CY6 and CY7). Connecting wire between internal primary parts (marked with "B") shall be also removed from the equipment. Metal bottom plate is separated from primary circuit by reinforced insulation; there is also reinforced insulation between primary and secondary circuit. Additional insulation foil provided between PCB and bottom metal plate not protectively earthed.

foil provided between PCB and bottom metal plate.



Open-frame power supply unit with PE: Faston blade terminal used for connection of the protective earthing. PCB shall be secured within the end product by four screws. Spacers provided between PCB of the power supply unit and end product plate (length of 10 mm). Shorten than 10,0 mm spacers are allowed when a plastic insulator, 0,4 mm minimum thickness and with dielectric withstand voltage rating of 4000 Vac minimum, is provided between the bottom side of the power supply unit and the system plate or chassis. End product consideration.

Open-frame power supply unit without PE: PCB shall be secured within the end product by four screws. Spacers provided between PCB of the power supply unit and end product plate (length of 10 mm). Shorten than 10,0 mm spacers are allowed when a plastic insulator, 0,4 mm minimum thickness and with dielectric withstand voltage rating of 4000 Vac minimum, is provided between the bottom side of the power supply unit and the system plate or chassis. End product consideration.

In the unit, there is single output plus fan voltage for 20 CFM airflow (External Fan is optional used).

Explanation of the test program:

1) The products were tested to be suitable for connection to 20A (USA and IEC) branch circuit The unit is approved for TN mains star connections and IT mains with 230 Vac phase to phase voltages. The unit provides internally two fuses (F1, F2). For DC input, end user must provide DC rated fuse on the (+) side of the input. Fuse rating is 3 A / 350 Vdc.

2) Power supply unit was evaluated only for Means of Operator Protection (not evaluated for Means of Patient Protection).

a) Power supply unit provided with protective earth:

- 2 x MOOP between primary and secondary circuit of the power supply unit

- 1 x MOOP between primary and protective earth

b) Power supply unit provided without protective earth (see note 6 for details):

- 2 x MOOP between primary and secondary circuit

- 2 x MOOP between primary and external metal plate not protectively earthed

3) All secondary output circuits are separated from mains by reinforced insulation and rated SELV. The outputs provide hazard energy level, therefore accessibility of the output should be considered in the end use product.

4) Safety Instructions: Built in product, safety instructions are end product considerations.

5) The input and output terminals and connectors are evaluated for factory wiring.

6) The power supply is rated as class I (provided with PE) or as power supply unit without PE (class II construction). For power supply unit without PE capacitors CY1, CY2, CY3, CY4, CY5, CY6, CY7 and connecting wire marked as "B" shall be removed from the equipment. There is reinforced insulation between screws on the primary side and primary side of the power supply unit (after removal of above mentioned elements).

7) Power supply (provided with protective earthing) shall be properly bonded to the main protective bonding termination in the end product. The earth leakage current is below 3,5 mA.

8) Power supply shall be provided as open-frame power supply unit or power supply unit with perforated enclosure.

9) The transformer T1 provides reinforced insulation. This transformer is built up to fulfil the requirement of insulation class B and provide in addition an UR (OBJY2) insulation system (See also list of safety critical components).

10) The equipment has been evaluated for use in a Pollution Degree 2 and overvoltage category II environment and a maximum altitude of 2000 m.



11) A suitable Electrical and Fire enclosure shall be provided in the end equipment.

12) Approval within the end product: Leakage current measurement should be verified with the unit built into the end product.

13) The product with 50% output power was evaluated for a maximum ambient temperature of 70°C for AC input voltage with 20 CFM airflow cooling. The product with 50% output power was evaluated for a maximum ambient temperature of 55°C for DC input voltage with 20 CFM airflow cooling. The product with 50% output power was evaluated for a maximum ambient temperature of 55°C for AC input voltage with air convention cooling. The product with 50% output power was evaluated for a maximum ambient temperature of 55°C for AC input voltage with air convention cooling. The product with 50% output power was evaluated for a maximum ambient temperature of 50°C for DC input voltage with air convention cooling. The product with 100% output power was evaluated for a maximum ambient temperature of 40°C for AC and DC input voltage with air convention cooling. The temperature test was performed 100 mm above bench. See next page for air flow direction.

14) Touch current measured on the output terminal exceeded the limit for touch leakage current. Power supply unit is intended for building and when installed within the end medical product, output terminals shall not be accessible from the outside without use of a tool.

15) Power supply unit is rated also for DC input voltage (130-320 Vdc according to different safety standards). End product medical device shall not be rated for more than 250 Vdc. Power supply unit is intended for building-in and not intended for direct connection to the mains.







| | History Sheet: | | | | | | | | |
|-----------------|-----------------|---|-----|--|--|--|--|--|--|
| Date | Report No. | Rev. No. | | | | | | | |
| 2011-05-05 | T223-0012/11 | Initial report issued. | - | | | | | | |
| 2013-05-14 | T223-0205/13 | Test Report re-write to new TRF used for power supply units (TRF No. IEC60601_1G_PS). | 1.0 | | | | | | |
| | | After review, no additional tests were considered necessary. | | | | | | | |
| See first page. | See first page. | Test report was updated to IEC 60601 1:2005 (Third Edition) + A1:2012 | 2.0 | | | | | | |
| | | After review, the followings tests were considered necessary: | | | | | | | |
| | | - 8.7 Leakage current measurements | | | | | | | |
| | | No modification of the products. | | | | | | | |

Technical Considerations:

1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:

- Clause 7.5 (Safety Signs),
- Clause 7.9 (Accompanying Documents),
- Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- Clause 10 (Radiation),
- Clause 14 (PEMS),
- Clause 16 (ME Systems)
- Risk Management was excluded from this investigation.

2. Risk Controls/ Engineering Considerations for component power supply:

For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the following:

• For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.

• For Power Supplies with No RM: End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Optocoupler U3, U4, U5, Y-Capacitor CY8

• For Power Supplies with No RM: End product Risk Management Process to consider the need for simultaneous fault condition testing.

• For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.

• For Power Supplies with No RM with Exposure Condition outside of Humidity Range: Power Supply tested with standard humidity procedure. End product Risk Management Process to determine risk acceptability criteria.

• For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.



• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.

• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.

• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.

• For Power Supplies with No RM and Not tested with Test Corner: Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.

• For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.

• For Power Supplies with No RM or Units with Liquids: End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.

• For Power Supplies with No RM or Units with Indicators: End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.

• For Power Supplies with No RM or Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply

• For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply

• For Power Supplies with Thermal Cut-off and No RM: End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply

| SI® | | | Report No. T | 221-0013/17 | |
|--------|--------------------|--|-----------------|-------------|---------|
| | | | | | |
| Clause | Requirement + Test | | Result - Remark | | Verdict |

INSULATION DIAGRAM

Block diagram for power supply units with PE:



Block diagram for power supply units without PE:



| SI® | Page 17 of 233 | Report No. T | 221-0013/17 |
|--------|--------------------|-----------------|-------------|
| | IEC 60601-1 | | |
| Clause | Requirement + Test | Result - Remark | Verdict |

| TABLE: INSULATION DIAGRAM | | | | | | | | | | | |
|---|-------------------------|------|------------------|-----------------|-------------------|--------------------------|-------------------|--------------------|---|--|--|
| Pollution degree PD 2 | | | | | | | | | | | |
| Overv | oltage category | , | | : OVC | II | | | | | | |
| Altitude Up to 2.000 meters | | | | | | | | | | | |
| Additional details on parts considered as applied parts Image: Considered as applied parts Image: Considered as applied parts | | | | | | | _ | | | | |
| Area | Number and type of | СТІ | Wo vo | rking Itage | Required creepage | Require d | Measure d | Measure d | Remarks | | |
| | Means of Protection: | | V _{rms} | V _{pk} | (mm) | clearanc e (mm) | creepag e (mm) | clearanc e (mm) | | | |
| | MOOP, MOPP | | | | | - () | - () | - () | | | |
| | | Р | ower su | pply unit | with proted | tive earthi | ng (PE) | | | | |
| A | 1xMOOP | IIIb | 240 | 340 | 2,5 | 2,5 2,0 3,7 3,7 F | | | Primary to primary before fuse (for 240 Vac) | | |
| A | 1xMOOP | IIIb | 320 Vdc | 320 Vdc | 3,2 | 3,2 2,0 3,7 3,7 | | | | | |
| В | | IIIb | 240 | 340 | Short circu | Short circuit performed. | | | | | |
| В | | IIIb | 320 Vdc | 320 Vdc | Short circu | it performe | d. | | Primary to primary after fuse (for 320 Vdc) | | |
| С | 1xMOOP | IIIb | 240 | 340 | 2,5 | 2,0 | 4,0 | 2,5 | Primary to earth (for 240 Vac) | | |
| С | 1xMOOP | IIIb | 320 Vdc | 320 Vdc | 3,4 | 2,0 | 4,0 | 2,5 | Primary to earth (for 320 Vdc) | | |
| E | | IIIb | | | Short circu | Short circuit performed. | | | | | |
| E | | IIIb | | | Short circu | Short circuit performed. | | | | | |
| F | | IIIb | | | Short circu | it performe | d. | | Secondary to secondary (for 240 Vac) | | |

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| | IEC 60601-1 | | | | | | | | | | | |
|-------|---|-----|------|----------------|------------|-------------|-------------|---------|------|--|--|--|
| Claus | ause Requirement + Test Result - Remark | | | | | | | Verdict | | | | |
| F | | | IIIb | | | Short circu | it performe | d. | | Secondary to secondary (for 320 Vdc) | | |
| D1 | 2xM0 | JOP | IIIb | 240 (230,3) | 392 | 5,0 | 4,0 | 10,7 | 10,7 | Primary to secondary in transformer T1 (for 240 Vac) | | |
| D1 | 2xM0 | OOP | IIIb | 325 | 544 | 6,8 | 6,4 | 10,7 | 10,7 | Primary to secondary in transformer T1 (for 320 Vdc) | | |
| D2 | 2xM0 | OOP | IIIb | 240 (230,3) | 392 | 5,0 | 4,0 | 9,8 | 8,5 | Primary to secondary in transformer T1 (for 240 Vac) | | |
| D2 | 2xM0 | JOP | IIIb | 325 | 544 | 6,8 | 6,4 | 9,8 | 8,5 | Primary to secondary in transformer T1 (for 320 Vdc) | | |
| D3 | 2xM0 | JOP | IIIb | 240 (216,3) | 400 | 5,0 | 4,0 | 7,4 | 7,4 | Primary to secondary on PCB near Optical insulators (for 240 Vac) | | |
| D3 | 2xM0 | OOP | IIIb | 362 | 384 | 7,4 | 6,4 | 7,4 | 7,4 | Primary to secondary on PCB near Optical insulators (for 320 Vdc) | | |
| D4 | 2xM0 | JOP | IIIb | 240 (230,3) | 392 | 5,0 | 4,0 | 9,8 | 6,9 | Primary to secondary on PCB (for 240 Vac) | | |
| D4 | 2xM0 | JOP | IIIb | 325 | 544 | 6,8 | 6,4 | 9,8 | 6,9 | Primary to secondary on PCB (for 320 Vdc) | | |
| | | | F | Power su | upply unit | without pr | otective ea | arthing | | | | |
| A | 1xM0 | JOP | IIIb | 240 | 340 | 2,5 | 2,0 | 3,7 | 3,7 | Primary to primary before fuse (for 240 Vac) | | |

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| | IEC 60601-1 | | | | | | | | | | | |
|---------------------------|-------------|-----|------|----------------|---------|--------------------------|--------------------------|--------|----------|------|--|--|
| Clause Requirement + Test | | | | | | | | Result | - Remark | | Verdict | |
| A | 1xMC | OP | IIIb | 320 Vdc | 320 Vdc | 3,2 | 2,0 | | 3,7 | 3,7 | Primary to primary before fuse (for 320 Vdc) | |
| В | | | IIIb | 240 | 340 | Short circu | Short circuit performed. | | | | Primary to primary after fuse (for 240 Vac) | |
| В | | | IIIb | 320 Vdc | 320 Vdc | Short circu | Short circuit performed. | | | | Primary to primary after fuse (for 320 Vdc) | |
| F | | | IIIb | | | Short circu | Short circuit performed. | | | | Secondary to secondary (for 240 Vac) | |
| F | | | IIIb | | | Short circuit performed. | | | | | Secondary to secondary (for 320 Vdc) | |
| D1 | 2xMC | OP | IIIb | 240 (230,3) | 392 | 5,0 | 4,0 | | 10,7 | 10,7 | Primary to secondary in transformer T1 (for 240 Vac) | |
| D1 | 2xMC | OP | IIIb | 325 | 544 | 6,8 | 6,4 | | 10,7 | 10,7 | Primary to secondary in transformer T1 (for 320 Vdc) | |
| D2 | 2xMC | OP | IIIb | 240 (230,3) | 392 | 5,0 | 4,0 | | 9,8 | 8,5 | Primary to secondary in transformer T1 (for 240 Vac) | |
| D2 | 2xMC | OP | IIIb | 325 | 544 | 6,8 | 6,4 | | 9,8 | 8,5 | Primary to secondary in transformer T1 (for 320 Vdc) | |
| D3 | 2xMC |)OP | IIIb | 240 (216,3) | 400 | 5,0 | 4,0 | | 7,4 | 7,4 | Primary to secondary on PCB near Optical insulators (for 240 Vac) | |
| D3 | 2xMC |)OP | IIIb | 362 | 384 | 7,4 | 6,4 | | 7,4 | 7,4 | Primary to secondary on PCB near Optical insulators (for 320 Vdc) | |

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| | IEC 60601-1 | | | | | | | | | | | | |
|-------|-------------|----------|------------|----------------|---------|-----|-----|-----------------|-----|-----|--|--|--|
| Claus | e | Requiren | nent + Tes | t | | | | Result - Remark | | | Verdict | | |
| D4 | 2xM0 | OOP | IIIb | 240 (230,3) | 392 | 5,0 | 4,0 |) | 9,8 | 6,9 | Primary to secondary on PCB (for 240 Vac) | | |
| D4 | 2xM0 | OOP | IIIb | 325 | 544 | 6,8 | 6,4 | ŀ | 9,8 | 6,9 | Primary to secondary on PCB (for 320 Vdc) | | |
| E | 2xM0 | DOP | IIIb | 240 | 340 | 5,0 | 4,0 |) | 7,0 | 4,0 | Primary to primary mounting tracks (connected to enclosure) For 240 Vac) | | |
| E | 2xM0 | DOP | IIIb | 320 Vdc | 320 Vdc | 6,8 | 4,0 |) | 7,0 | 4,0 | Primary to primary mounting tracks (connected to enclosure) For 320 Vdc) | | |

Supplementary Information:

Required creepage distances were interpolated.

() means, that maximum rated input voltage was applied, but the measured value is mentioned in brackets.

For Power Supply Unit without protective earthing (PE) the following elements shall be removed from the equipment: CY1, CY2, CY3, CY4, CY5, CY6, CY7 and connecting wire between internal primary parts (marked with "B"). Additional slots (width of 1,2 mm) provided in place of CY1, CY5, CY6 and CY7 to achieve required creepage distance between primary and primary mounting tracks (connected to 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.

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Clause

Requirement + Test

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Result - Remark

Verdict

| 4 | GENERAL REQUIREMENTS | | Р |
|-----|---|--|-----|
| 4.1 | Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse | | Р |
| 4.2 | RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS | RM is not included for component power supply, the acceptability of risk of the power supply is determined as part of the end product. | N/A |
| 4.3 | Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS. | RM is not included for component power supply, the acceptability of risk of the power supply is determined as part of the end product. | N/A |
| 4.4 | EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE: | RM is not included for component power supply, the expected service life and acceptability of risk of the power supply are determined as part of the end product. | 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 are comparable to the RESIDUAL RISKS resulting from requirements of this standard | RM is not included, no alternative means of addressing particular risks were considered | 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 | RM is not included in the investigation of component power supply | N/A |
| 4.7 | ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2: | RM is not included; component power supply remained Single Fault Safe, acceptability of risk to be determined as part of the end product. | N/A |
| | | Short circuit or open circuit of relevant single components performed. See Table 13.2: Single fault conditions in accordance with 13.2.2 to 13.2.13, inclusive. | |
| | Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically | See Appended Table 13.2 for simulated physical test. | Ρ |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|---|--|---------|
| | 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 | Short circuit or open circuit of relevant single components performed. See Table 13.2: Single fault conditions in accordance with 13.2.2 to 13.2.13, inclusive. | Ρ |
| 4.8 | All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified : | All components are suitable and used within their rating. See appended table 8.10. | N/A |
| | Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS | | N/A |
| | Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following | | Ρ |
| | a) Applicable safety requirements of a relevant IEC or ISO standard | Approved critical components used. | Ρ |
| | b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard | | Р |
| 4.9 | A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK | RM not included; components were identified where single fault could cause a hazard as High-Integrity Component. End product to determine the suitability of the component to prevent unacceptable Risk. | 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 | RM not included; components were identified where single fault could cause a hazard as High-Integrity Component. End product to determine the suitability of the component to prevent unacceptable Risk. | N/A |
| 4.10 | Power supply | | Р |
| 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 | Power supply unit is intended for building-in. Not directly connected to the mains. Separate power supply unit not specified by the manufacturer. | Ρ |
| 4.10.2 | Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS: | | Р |
| | - 250 V for hand-held me equipment (V) | Not hand-held ME Equipment. | N/A |
| | - 250 V d.c. or single-phase a.c., or 500 V poly- phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input \leq 4 kVA (V) | 100-240 Vac | Р |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|--|--|---------|
| | – 500 V for all other ME EQUIPMENT and ME SYSTEMS | | N/A |
| 4.11 | Power input | | Р |
| | Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10% | See appended Table 4.11 | Ρ |
| | - 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 | See appended Table 4.11 | Ρ |
| | Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of relevant voltage range | | N/A |
| | Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage: | See appended Table 4.11 Power input expressed in Watt. | N/A |

| 5 | GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT | | Р |
|-----|--|---|-----|
| 5.1 | TYPE TESTS determined in consideration of Clause 4, in particular 4.2 | | Р |
| | Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods | RM not provided: All test were conducted | N/A |
| | RISK MANAGEMENT FILE identified combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION. | RM not included: End product Risk Management must determine the need for simultaneous fault tests. | 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 | Type test performed on multiple samples. | Ρ |
| 5.3 | a) Tests conducted within the environmental conditions specified in technical description | | Р |
| | Temperature (°C), Relative Humidity (%): | 0-70°C (derated output power from 40°C to 70°C) | _ |
| | | 0-90% non-condensing | |
| | Atmospheric Pressure (kPa): | The unit was evaluated for use up to 2.000 meters altitude. | _ |
| | | Atmospheric pressure not specified by the manufacturer. | |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|--|---|---------|
| | b) ME EQUIPMENT shielded from other influences that might affect the validity of tests | No other influences | Р |
| | c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained | Temperature tests. | Ρ |
| 5.4 | a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use | See Appended RM Results Table 5.4a | Р |
| | b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favourable for the relevant test per instructions for use | No adjustable or controlled operating values provided. | 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 | | N/A |
| | d) Potable water used for cooling | No such cooling provided. | N/A |
| 5.5 | a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V) | | Р |
| | b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz) | 50-60 Hz | Р |
| | c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current | Supply voltage: a) 100-240 Vac b) 130-320 Vdc | Ρ |
| | d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered: | Shall be determined as part of the end product. Unit provided with non- reversible plug. | N/A |
| | e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions | | N/A |
| | f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use | | N/A |
| 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 | Considered. | Ρ |
| | Alternatively, upon repair and modification of the sample, only the relevant tests conducted | Considered. | Р |

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|-------------|--|--|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 5.7 | ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3 | RM not provided, end product Risk Analysis to determine whether or not additional testing should be considered Complete power supply unit was subject to standard humidity preconditioning treatment. | N/A |
| | 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 (relative humidity 93%±3%) and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 48 h for units rated IPX0 | | Ρ |
| | - For units rated higher than IPX0 test time extended to 168 h. | | N/A |
| 5.8 | Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent influencing results of any subsequent test | Considered. | Р |
| 5.9 | Determination of APPLIED PARTS and ACCESSIBLE PARTS | ARTS | N/A |
| 5.9.1 | APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS | See clause 4.6 Remark | N/A |
| 5.9.2 | ACCESSIBLE PARTS | | N/A |
| 5.9.2.1 | Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position | See Appended Table 5.9.2 Power supply unit is intended for building-in. | N/A |
| | | Shall be evaluated during end medical product approval. | |
| | Openings preventing entry of test finger of Fig. 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N | | N/A |
| | When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening | | N/A |
| 5.9.2.2 | Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s | | N/A |

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|---------|---|-------------------------|-------------|
| | IEC 60601-1 | | |
| Clause | Requirement + Test | Result - Remark | Verdict |
| | All additional parts that became accessible checked using standard test finger and by inspection | | N/A |
| 5.9.2.3 | Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS | No actuating mechanism. | N/A |
| | Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL.: | No actuating mechanism. | N/A |

| 6 | CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS | | Р |
|-----|--|--|-----|
| 6.2 | CLASS I ME EQUIPMENT, externally powered | Power supply unit can be classified as Class I equipment (provided with protective earthing). | Ρ |
| | | See summary of testing for details. | |
| | CLASS II ME EQUIPMENT, externally powered | Power supply unit can be classified as Class II equipment (provided without protective earthing). | Ρ |
| | | See summary of testing for details. | |
| | INTERNALLY POWERED ME EQUIPMENT | Equipment is not internally powered equipment. | N/A |
| | EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements | | N/A |
| | TYPE B APPLIED PART | No applied parts provided. | N/A |
| | TYPE BF APPLIED PART | | N/A |
| | TYPE CF APPLIED PART | | N/A |
| | DEFIBRILLATION-PROOF APPLIED PARTS | | N/A |
| 6.3 | ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN1N2) as per IEC 60529 : | Power supply unit is intended for building-in. | N/A |
| 6.4 | ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use | No such parts. | 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 | Power supply not investigated for OXYGEN RICH ENVIRONMENT | N/A |

| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|--|---|---------|
| 6.6 | CONTINUOUS OF Non-CONTINUOUS OPERATION | The equipment is intended for continuous operation. | Р |

| 7 | ME EQUIPMENT IDENTIFICATION, MARKING, A | ND DOCUMENTS | Р |
|-------|--|--|-----|
| 7.1.2 | Legibility of Markings Test for Markings | See Appended Table 7.1.2 | N/A |
| | specified in Olduse 7.2-7.0 | EUT is intended for building- in; therefore markings are not visible from the outside. | |
| | | Power supply unit can be installed within the medical product by trained personnel (not related to operator). | |
| 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 | | Ρ |
| | a) After tests, adhesive labels didn't loosen up or curl up at edges and markings complied with requirements in Clause 7.1.2 | See appended Tables 7.1.3 and 8.10 | Ρ |
| | b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test : | See appended Tables 7.1.3 and 8.10 | Р |
| 7.2 | Marking on the outside of ME EQUIPMENT or ME EQ | UIPMENT parts | Р |
| 7.2.1 | At least markings in 7.2.2, 7.2.5, 7.2.6 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings | See attached copy of Marking Plate. All required marking are provided on the outer side of the power supply unit. | Ρ |
| | Remaining markings fully recorded in ACCOMPANYING DOCUMENTS: | See above. | N/A |
| | Markings applied to individual packaging when impractical to apply to ME EQUIPMENT | Packaging not part of the investigation. | N/A |
| | A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Single Use Only", "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01) | | N/A |
| 7.2.2 | ME EQUIPMENT marked with: | | Р |
| | – the name or trademark and contact information of the MANUFACTURER | Trademark mentioned on type label. EUT is for building-in and not final ME Equipment. Contact information is part of end medical equipment investigation. | Ρ |
| | - a MODEL OR TYPE REFERENCE | See attached copy of Marking Plate | Р |

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| - a serial number or lot or batch identifier; and See attached Plate - the date of manufacture or use by date See attached Plate Plate Plate | copy of Marking P copy of Marking P |
|--|---|
| - the date of manufacture or use by date See attached Plate | copy of Marking P |
| | |
| Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, orRM not provid Risk Analysis | ed, end product N/A o determine additional be considered |
| Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and | N/A |
| - a MODEL OR TYPE REFERENCE | N/A |
| Software forming part of a PEMS identified with a unique identifier, such as revision level or date of release/issue, and identification are available to designated persons | corporated. N/A |
| 7.2.3Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTSNot relevant fEUT is power intended for b | or the operator. N/A supply unit uilding-in. |
| Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted | N/A |
| 7.2.4 ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and | s provided. N/A |
| - with a MODEL or TYPE REFERENCE | N/A |
| – a serial number or lot or batch identifier | N/A |
| the date of manufacture or use by date | N/A |
| Markings applied to individual packaging when not practical to apply to ACCESSORIES | N/A |
| 7.2.5 ME EQUIPMENT intended to receive power from other electrical equipment in an ME SYSTEM and compliance with the requirements of this standard is dependent on that other equipment, one of the following is provided: | nal N/A to be performed duct |
| 7.2.6 Connection to the Supply Mains | Р |
| Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point | g plate. P of input led on the input terminal: |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|---------|---|---|---------|
| | For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to SUPPLY MAINS connection | EUT is 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 or 130-320 Vdc Markings provided on the marking plate. | Р |
| | Multiple RATED supply voltages or multiple RATED supply voltages are separated by (V/V): | | N/A |
| | – Nature of supply (e.g., No. of phases, except single-phase) and type of current: | | Р |
| | Symbols 1-5, Table D.1 (symbols of IEC 60417- 5032, 5032-1, 5032-2, 5031, and 5033, all 2002-10) used, optionally, for same parameters: | | Р |
| | – RATED supply frequency or RATED frequency range in hertz: | Provided on the marking plate. | Р |
| | – Symbol 9 of Table D.1 (symbol IEC 60417- 5172, 2003-02) used for CLASS II ME EQUIPMENT : | Provided on the marking plate of power supply unit without protective earthing. | Р |
| 7.2.7 | RATED input in amps or volt-amps, (A, VA) : | Rated input expressed in Amperes. | Р |
| | RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) : | Rated input expressed in Amperes. | Р |
| | RATED input for one or more RATED voltage ranges provided for upper and lower limits of the range or ranges when the range(s) is/are greater than ± 10 % of the mean value of specified range (A, VA,W) | Rated input specified for lower and upper voltage range. | Ρ |
| | Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) | | N/A |
| | Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA) | | N/A |
| | Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W): | | N/A |
| 7.2.8 | Output connectors | | Р |
| 7.2.8.1 | See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT | | N/A |
| 7.2.8.2 | Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment | | Р |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|--|--|---------|
| | Rated Voltage (V), Rated Current (A) | Provided on the marking plate. | _ |
| | Rated Power (W), Output Frequency (Hz): | DC output voltage. | _ |
| 7.2.9 | ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for ME EQUIPMENT or parts rated IPX0: | | N/A |
| 7.2.10 | Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6) | No Applied Parts in power supply | N/A |
| 7.2.11 | ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION | No markings provided; therefore power supply unit is intended for continuous operation. | Ρ |
| | DUTY CYCLE for ME EQUIPMENT intended for non- CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time | EUT is designed for continuous operation. | N/A |
| 7.2.12 | Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder | No accessible fusses provided. | N/A |
| | | Power supply unit is intended for building-in. | |
| | Fuse type: | | _ |
| | Voltage (V) and Current (A) rating | | |
| | Operating speed (s) and Breaking capacity: | | — |
| 7.2.13 | A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR: | | N/A |
| | Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use | Component, to be determined as part of end product. | N/A |
| 7.2.14 | HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, 2002-10) | | N/A |
| 7.2.15 | Requirements for cooling provisions marked (e.g., supply of water or air) | Component, to be determined as part of end product. | N/A |
| 7.2.16 | ME EQUIPMENT with limited mechanical stability | Component, to be determined in end-product evaluation. | N/A |
| 7.2.17 | Packaging marked with special handling instructions for transport and/or storage | Component, to be determined as part of end product. | N/A |
| 7.2.18 | RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and | | N/A |

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| 7.2.19 | Symbol 7 of Table D.1 (IEC 60417-5017, 2002-10) marked on FUNCTIONAL EARTH TERMINAL | | 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 | Component, to be determined as part of end product. | N/A |
| | No marking applied when an interlock provided | | N/A |
| 7.3 | Marking on the inside of ME EQUIPMENT OR ME EQUIF | PMENT 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 elements provided. | N/A |
| | A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL | | N/A |
| 7.3.2 | Symbol 24 of Table D.1 (symbol IEC 60417-5036, 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts | No such parts within the equipment. | N/A |
| 7.3.3 | Type of battery and mode of insertion when applicable is marked | No battery 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 | | 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) : | | N/A |
| | An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS: | Component; to be determine in the end-product | N/A |
| 7.3.4 | Fuses, replaceable THERMAL CUT-OUTS and OVER- CURRENT RELEASES, accessible by use of a TOOL | Internal fuse marking is located on PCB adjacent to the fuse. | Р |
| | Identified by specification adjacent to the component, or | | Р |
| | by reference to ACCOMPANYING DOCUMENTS | | N/A |
| | Voltage (V) and Current (A) rating: | See appended table 8.10. | _ |
| | Operating speed(s), size & breaking capacity.: | See appended table 8.10. | _ |
| 7.3.5 | PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1 | Symbol No. 6 provided near protective earth terminal: S/N: RehS000158101/07 NRUT CONNECTOR REV: X G | Ρ |
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| | Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made | | Ρ |
| 7.3.6 | Symbol 7 of Table D.1 (IEC 60417-5017, 2002 -10) marked on FUNCTIONAL EARTH TERMINALS | No functional earthing is provided. | N/A |
| 7.3.7 | Terminals for supply conductors marked adjacent to terminals,: | Input terminals marked with L and N near input terminal: S/N: RoHS000158101/07 REV: X E I I I I | N/A |
| | Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings | | N/A |
| | Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 (Code in IEC 60445) | Not permanently installed equipment. | N/A |
| | Marking for connection to a 3-phase supply, if necessary, complies with IEC 60445 | | N/A |
| | Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made | | Ρ |
| 7.3.8 | "For supply connections, use wiring materials suitable for at least X °C" (where X > than max temperature measured in terminal box or wiring compartment under NORMAL USE), or equivalent, marked at the point of supply connections | | N/A |
| | Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made | | N/A |
| 7.4 | Marking of controls and instruments | | Р |
| 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, 2002-10, and IEC 60417-5008, 2002-10), or | No mains switch provided. Power supply unit is intended for building-in. | N/A |
| | – indicated by an adjacent indicator light, or | A green LED is illuminated when the unit is operating. | Р |
| | - indicated by other unambiguous means | | N/A |
| | The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 2002-10), and | No push-buttons provided. | N/A |
| | status indicated by adjacent indicator light | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | status indicated by other unambiguous means | | N/A |
| | The "on/off" positions of push button switch with momentary on position marked with symbol 15 of Table D.1 (symbol 60417-5011 2002-10), or | | N/A |
| | – status indicated by adjacent indicator light | | N/A |
| | status indicated by other unambiguous means | | N/A |
| 7.4.2 | Different positions of control devices/switches indicated by figures, letters, or other visual means | | N/A |
| | Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE | Component; final determination to be performed in the end-product | N/A |
| | – or an indication of direction in which magnitude of the function changes | | N/A |
| | Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009 (2002-10) (Table D.1, Symbol 29). | No stand-by condition. | N/A |
| 7.4.3 | Numeric indications of parameters on ME EQUIPMENT expressed in SI units according to ISO 80000-1 except the base quantities listed in Table 1 expressed in the indicated units | | N/A |
| | ISO 80000-1 applied for application of SI units, their multiples, and certain other units | | N/A |
| | All Markings in Sub-clause 7.4 complied with tests and criteria of 7.1.2 and 7.1.3 | See Appended Tables 7.1.2 and 7.1.3. | N/A |
| 7.5 | Safety signs | | N/A |
| | Safety sign with established meaning used. | | 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 sign provided. | N/A |
| | Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT | | N/A |
| | Specified colours in ISO 3864-1 used for safety signs: | | N/A |
| 7.6 | Symbols | | Р |
| 7.6.1 | Meanings of symbols used for marking described in instructions for use: | Meaning of symbols described within technical specification provided by the manufacturer. | Ρ |

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| | IEC 60601-1 | | |
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| 7.6.2 | Symbols required by this standard conform to IEC or ISO publication referenced | | Р |
| 7.6.3 | Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable | | N/A |
| 7.7 | Colours of the insulation of conductors | Colours of the insulation of conductors | |
| 7.7.1 | PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation | No internal protective earth conductors provided. | N/A |
| | | EUT is power supply unit intended for building-in. | |
| 7.7.2 | Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations | | N/A |
| 7.7.3 | Green and yellow insulation identify only following conductors: | | N/A |
| | - PROTECTIVE EARTH CONDUCTORS | | N/A |
| | - conductors specified in 7.7.2 | | N/A |
| | - POTENTIAL EQUALIZATION CONDUCTORS | | N/A |
| | - FUNCTIONAL EARTH CONDUCTORS | | N/A |
| 7.7.4 | Neutral conductors of POWER SUPPLY CORDS are "light blue" specified in IEC 60227-1 or IEC 60245-1 | No power supply cord is used. | N/A |
| 7.7.5 | Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1 | No power supply cord is used. | N/A |
| 7.8 | Indicator lights and controls | | Р |
| 7.8.1 | Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required) | No red indicator light provided. | N/A |
| | Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required) | No yellow indicator light provided. | N/A |
| | Green indicator lights mean: Ready for use | A green LED is illuminated when the unit is operating. | Р |
| | Other colours, if used: Meaning other than red, yellow, or green (colour, meaning) | No other colours used. | N/A |
| 7.8.2 | Red used only for emergency control | | N/A |
| 7.9 | ACCOMPANYING DOCUMENTS | Component, to be determined in end-product evaluation. | N/A |

| 8 | PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT | | Р |
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| 8.1 | Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL OR SINGLE FAULT CONDITIONS | | Ρ |

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| | NORMAL CONDITION considered as simultaneous occurrence of situations identified in 8.1a) | | Р |
| | SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b) : | The following needs to be considered in the end product: - interruption of any one power-carrying conductor - unintended movement of a component - accidental detachment of conductors and connectors | N/A |
| | ACCESSIBLE PARTS determined according to 5.9 | | Р |
| | LEAKAGE CURRENTS measured according to 8.7 | | Р |
| 8.2 | Requirements related to power sources | | N/A |
| 8.2.1 | Connection to a separate power source | | N/A |
| | When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM | Not specified. | N/A |
| | Tests performed with ME EQUIPMENT connected to separate power supply when one specified | | N/A |
| | When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined | | N/A |
| 8.2.2 | No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source | Component, to be determined in end-product evaluation | N/A |
| | ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE | Component, to be determined in end-product evaluation | N/A |
| | Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset | Component, to be determined in end-product evaluation | N/A |
| 8.3 | Classification of APPLIED PARTS | No Applied Parts | N/A |
| 8.4 | Limitation of voltage, current or energy | | Р |
| 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 such patient connections provided. | N/A |
| 8.4.2 | ACCESSIBLE PARTS and APPLIED PARTS | | Р |

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| Clause | Requirement + Test | Result - Remark | Verdict | |
| | b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA): | See appended Table 8.7 EUT is intended for building- in. Measurements performed only for reference. Shall be evaluated during end medical product approval. | Ρ | |
| | 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 | The likelihood of the current flowing through body of OPERATOR to be determined in end-product evaluation | N/A | |
| | accessible contacts of connectors | | N/A | |
| | contacts of fuseholders accessible during replacement of fuse | | N/A | |
| | contacts of lampholders accessible after removal of lamp | | N/A | |
| | - parts inside an ACCESS COVER that can be opened without a TOOL, or where a TOOL is needed but the instructions for use instruct an OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER | | N/A | |
| | Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.): | See appended Table 8.4.2 | Ρ | |
| | 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 appended Table 8.4.2 | Ρ | |
| | Energy did not exceed 240 VA for longer than 60 s or stored energy available did not exceed 20 J at a potential of 2 V or more (VA or J): | See appended Table 8.4.2 | Р | |
| | 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 appended Table 8.4.2 | N/A | |
| | d) Voltage and energy limits specified in c) above also applied to the following: | | 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 | EUT is intended for building- in. | N/A | |
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| | - internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by the RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL | | N/A |
| | Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N | | N/A |
| | Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N | | N/A |
| | Test repeated with a TOOL specified in instructions for use | | N/A |
| | Test rod freely and vertically suspended through openings on top of ENCLOSURE | | N/A |
| | e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION | | N/A |
| | A TOOL is required when it is possible to prevent the devices from operating | | N/A |
| 8.4.3 | Worst case voltage between pins of plug and between either supply pin and ENCLOSURE did not exceed 60 V one sec after disconnecting the plug of ME EQUIPMENT or its parts (V) : | See appended Table 8.4.3 Test performed only for reference. EUT is intended for building- in. | Ρ |
| | When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 μC : | | 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: | See appended Table 8.4.4 | N/A |
| | A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL | | N/A |
| | Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, 2002-10), and manual discharging device specified in technical description | | N/A |
| 8.5 | Separation of parts | | Р |
| 8.5.1 | MEANS OF PROTECTION (MOP) | | Р |

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| 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 | Two means of operator protection (2 x MOOP) provided between primary and secondary circuit. | Ρ |
| | | protection (1 x MOOP) provided between primary circuit and protective earth. | |
| | 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 | Protection categorized as operator protection. | Р |
| | Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION | | N/A |
| | Components and wiring forming a MEANS OF PROTECTION comply with 8.10 | | Р |
| | 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. | Ρ |
| 8.5.1.2 | MEANS OF PATIENT PROTECTION (MOPP) | EUT not categorized as patient protection. | N/A |
| | Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6 | | N/A |
| | CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12 | | N/A |
| | PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6 | | N/A |
| | A Y (Y1 or Y2) capacitor complying with IEC 60384-14 considered one MEANS OF PATIENT PROTECTION | See Appended Tables 8.8.3 and 8.10 | N/A |
| | Single Y1 capacitor used for two MEANS OF PATIENT PROTECTION when the working voltage is less than 42,4 V peak a.c. or 60 V d.c | See Appended Tables 8.8.3 and 8.10 | N/A |
| | Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance | | N/A |
| | Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF): | | — |
| 8.5.1.3 | MEANS OF OPERATOR PROTECTION (MOOP) | | Р |
| | Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with: | | Р |

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| | dielectric strength test of 8.8 at test voltage of Table 6; or | | Р |
| | – requirements of IEC 60950-1 for INSULATION CO-ORDINATION | | N/A |
| | CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with: | | Р |
| | - limits of Tables 13 to 16 (inclusive); or | | Р |
| | - requirements of IEC 60950-1 for INSULATION CO-ORDINATION | | N/A |
| | PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6 | | Р |
| | – or with requirements and tests of IEC 60950-1 for protective earthing | See Attachment # | N/A |
| | A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION | See Appended Tables 8.8.3 and 8.10 | Р |
| | | Approved Y2 capacitor provided between primary and protective earth. | |
| | A Y1 (IEC 60384-14) capacitor is considered two MEANS OF OPERATOR PROTECTION | See Appended Tables 8.8.3 and 8.10 | Р |
| | | Approved Y1 capacitor provided between primary and secondary circuit. | |
| | Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance | Single capacitor used. | N/A |
| | Voltage $_{Total \; Working}$ (V) and C $_{Nominal}$ (µF) : | | |
| | 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 | Approved components used (high integrity components). | N/A |
| | A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION | | N/A |
| | A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION : | | Р |
| 8.5.2 | Separation of PATIENT CONNECTIONS | No PATIENT CONNECTIONS | N/A |
| 8.5.3 | MAXIMUM MAINS VOLTAGE | | Р |
| | - 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 mains voltage: 240 Vac or 320 Vdc. EUT is not intended for direct connection to the mains. | Ρ |

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| | When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V | | N/A |
| | – MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for poly-phase ME EQUIPMENT (V) | Single phase equipment. | N/A |
| | – for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V | Not internally powered equipment. | N/A |
| 8.5.4 | WORKING VOLTAGE | | Р |
| | – Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V): | Input voltage: 240 Vac or 320 Vdc. | Р |
| | - WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V) | | N/A |
| | - WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) | See Insulation Diagram and Insulation Table | Ρ |
| 8.5.5 | DEFIBRILLATION-PROOF APPLIED PARTS | No DEFIBRILLATION-PROOF APPLIED PARTS | N/A |
| 8.6 | Protective and functional earthing and potential | equalization of ME EQUIPMENT | Р |
| 8.6.1 | Requirements of 8.6.2 to 8.6.8 applied | | Р |
| | Parts complying with IEC 60950-1 for protective earthing and serving as MEANS OF OPERATOR PROTECTION but not PATIENT PROTECTION exempted from requirements of 8.6.2 to 8.6.8 | | N/A |
| 8.6.2 | PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR | Earth quick connector used for connection of protective earth conductor. EUT is intended for building- in. | Ρ |
| | ME EQUIPMENT (V) Not internally powered equipment. - for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V Not internally powered equipment. :4 WORKING VOLTAGE - Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V): Input voltage: 240 Vac or 320 Vdc. - WORKING VOLTAGE for d.c. voltages with peak-to-peak ripple less than 10% of average value or peak voltage walue (V) - - WORKING VOLTAGE for each MEANS OF PROTECTION forming DUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V) See Insulation Diagram and Insulation Table .5 DEFIBRILLATION-PROOF APPLIED PARTS No DEFIBRILLATION-PROOF APPLIED PARTS .6 Protective and functional earthing and potential equalization of ME EQUIPMENT - .1 Requirements of 8.6.2 to 8.6.8 applied - Parts complying with IEC 60950-1 for protective earthing and serving as MEANS Or OPERATOR 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 in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD SO COMPINY to 8.1.4.3, and Cannot be loosened without TOOL Supply conductors are no fixed. EUT is intended for building- in. End produc | N/A | |
| | Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside: | EUT is intended for building- in. End product consideration. | N/A |
| | Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as | | N/A |

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| Clause 8.6.3 8.6.4 8.6.5 8.6.6 | Requirement + Test | Result - Remark | Verdict |
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| | PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing | | Ρ |
| 8.6.3 | PROTECTIVE EARTH CONNECTION not used for a moving part | Final determination in the end- product | N/A |
| 8.6.4 | a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop | See appended Table 8.6.4 | Ρ |
| | b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits | See appended Table 8.6.4 & Clause 8.7 | N/A |
| 8.6.5 | Surface coatings | | N/A |
| | Poorly conducting surface coatings on conductive elements removed at the point of contact | | N/A |
| | Coating not removed when requirements for impedance and current-carrying capacity met | | N/A |
| 8.6.6 | Plugs and sockets | | N/A |
| | PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections | | N/A |
| | - applied also where interchangeable parts are PROTECTIVELY EARTHED | | N/A |
| 8.6.7 | Terminal for connection of a POTENTIAL EQUALIZATION | | N/A |
| | Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE | No potential equalization terminal provided. | N/A |
| | -accidental disconnection avoided in NORMAL USE | | N/A |
| | Terminal allows conductor to be detached without a TOOL | | N/A |
| | - Terminal not used for a PROTECTIVE EARTH CONNECTION | | N/A |
| | Terminal marked with symbol 8 of Table D.1 | | N/A |
| | Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard | | N/A |
| | Power SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR | | N/A |
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| Clause | Requirement + Test | Result - Remark | Verdict |
| 8.6.8 | FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION | | N/A |
| 8.6.9 | Class II ME EQUIPMENT | | N/A |
| | Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow | No power supply cord provided. EUT is intended for building- in. | N/A |
| | ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth. | | N/A |
| | Two MEANS OF PROTECTION provided between insulation of internal screens and all internal wiring connected to them and ACCESSIBLE PARTS | | N/A |
| 8.7 | LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT | rs | Р |
| 8.7.1 | a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3 | See appended Tables 8.7 | Р |
| | 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 | Ρ |
| 8.7.2 | Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except | | Ρ |
| | – where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b) | Impedance of protective earth connections not exceeded. | N/A |
| | the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time | Considered. | Р |
| | – LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION | | N/A |
| | SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE ON APPLIED PARTS and non- PROTECTIVELY EARTHED parts of ENCLOSURE | | N/A |
| 8.7.3 | Allowable Values | | Р |
| | a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b.: | See appended Table 8.7 Leakage current meter with frequency characteristics as specified on Fig. 12 b) used. | Ρ |

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| Clause | Requirement + Test | Result - Remark | Verdict |
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| | b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz | See appended Table 8.7 No applied parts provided. | 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}) | See appended Table 8.7 | Ρ |
| | d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION (I _{ENC} , I _{ESFC}): | See appended Tables 8.7 | Р |
| | Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 | See appended Table 8.7 EUT 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 | Maximum measured value with non-frequency weighted device was 0,32 mA. Revision No. 2.0 | Ρ |
| | f) LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non- PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION | No functional earth conductor provided. | N/A |
| 8.7.4 | LEAKAGE and PATIENT AUXILIARY CURRENTS measurements | See appended Table 8.7 | Р |
| 8.8 | Insulation | | Р |
| 8.8.1 | Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing | | Р |
| | Insulation exempted from test (complies with clause 4.8) | | N/A |
| | Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8 | | N/A |
| 8.8.2 | Distance through solid insulation or use of thin | sheet material | Р |
| | Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with: | | Р |
| | a) 0.4 mm, min, distance through insulation, or | Approved optocoupler between primary and secondary provided. | Р |
| | b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of: | | Р |
| | – at least two layers of material, each passed the appropriate dielectric strength test: | See appended Table 8.8.3 | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | – or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test : | See appended Table 8.8.3 Approved triple insulation wire on primary side used to achieve reinforced insulation between primary and secondary. | Ρ |
| | | Additionally one layer of insulation tape provided between primary and secondary windings. | |
| | Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION | Transformer tape. | Ρ |
| | Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION | Transformer tape. | Ρ |
| | BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when | | Ρ |
| | c) Wire with solid insulation, other than solvent based enamel, complying with a) | | N/A |
| | d) Wire with multi-layer extruded or spirally wrapped insulation complying with b) and complying with Annex L | | N/A |
| | e) Finished wire with spirally wrapped or multi- layer extruded insulation, complying with Annex L | | N/A |
| | BASIC INSULATION: minimum two wrapped layers or one extruded layer | | N/A |
| | – SUPPLEMENTARY INSULATION: minimum two layers, wrapped or extruded | | N/A |
| | – REINFORCED INSULATION: minimum three layers, wrapped or extruded | | N/A |
| | In d) and e), for spirally wrapped insulation with CREEPAGE DISTANCES between layers less than in Table 12 or 16 (Pollution Degree 1) depending on type of insulation, path between layers sealed as a cemented joint in 8.9.3.3 and test voltages of TYPE TESTS in L.3 equal 1.6 times of normal values | | N/A |
| | Protection against mechanical stress provided where two insulated wires or one bare and one insulated wire are in contact inside wound component, crossing at an angle between 45° and 90° and subject to winding tension | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | Finished component complied with routine dielectric strength tests of 8.8.3: | See appended Table 8.8.3 | N/A |
| | Tests of Annex L not repeated since material data sheets confirm compliance | See Table 8.10 and Material Information Attachment | N/A |
| 8.8.3 | Dielectric Strength | | Р |
| | Solid insulating materials with a safety function withstood dielectric strength test voltages: | See appended Table 8.8.3 | Ρ |
| 3.8.4 | Insulation other than wire insulation | | Р |
| 8.8.4.1 | Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT | | Р |
| | ME EQUIPMENT and design documentation examined: | EUT is intended for building- in. | N/A |
| | | Satisfactory evidence of compliance provided. | |
| | | See list of critical components for details. | |
| | RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests | Final determination in the end- product | N/A |
| | Satisfactory evidence of compliance provided by manufacturer for resistance to heat | Manufacturer is using approved materials with adequate temperature characteristics. | Ρ |
| | | No additional test was considered required. | |
| | Tests conducted in absence of satisfactory evidence for resistance to heat: | | N/A |
| | a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus: | See Table 8.8.4.1 | N/A |
| | b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C \pm 2 ° C or ambient indicated in technical description \pm 2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C) | See Table 8.8.4.1 | N/A |
| | Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION | No such parts provided. | N/A |
| 8.8.4.2 | Resistance to environmental stress | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
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| | 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 | EUT is intended for building- in. | N/A |
| | Ceramic and similar materials not tightly sintered, and beads alone not used as SUPPLEMENTARY OR REINFORCED INSULATION | No such materials used for insulation. | N/A |
| | Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION | | N/A |
| | Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 MPa ± 70 kPa, with an effective capacity of at least 10 times volume of samples | Rubber not used for insulation. | N/A |
| | There were no cracks visible to naked eyes after samples kept in cylinder at 70 °C ± 2 °C for 96h, and afterwards, left at room temperature for at least 16h | | N/A |
| 8.9 | CREEPAGE DISTANCES and AIR CLEARANCES | | Р |
| 8.9.1.1 | CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 12 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15 | | Р |
| | - Insulation between parts of opposite polarity of the MAINS PART on the supply mains side of any mains fuse or OVER-CURRENT RELEASE, one MEANS OF OPERATOR PROTECTION are ≥ to values in Table 13, Table 14 and Table 16 | | Ρ |
| 8.9.1.2 | Tables 12 to 16 (inclusive) not applied toCREEPAGE and CLEARANCES forming MEANS OFOPERATOR PROTECTION per IEC 60950-1 forINSULATION CO-ORDINATION and used underconditions compliance was tested | Tables 12 to 16 (inclusive) applied. | 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 insulation material. | N/A |
| 8.9.1.4 | When min CREEPAGE derived from Tables 12 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE | Considered. | Ρ |
| 8.9.1.5 | ME EQUIPMENT RATED to operate at an altitude of 2000 m | EUT was evaluated for use up to 2.000 meters. | Р |
| | ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m) | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
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| | 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 | | N/A |
| | CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE | | N/A |
| 8.9.1.6 | When WORKING VOLTAGE was between those in Tables 12 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows: | | Р |
| | - CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm) | See Insulation Diagram/Table. Considered. | Ρ |
| | - 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) | See Insulation Diagram/Table. No such voltages obtained during normal use of the equipment. | 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 | No such voltages obtained during normal use of the equipment. | N/A |
| 8.9.1.7 | Material groups classified in accordance with Table 9 (Material Group) | See Insulation Diagram/Table. | Р |
| | Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112 | | N/A |
| | Material of unknown group considered IIIb | Material group IIIb considered. | Р |
| 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 | Equipment was evaluated for use within pollution degree 2 environmental. | Ρ |
| | Pollution degree 3: Micro-environment subject to conductive pollution, or dry non- conductive pollution that could become conductive due to expected condensation | | N/A |
| | - Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions | | N/A |
| | Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION | | N/A |
| | Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | Means employed according to Annex M to reduce the pollution degree: | No means employed of reduction of the pollution degree of internal environment through the use of additional protection. | 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 | | Ρ |
| | V _{MT} Peak (V): | 2500 | — |
| | V _{MN} r.m.s (V): | 300 | - |
| 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 | Considered. | Ρ |
| 8.9.1.11 | SUPPLY MAINS overvoltage category II applied according to IEC 60664-1 | | Ρ |
| | For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used | | N/A |
| | When PATIENT protection (Table 12) is required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for CI. 8.9 used | No applied parts provided. | N/A |
| 8.9.1.12 | A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15) | | N/A |
| | Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT | | N/A |
| | Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS | | N/A |
| | Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I | | N/A |
| | Table 15 column for circuits not subject to transient over-voltages applied to: | | N/A |
| | d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and | | N/A |
| | - circuits in INTERNALLY POWERED ME EQUIPMENT | EUT is not internally powered equipment. | N/A |

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N/A

| Clause | Requirement + Test | Result - Remark | Verdict |
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| 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: | No such voltages under normal use of the equipment. | N/A |
| | – CLEARANCE was at least 5 mm | | N/A |
| | - insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or | | N/A |
| | – a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and | | N/A |
| | CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I | | 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 | | 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 | Considered. | Ρ |
| 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 parts 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 described in 13.1 for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied | See appended Table 8.9.2 Sufficient creepage and clearance distances provided between parts of opposite polarity before mains fuses. Short circuit performed after primary fuses. | Ρ |
| | b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths | No hazardous situation. Considered. | Р |
| | c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by moulding, or there is no reduction of a distance below specified value by deformation or movement of parts | | Р |
| | Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE | Considered. | Р |

8.9.3

Spaces filled by insulating compound

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| Clause | Requirement + Test | Result - Remark | Verdict |
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| 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 | Approved optocoupler between primary and secondary provided. No other parts filled with insulation compound. | N/A |
| | Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted | | N/A |
| 8.9.3.2 | For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6 | See appended Table 8.9.3.2 | N/A |
| | Cracks or voids in insulating compound affecting homogeneity of material didn't occur | | N/A |
| 8.9.3.3 | Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint | | N/A |
| | A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows: | | N/A |
| | - One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage | See appended Table 8.9.3.4 | N/A |
| | - The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage | | N/A |
| 8.9.3.4 | One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times: | See appended Table 8.9.3.4 | N/A |
| 8.10 | Components and wiring | | Р |
| 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 | All components mounted securely. | N/A |
| 8.10.2 | Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION: | Conductors and connections adequately secured. | N/A |

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| | Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION described in 13.1 | | Ρ |
| | Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION | Considered. | Р |
| | Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS described in 13.1 due to poor contact | | Ρ |
| 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 test finger: | No flexible cords provided. | N/A |
| 8.10.4 | Cord-connected HAND-HELD parts and cord-connected evices | ected foot-operated control | N/A |
| 8.10.4.1 | Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION | No cord-connected hand-held parts and cord-connected foot- operated control device provided. | N/A |
| | d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple | | N/A |
| | 42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit | | N/A |
| 8.10.4.2 | Connection and anchorage at both ends 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 described in 13.1 | | 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 described in 13.1 | | N/A |
| 8.10.5 | Mechanical protection of wiring | | N/A |
| | a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION described in 13.1 | No moving parts provided. | 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 described in 13.1 | No access cover. EUT is intended for building- in. | N/A |

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Clause

8.10.6

Requirement + Test

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Result - Remark Verdict Guiding rollers of insulated conductors prevent --bending of movable insulated conductors around a radius of less than five times the N/A outer diameter of the lead concerned in NORMAL

| 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 | See appended Table 8.10 No insulation sleeve used. | N/A |
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| | b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics | | N/A |
| | c) Insulated conductors 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 | See appended Table 8.10 | N/A |
| 8.11 | MAINS PARTS, components and layout | | Р |
| 8.11.1 | a) ME EQUIPMENT provided with means of | See appended Table 8.10 | N/A |
| | electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles | EUT is intended for building- in. | |
| | | End product consideration. | |
| | 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) | EUT is not permanently installed equipment. | N/A |
| | PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position if reconnection would result in a HAZARDOUS SITUATION or | EUT is not permanently installed equipment. | N/A |
| | any OPERATOR including SERVICE PERSONNEL is unable to view the means of isolation from their intended position | | N/A |
| | The locking mechanism by the RESPONSIBLE ORGANIZATION, and | | N/A |
| | - the isolation device specified in the ACCOMPANYING DOCUMENTS | | N/A |
| | b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description | | 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 | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead | | N/A |
| | e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447 | | N/A |
| | f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS switch to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a) | | N/A |
| | g) A fuse or a semiconductor device not used as an isolating means | | N/A |
| | 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 | | N/A |
| | i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering | | N/A |
| | A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient) | | N/A |
| | For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause | | N/A |
| | Standard test finger of Fig 6 applied | | N/A |
| 8.11.2 | MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2 | No MULTIPLE SOCKET-OUTLETS provided. | 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 | No power supply cord provided. EUT is intended for building- | N/A |
| | | in. | |
| 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 appended Table 8.10 | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|----------|--|---------------------------|---------|
| | 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 appended Table 8.10 | N/A |
| 8.11.3.3 | NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 (mm ² Cu) | | 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 appended Table 8.10 | N/A |
| 8.11.3.5 | Cord anchorage (for APPLIANCE COUPLERS not cor | nplying with IEC 60320-1) | N/A |
| | a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage | | N/A |
| | b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4: | | N/A |
| | – insulating material, or | | N/A |
| | - metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or | | N/A |
| | - metal provided with an insulating lining affixed to cord anchorage, except when it is a flexible bushing forming part of the cord guard in 8.11.3.6, and complying with the requirements for one MEANS OF PROTECTION | | N/A |
| | c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation | | N/A |
| | d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components other than parts of cord anchorage | | N/A |
| | e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals when cord anchorage fails | | N/A |
| | f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
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| | 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 appended Table 8.11.3.5 | N/A |
| | Cord subjected to a torque in Table 18 for 1 min immediately after pull tests | | N/A |
| | Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position | | N/A |
| | CREEPAGE and CLEARANCES not reduced below limits in 8.9 | | N/A |
| | It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged | | 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 | | N/A |
| | Cord guard complied with test of IEC 60335- 1:2001, Clause 25.14, or | | N/A |
| | ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x D ² gram attached to the free end of cord (g) : | See appended Table 8.11.3.6 | N/A |
| | Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance | | N/A |
| | Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D : | See appended Table 8.11.3.6 | 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 | EUT is intended for building- in. Not directly connected to the mains. | N/A |
| | | End product consideration. | |
| | Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away | | N/A |
| | Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors | | N/A |

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| Result - Remark | Verdict |
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| Clause | Requirement + Test | Result - Remark | Verdict |
|----------|--|---|---------|
| | Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors | | N/A |
| 8.11.4.2 | Arrangement of MAINS TERMINAL DEVICES | | N/A |
| | a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection | | N/A |
| | b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6 | | N/A |
| | c) Marking of MAINS TERMINAL DEVICES complied with 7.3 | | N/A |
| | d) MAINS TERMINAL DEVICES not accessible without use of a TOOL | | N/A |
| | e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction | | N/A |
| 8.11.4.3 | Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times | | N/A |
| 8.11.4.4 | Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by test of 8.11.3.4 | | N/A |
| 8.11.4.5 | Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors, and covers fitted without damage to conductors or their insulation | | N/A |
| | Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test | | N/A |
| 8.11.5 | Mains fuses and OVER-CURRENT RELEASES | | Р |
| | A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection per clause 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT: | See appended Table 8.10 and Appended RM Results Table 8.11.5 Primary fuses provided in both supply leads. | Ρ |
| | - neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT | Not permanently installed equipment. | N/A |

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| IEC 60601-1 | | | |
|-------------|---|---|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Effect of short-circuit fault conditions in other circuits VERIFIED before eliminating fuses or OVER-CURRENT RELEASES | Fuses or over-current releases are not eliminated. | N/A |
| | Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit | See appended Table 8.10 | Р |
| | A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR | Not provided. | Р |
| | Fuses complying with IEC 60127 have high breaking capacity (1 500 A) and prospective short-circuit current > 35 A or 10 times current | Approved primary fuses incorporated within the equipment. | N/A |
| | rating of the fuse, whichever is greater | EUT is intended for building- in. | |
| | | EUT is not intended for direct connection to the mains. | |
| | | There was no damage of primary fuses during short- circuits testing; therefore those fuses are acceptable. | |
| 8.11.6 | Internal wiring of the MAINS PART | | Р |
| | a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices is not less than minimum required for POWER SUPPLY CORD as in clause 8.11.3.3 (mm ² Cu) | Only PCB tracks used. | N/A |
| | b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents: | See appended Table 8.10 | Ρ |
| | 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 | | N/A |

| 9 | PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS | | Р |
|-----|--|--|-----|
| 9.1 | ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3) | | Ρ |
| 9.2 | HAZARDS associated with moving parts | Final determination in the end product. | N/A |
| 9.3 | Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage | Final determination in the end product. | N/A |
| | avoided or covered: | No rough surfaces, no sharp corners and no sharp edges. | |
| | | EUT is intended for building-in. | |

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|-------------|---|--|-------------------------|--|
| IEC 60601-1 | | | | |
| Clause | Requirement + Test | Result - Remark | Verdict | |
| 9.4 | Instability HAZARDS | Component, to be determined as part of end product | N/A | |
| 9.5 | Expelled parts HAZARD | No such parts | N/A | |
| 9.6 | Acoustic energy (including infra- and ultrasound) and vibration | Component, to be determined as part of end product | N/A | |
| 9.7 | Pressure vessels and parts subject to pneumatic and hydraulic pressure | No such parts | N/A | |
| 9.8 | HAZARDS associated with support systems | Component, to be determined in the end product. | N/A | |

| 10 | PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS | | N/A |
|----|---|--|-----|
| | X-Radiation | Not applicable to component power supply | N/A |

| 11 | PROTECTION AGAINST EXCESSIVE TEMPERAT | TURES AND OTHER | Р |
|--------|---|--|-----|
| 11.1 | Excessive temperatures in ME EQUIPMENT | | Р |
| 11.1.1 | Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T | See appended Table 11.1.1 and appended RM Results Table 11.1.1 | Ρ |
| | Surfaces of test corner did not exceed 90 °C | Test corner not used. | N/A |
| | | EUT is intended for building-in. | |
| | THERMAL CUT-OUTS did not operate in NORMAL CONDITION | Not operated. | Р |
| 11.1.2 | Temperature of APPLIED PARTS | No such parts | N/A |
| 11.1.3 | Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE | See appended Table 11.1.3 Acceptability of obtained values to be determined in the end product. | N/A |
| | | Temperature measurements performed. | |
| | Test corner not used where engineering | Test corner not used. | N/A |
| | indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE | EUT is power supply unit intended for building-in. | |
| 11.1.4 | GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL | No such guards. | N/A |
| 11.2 | Fire prevention | | N/A |
| 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 | EUT is component without enclosure intended for building-in. | N/A |

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| | IEC 60601-1 | | |
|--------|---|--|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 11.2.2 | Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS | Component, not evaluated for use with Oxygen Rich Environment | N/A |
| 11.2.3 | SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered | Component, not evaluated for use with Oxygen Rich Environment | N/A |
| 11.3 | Constructional requirements for fire ENCLOSURES | S OF ME EQUIPMENT | N/A |
| | ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2 | Final determination to be competed in the end product EUT is intended for building-in. | N/A |
| | | Power supply unit is provided without external fire enclosure. | |
| | Constructional requirements were met, or | | N/A |
| | a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials | See appended Table 8.10 | N/A |
| | Flammability classification of connectors, printed circuit boards, and insulating material on which components are mounted is FV-2, or better, based on IEC 60695-11-10 as decided by examination of materials data | See appended Table 8.10 | N/A |
| | If no FV Certification, FV tests based on IEC 60695-11-10 conducted on 3 samples of complete parts (or sections of it), including area with min. thickness, ventilation openings | | N/A |
| | b) Fire ENCLOSURE met following: | | N/A |
| | 1) No openings at bottom or, as specified in Fig 39, constructed with baffles as in Fig 38, or made of perforated metal as in Table 25, or a metal screen with a mesh ≤ 2 × 2 mm centre to centre and wire diameter of at least 0.45 mm | | N/A |
| | 2) No openings on the sides within the area included within the inclined line C in Fig 39 | | N/A |
| | 3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials, except constructions based on Table 25 and a mesh; FV-2 or better for TRANSPORTABLE ME EQUIPMENT, FV-1 or better for fixed EQUIPMENT, or STATIONARY EQUIPMENT per IEC 60695-11-10, determined by ENCLOSURE examination or flammability classification based on 11.3a): | See appended Table 8.10 | N/A |
| 11.4 | ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics | Not evaluated for use in the presence of flammable anaesthetics. | N/A |
| 11.5 | ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents | Not evaluated for use in the presence of flammable agent. | N/A |

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|--------|---|---|------------|
| | 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 | Final determination to be competed in the end product. | N/A |
| 11.6.5 | Ingress of water or particulate matter into ME EQ | UIPMENT and ME SYSTEMS | N/A |
| | ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and | Final determination to be competed in the end product | N/A |
| | subjected to tests of IEC 60529 (IP Code): | competed in the end product EUT is intended for buildingin. It is provided without external enclosure. | |
| | | It is provided without external enclosure. | |
| | ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE IN NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION: | See appended Tables 8.7 8.8.3 | 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 | Component, to be determined in end-product evaluation. | N/A |
| 11.8 | Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE | Component, to be determined in end-product evaluation. | N/A |
| | | | |

| 12 | ACCURACY OF CONTROLS AND INSTRUMENTS AGAINST HAZARDOUS OUTPUTS | S AND PROTECTION | N/A |
|------|--|---|-----|
| 12.1 | RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review: | Not applicable to component power supply Power supply unit is intended for building-in. No such controls and instruments provided. | N/A |
| | PROTECTION AGAINST HAZARDOUS OUTPUT | Not applicable to component power supply. | N/A |

| 13 | HAZARDOUS SITUATIONS AND FAULT CONDITIONS | | Р |
|--------|---|--|---|
| 13.1 | Specific HAZARDOUS SITUATIONS | | Р |
| 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 | | Ρ |
| 13.1.2 | .2 Emissions, deformation of ENCLOSURE or exceeding maximum temperature | | Р |
| | Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur | Not occur during single fault testing. | Р |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|--|--|---------|
| | – Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur | Power supply unit is provided without external enclosure and it is intended for building-in. | 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, 11.1.2.1, and 11.1.2.2 No applied parts provided. | N/A |
| | -Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded | | Р |
| | Limits for windings in Tables 26, 27, and 31 not exceeded | | Р |
| | Table 22 not exceeded in all other cases | | Р |
| | Temperatures measured according to 11.1.3 | | Р |
| | SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where: | | N/A |
| | Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION | See appended Table 13.1.2 | N/A |
| | or secondary circuits mounted on materials with a minimum flame rating of FV1, and | | N/A |
| | - Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and | | N/A |
| | - Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and | | N/A |
| | - Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide | | N/A |
| | - or components in the circuit have HIGH INTEGRITY CHARACTERISTICS | | N/A |
| | or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation | | N/A |
| | After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function | | N/A |
| 13.1.3 | – limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed: | See appended Table 8.7 | Р |
| | - voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed | See appended Table 8.7 Output voltage of the power | Ρ |
| | | | |

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|---|---|--|---------|
| 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 | Component, to be determined in end product evaluation. | N/A |
| 13. 2 | SINGLE FAULT CONDITIONS | | Р |
| 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 | Ρ |
| 13.2.2 – 13.2.12 | ME EQUIPMENT complied with 13.2.2 -13.2.12: | See appended Table 13.2 Final determination to be competed in the end product. | Р |
| 13.2.13 | ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to within 3 °C of the temperature in the test environment | | Ρ |
| | ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted | | Р |
| 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 tes of 13.2.13.2 to 13.2.13.4 (inclusive). | 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 | Approved capacitors and optocouplers connected between primary and secondary. | N/A |
| | of 13.2.13.2 to 13.2.13.4 (inclusive). | between primary and protective earth. | |
| | | Approved transformer bobbin provided within the transformer. | |
| | | No additional test was considered required. | |
| 13.2.13.2 | ME EQUIPMENT with heating elements | No Heating Elements provided | N/A |
| 13.2.13.3 | ME EQUIPMENT with motors | No motors provided in power supply | N/A |
| 13.2.13.4 | ME EQUIPMENT RATED FOR NON-CONTINUOUS OPERATION | DN | N/A |
| | ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated | EUT is rated for continuous operation. | N/A |
| | When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle | | N/A |
| | Motor winding temperatures did not exceed values in 13.2.10: | | N/A |
| | Insulation Class: | | _ |
| | Maximum temperature measured (°C): | | _ |
| | | | |

| 14 | PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) | N/A |
|----|--|-----|
|----|--|-----|

| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|---|---|---------|
| | | | |
| | Requirements of this clause not applied to power supply | No Such Parts/ PESS not relied upon for Basic Safety or Essential Performance | N/A |

| CONSTRUCTION OF ME EQUIPMENT | | Р |
|---|--|--|
| RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed | Final determination to be competed in the end product | N/A |
| through the application of a USABILITY | EUT is intended for building-in. | |
| 60601-1-6, when applicable: | In addition, green indicator provided to indicate power on. | |
| 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 | Not expected. | N/A |
| Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with | Power supply unit is intended for building-in. | N/A |
| adjacent parts or wiring | End product consideration. | |
| Mechanical strength | | N/A |
| Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE | | N/A |
| Push test conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular (30mm) plane surface, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable test tool : | See Appended Table 15.3. Final determination to be competed in the end product | N/A |
| No damage resulting in an unacceptable RISK sustained | | N/A |
| Impact test conducted by subjecting a complete ENCLOSURE or its largest non- reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, approx. 50 mm in diameter from a height of 1.3 m | See Appended Table 15.3. Final determination to be competed in the end product | N/A |
| No damage resulting in an unacceptable RISK sustained | | N/A |
| Drop test | | N/A |
| Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm ± 5 mm thick hardwood board lying flat on a concrete or rigid base | See Appended Table 15.3 EUT is power supply unit intended for building-in. | N/A |
| | CONSTRUCTION OF ME EQUIPMENT RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS in accordance with IEC 60601-1-6, when applicable | CONSTRUCTION OF ME EQUIPMENT RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABLITY ENGINEERING PROCESS in accordance with IEC 60601-1-6, when applicable Final determination to be competed in the end product EUT is intended for building-in. In addition, green indicator provided to indicate power on. 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, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring Not expected. Mechanical strength Power supply unit is intended for building-in. End product consideration. Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE See Appended Table 15.3. Final determination to be competed in the end product Push test conducted by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular (30mm) plane surface, except bottom of ENCLOSURE of an ME EQUIPMENT ARe, using a suitable test tool: See Appended Table 15.3. Final determination to be competed in the end product No damage resulting in an unacceptable Risk sustained Impact test conducted by subjecting a complete ENCLOSURE or its largest non- reinforced area, except for HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD ME EQUIPMENT, |

Clause

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Verdict

| Requirement + Test | Result - Remark | |
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| | No unacceptable RISK resulted | | N/A |
|----------|---|--|-----|
| 15.3.4.2 | Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 \pm 5 mm thick hardwood board lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE (cm) | See Appended Table 15.3. Final determination to be competed in the end product | N/A |
| | No damage resulting in an unacceptable RISK sustained | | N/A |
| 15.3.5 | Rough handling tests for MOBILE ME EQUIPMENT | | N/A |
| 15.3.6 | Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK | Power supply unit is intended for building-in. It is provided without external enclosure. | N/A |
| | Mould-stress relief test conducted by placing one sample of complete ME EQUIPMENT, ENCLOSURE or a portion of larger ENCLOSURE, for 7 hours in a circulating air oven at 10°C over the max temperature measured on ENCLOSURE in 11.1.3, but no less than 70 °C | | N/A |
| | No damage resulting in an unacceptable RISK | | N/A |
| 15.3.7 | INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT | EUT is power supply unit intended for building-in. | N/A |
| | Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK | Component, to be determined in end product evaluation. | N/A |
| 15.4 | ME EQUIPMENT components and general assembly | y | N/A |
| 15.4.1 | Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular | Final determination to be competed in the end product | N/A |
| 15.4.2 | Temperature and overload control devices | | Р |
| | | | |

| IEC 60601-1 | | | | |
|-------------|---|--|-----|--|
| Clause | Clause Requirement + Test Result - Remark | | | |
| 15.4.2.1 | a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION described in 13.1by resetting action as verified by review of the design documentation and RISK MANAGEMENT FILE | No automatic resetting thermal cut-out or over-current release provided. The unit provides thermo sensors switching off in case of mal function. This sensor is not used in permat mode | N/A | |
| | | Therefore, the sensors are not related to Safety. | | |
| | b) THERMAL CUT-OUTS with a safety function that are reset by a soldering not fitted in ME EQUIPMENT | No such component used. | N/A | |
| | c) An additional independent non-SELF- RESETTING THERMAL CUT-OUT is provided where a failure of a THERMOSTAT could in a HAZARDOUS SITUATION described in 13.1; the temperature of operation of the additional device is outside that attainable at the extreme setting of the normal control device, but within the temperature limit for the ME EQUIPMENT | No thermostat provided. | N/A | |
| | d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION described in 13.1 or the loss of ESSENTIAL PERFORMANCE | Final determination to be competed in the end product No thermal cut-out or over current release provided. | N/A | |
| | e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS | | N/A | |
| | f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following tests: | | N/A | |
| | Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17 as applicable | | Ρ | |
| | ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13 | See appended Table 13.2 | Ρ | |
| | SELF-RESETTING THERMAL CUT-OUTS and OVER- CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified according to appropriate standards | | N/A | |
| | In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) operated 200 times | | N/A | |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|----------|--|---|---------|
| | Manual reset THERMAL CUT-OUTS and OVER- CURRENT RELEASES Certified in accordance with appropriate IEC standards | Approved primary fuses incorporated within the power supply unit. | Р |
| | When certification based on IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety- related function is not available, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times | | N/A |
| | Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted | | N/A |
| | g) Protective device, provided on ME EQUIPMENT incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating | Not applicable to component power supply | 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: | Not applicable to component power supply | N/A |
| 15.4.2.2 | Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS | Not applicable to component power supply | N/A |
| 15.4.3 | Batteries | | N/A |
| 15.4.3.1 | Battery housings from which gases can escape during charging or discharging are ventilated to prevent unacceptable RISK from accumulation of gasses and possible ignition : | No battery incorporated. | N/A |
| | Battery compartments designed to prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as described in clause 13.1 | | 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 | Final determination to be competed in the end product | 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 | Final determination to be competed in the end product | N/A |
| 15.4.3.4 | Primary lithium batteries comply with IEC 80086-4 | Final determination to be competed in the end product | N/A |
| | Secondary lithium batteries comply with IEC 62133 | Final determination to be competed in the end product | N/A |

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| | IEC 60601-1 | | |
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| Clause | Requirement + Test | Result - Remark | Verdict |
| 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 : | Final determination to be competed in the end product | N/A |
| | Protective device has adequate breaking capacity to interrupt the maximum fault current | | N/A |
| | Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented | | N/A |
| | Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPs provided, or | | N/A |
| | Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION described in clause 13.1 | | 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 | Final determination to be competed in the end product EUT is intended for building-in. In addition, green indicator provided to indicate power on. | 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 | | 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 | | N/A |
| | Requirement not applied to heated stylus-pens for recording purposes | | N/A |
| | Indicator lights provided on ME EQUIPMENT to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION | A green LED is illuminated when the unit is power on. | Ρ |
| | Colours of indicator lights complied with 7.8.1 | | Р |
| | Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE | No charging mode provided. | N/A |
| 15.4.5 | Pre-set controls | No such parts in power supply | N/A |
| 15.4.6 | Actuating parts of controls of ME EQUIPMENT | No such parts in power supply | N/A |
| 15.4.7 | Cord-connected HAND-HELD and foot-operated control devices | No such parts in power supply | N/A |

| IEC 60601-1 | | | |
|-------------|--|---|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 15.4.8 | Aluminium wires less than 16 mm ² in cross- sectional area are not used | | N/A |
| 15.4.9 | Oil container in PORTABLE ME EQUIPMENT | No such parts in power supply | N/A |
| 15.5 | MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and separation in accordance with 8.5 | transformers providing | Р |
| 15.5.1 | Overheating | | Р |
| 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 | Ρ |
| | During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31 | | Ρ |
| | Dielectric strength test of 8.8.3 conducted on | See appended Table 15.5.2 | N/A |
| | transformer after short circuit and overload tests: | Switch mode transformer incorporated within the equipment. | |
| | | Dielectric strength test according to Clause 8.8.3 performed. | |
| 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 | Ρ |
| | Short circuit applied directly across output windings for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2 a) or 2x frequency and 2x voltage test of 15.5.2 b) | Short circuit performed on transformer output windings. | Ρ |
| 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: | See appended Table 15.5.1.3 | Ρ |
| 15.5.2 | Transformers operating at a frequency above 1 kHz tested in accordance with clause 8.8.3: | Switch mode transformer provided; therefore this test not relevant. | N/A |
| | Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION | | N/A |
| | Dielectric strength tests were conducted in accordance with requirements of this clause with no breakdown of insulation system and no detectable deterioration of transformer: | See appended Table 15.5.2 | N/A |
| 15.5.3 | Transformers forming MEANS OF PROTECTION as required by 8.5 comply with | See appended Table 8.10 | Р |
| | Means provided to prevent displacement of end turns beyond the inter-winding insulation | - | Р |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|---|-------------------------------------|---------|
| | - protective earth screens with a single turn have insulated overlap not less than 3mm and the width of the screen is at least equal to the axial winding length of the primary side | | N/A |
| | - Exit of wires form internal windings of toroid transformers protected with double sleeving providing 2 MOPs and a total wall thickness of 0.3mm extending 20mm from the windings | No toroid transformer construction. | N/A |
| | - insulation between primary and secondary windings complies with 8.8.2 | | Р |
| | - CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4 and the exceptions of this sub-clause | | Р |

| 16 | ME SYSTEMS | | N/A |
|----|---------------------------|--|-----|
| | Evaluation of ME SYSTEMS: | Component power supply; compliance determined in the end product | N/A |

| 17 | ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS | | |
|----|--|--|-----|
| | RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review.: | Not applicable to component power supply system; to be determined in the end product | N/A |

| ANNEX G | PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES | | |
|---------|--|--|-----|
| | Parts of CATEGORY APG ME EQUIPMENT in which a Not evaluated for use with FLAMMABLE ANESTHETIC MIXTURE WITH AIR OCCURS Flammable Anesthetic Mixture | | N/A |

| ANNEX L | INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION | | N/A |
|---------|--|--|-----|
| L.1 | BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters | | N/A |
| L.2 | Wire construction | | N/A |
| | Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component | | N/A |
| | Layers of spirally wrapped wire insulation are sufficiently secured to maintain the overlap | | N/A |
| L.3 | Type Test | | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|---|-----------------|---------|
| | The wire subjected to tests of L.3.1 to L.3.4 at a temperature and a relative humidity specified | | N/A |
| | Temperature (°C) | | _ |
| | Humidity (%): | | — |
| L.3.1 | Dielectric strength | · | N/A |
| | Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with test voltages at least twice Tables 6 & 7, but not less than below with no breakdown: | | N/A |
| | - 3000 V for BASIC and SUPPLEMENTARY | | N/A |
| | -6000 V for PEINEOPCED INSULATION (V) | | Ν/Δ |
| 32 | Elevibility and adherence | | N/A |
| L.U.2 | Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1 | | N/A |
| | Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown | | N/A |
| | Test voltage was at least the voltage in Tables 6 and 7but not less than the following: | | N/A |
| | – 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) | | N/A |
| | - 3000 V for REINFORCED INSULATION (V) | | N/A |
| | Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa | | N/A |
| 3.3 | Heat Shock | 1 | 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 | | N/A |
| | Test voltage was at least the voltage in Tables 6 and 7, but not less than the following: | | N/A |
| | - 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) | | N/A |
| | - 3000 V for REINFORCED INSULATION (V) | | N/A |
| | Oven temperature based on Table L.2 (°C): | | _ |
| | Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm ²) | | N/A |

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| IEC 60601-7 | 1 |
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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|---|--|---------|
| | Dielectric strength test conducted at room temperature after removal from the oven | | N/A |
| L.3.4 | Retention of electric strength after bending | | N/A |
| | Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests | | N/A |
| | Test voltage was at least the voltage in Tables 6 and 7, but not less than the following: | | N/A |
| | - 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) | | N/A |
| | - 3000 V for REINFORCED INSULATION (V) | | N/A |
| | Test voltage applied between the shot and conductor. | | N/A |
| | Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm ²) | | N/A |
| L.4 | Tests during manufacture | | N/A |
| L.4.1 | Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3: | See attached manufacturer's routine testing verification | 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: | | N/A |
| | - 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V) | See manufacturer's routine testing verification | N/A |
| | - 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V): | See manufacturer's routine testing verification | N/A |
| L.4.3 | Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1): | See manufacturer's routine testing verification | N/A |
| | Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than: | | N/A |
| | - 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION | See manufacturer's routine testing verification | N/A |
| | - 6000 V r.m.s. or 8400 V peak for REINFORCED | See manufacturer's routine testing verification | N/A |

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| Clause | Requirement + Test | | Result - Remark | | Verdict |

| 4.2.2 | 2 RM RESULTS TABLE: General requirements for RISK MANAGEMENT | | |
|-------|---|-----|--|
| | | | |
| 4.3 | TABLE: ESSENTIAL PERFORMANCE | N/A | |
| | | | |
| 4.5 | RM RESULTS TABLE: Equivalent Safety for ME Equipment of ME System | N/A | |
| | | | |
| 4.6 | RM RESULTS TABLE: ME Equipment or system parts contacting the patient | N/A | |
| | | | |
| 4.7 | RM RESULTS TABLE: Single Fault Condition for ME Equipment | N/A | |
| | | | |
| 4.8 | RM RESULTS TABLE: Components of ME Equipment | N/A | |
| | | | |
| 4.9 | RM RESULTS TABLE: Use of components with high-integrity characteristics | N/A | |

| 4.11 | TABLE: Power Input | | | | | Р | | |
|--|---------------------------|----------------|-------------------|----------------|--------------------|-------------------------|--|--|
| Operat | ting Conditions / Ratings | Voltage (V) | Frequency (Hz) | Current (A) | Power (W or VA) | Power factor (cos φ) | | |
| | GT(M)91110P24055-X.X-F | A(W)-S or -H | HOXXX or -HO | XXX or -HI | XXX (AC input |) | | |
| Rated load 4.36A@55Vdc | | 90 | 50 | 3.1 | 280 | | | |
| Rated load 4.36A@55Vdc | | 100 | 50 | 2.8 | 277 | | | |
| Rated load 4,36A@55Vdc | | 200 | 50 | 1,4 | 269 | | | |
| Rated load 4,36A@55Vdc | | 240 | 50 | 1,1 | 268 | | | |
| Rated load 4.36A@55Vdc | | 264 | 50 | 1.0 | 267 | | | |
| GT(M)91110P24055-X.X-FA(W)-S or -HIOXXX or -HOXXX or -HIXXX (DC input) | | | | | | | | |
| Ra | ted load 4,36A@55Vd | 130 | DC | 2,1 | 273 | | | |
| Rated load 4.36A@55Vd | | 200 | DC | 1,4 | 270 | | | |
| Ra | ted load 4.36A@55Vd | 300 | Dc | 0.9 | 263 | | | |
| Ra | Rated load 4.36A@55Vd | | DC | 0.8 | 262 | | | |
| | GT(M)91110P24012-FA(| W)-S or -HIC | DXXX or -HOX | XX or –HIXX | X (AC input) | | | |
| Ra | ated load 20A@12Vdc | 90 | 50 | 3.2 | 289 | | | |
| Rated load 20A@12Vdc | | 100 | 50 | 2.9 | 286 | | | |
| Rated load 20A@12Vdc | | 200 | 50 | 1,4 | 277 | | | |
| Rated load 20A@12Vdc | | 240 | 50 | 1,2 | 276 | | | |
| Rated load 20A@12Vdc | | 264 | 50 | 1,1 | 275 | | | |
| | GT(M)91110P24012-FA(| W)-S or -HIC | OXXX or -HOX | XX or -HIXX | X (DC input) | | | |
| Rated load 20A@12Vdc | | 130 | DC | 2,2 | 283 | | | |
| Rated load 20A@12Vdc | | 200 | DC | 1,4 | 279 | | | |
| Rated load 20A@12Vdc | | 300 | DC | 0.9 | 275 | | | |
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| IEC 60601-1 | | | | | | |
| Clause | Requirement + Test | Result - Remark | | Verdict | | |

| 4.11 | TABLE: Power Input | | | | | | |
|--------------------------------|--------------------|----------------|-------------------|----------------|--------------------|-------------------------|--|
| Operating Conditions / Ratings | | Voltage (V) | Frequency (Hz) | Current (A) | Power (W or VA) | Power factor (cos φ) | |
| Rat | ted load 20A@12Vdc | 320 | DC | 0.8 | 274 | | |

Supplementary Information:

The steady-state input current did not exceed the rated current at the rated voltage by more than 10% under the maximum normal load.

Rated input current: 4,0-2,0 A (for 100-240 Vac)

Rated input current: 3,0-1,5 A (for 130-320 Vdc)

| 5.1 | RM RESULTS TABLE: Type Tests | | |
|---------------------|--|--|---------|
| Clause of ISO 14971 | Document Ref. in RMFResult - Remarks(Document No. & paragraph) | | Verdict |
| 4.2 | | | |
| 4.3 | | | |
| 4.4 | | | |

| 5.9.2 | TABLE: Determination of ACCESSIBLE parts | | | | |
|----------------------------|--|------------------------------|----------|--|--|
| Location | | Determination method (NOTE1) | Comments | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| Supplementary information: | | | | | |

NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook.

| 7.1.2 | TABLE: Legibility of Marking | | | |
|--------------------------------------|------------------------------|-----------------------------|---------|--|
| Markings tested | | Ambient Illuminance (Ix) | Remarks | |
| Outside Markings (Clause 7.2) | | | | |
| Inside Markings (Clause 7.3) | | | | |
| Controls & Instruments (Clause 7.4): | | | | |
| Safety Signs (Clause 7.5) | | | | |
| Symbols (| Clause 7.6) | | | |

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| Clause | Requirement + Test | | Result - Remark | | Verdict | | |

7.1.2 TABLE: Legibility of Marking

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) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

| 7.1.3 | TABLE: Durability of marking test | | | | |
|--|-----------------------------------|--------------------------------|---------------|-------|--|
| Characteristics of the Marking Label tested: | | | | marks | |
| Material of M | larking Label: | Sticker | See 1) below. | | |
| Ink/other prir | nting material or process: | Laser printing | See 1) below. | | |
| Material (cor | nposition) of Warning Label | No warnings provided. | | | |
| Ink/other prir | nting material or process: | | | | |
| Other | : | Input terminal identification. | See 2) be | elow. | |

Supplementary information:

Marking rubbed by hand, first for 15 s with a cloth rag soaked with distilled water, then for 15 s with a cloth rag soaked with ethanol 96%, and then for 15 s with a cloth rag soaked with isopropyl alcohol.

1) Marking plate provided on the outer enclosure:



POSITION THIS LABEL ON THE VISIBLE SIDE OF CAPACITOR

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| | | IEC 60601-1 | | | |
| Clause | Requirement + Test | | Result - Remark | | Verdict |
| 7.1.3 | TABLE: Durability of ma | rking test | | | Р |
| Characteris | stics of the Marking Label | tested: | | Rem | narks |
| 2) Marking (| provided on the capacitor n | ear input terminal: | | | |
| SERIAL NUME RoHSOC | BER AND DATE CODE | BOM REVISION I | LEVEL | | |

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| Clause | Requirement + Test | | Result - Remark | | Verdict | |

| 7.2.2 | RM RESULTS TABLE: Identification | N/A |
|---------|--|-----|
| | | |
| 7.2.13 | RM RESULTS TABLE: Physiological effects (safety signs and warning) | N/A |
| | | |
| 7.2.17 | RM RESULTS TABLE: Protective packaging | N/A |
| | | |
| 7.3.3 | RM RESULTS TABLE: Batteries | N/A |
| | | |
| 7.3.7 | RM RESULTS TABLE: Supply terminals | N/A |
| | | |
| 7.4.2 | RM RESULTS TABLE: Control devices | N/A |
| | | |
| 7.5 | RM RESULTS TABLE: Safety signs | N/A |
| | | |
| 7.9.2.4 | RM RESULTS TABLE: Electrical power source | N/A |
| | | |
| 7.9.3.2 | RM RESULTS TABLE: Replacement of fuses, power supply cords, other parts | N/A |
| | | |
| 8.1 b | RM RESULTS TABLE: Fundamental rule of protection against electric shock - accidental detachment of conductors and connectors | N/A |

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

| 8.4.2 | TABL | E: TABL | E: TABLE: Working Voltage / Power Measurement | | | | | Р |
|---|-------|-----------|---|-------------------------------------|---------------|---------------|--------------|------|
| Test supply | volta | ge/freque | ncy (V/Hz) | 1 | | : | 240/50 | I |
| Location | n | | | Measured valu | les | | | |
| From/To |) | Vrms | Vpk or Vdc | Peak-to-peak ripple ² | Power W/VA | Energy (J) | Rem | arks |
| | | | Wo | rking voltage of | Transforme | er T1 | | |
| Pin 1 to PE | | 168,6 | 336,0 | | | | Output load: | - |
| Pin 2 to PE | | 170,7 | 352,0 | | | | 4,36A@55V0 | IC |
| Pin 4 to PE | | 234,7 | 392,0 | | | | | |
| Pin 5 to PE | | 220,5 | 392,0 | | | | | |
| Pin 4 to Pin | FL1 | 177,0 | 352,0 | | | | | |
| Pin 4 to Pin | FL2 | 230,3 | 392,0 | | | | | |
| | | | Work | ing voltage of O | ptical insula | tor U3 | | |
| Pin 1 to pin | 3 | 174,1 | 344,0 | | | | Output load: | le. |
| Pin 1 to pin | 4 | 171,9 | 344,0 | | | | 4,36A@55V0 | IC |
| Pin 2 to pin | 3 | 173,0 | 344,0 | | | | | |
| Pin 2 to pin | 4 | 170,6 | 344,0 | | | | | |
| | | | Work | ing voltage of O | ptical insula | tor U4 | | |
| Pin 1 to pin | 3 | 206,6 | 392,0 | | | | Output load: | |
| Pin 1 to pin | 4 | 196,1 | 376,0 | | | | 4,30A@55V0 | |
| Pin 2 to pin | 3 | 216,4 | 400,0 | | | | | |
| Pin 2 to pin | 4 | 205,1 | 384,0 | | | | | |
| | | | Work | ing voltage of O | ptical insula | tor U5 | | |
| Pin 1 to pin | 3 | 169,5 | 336,0 | | | | Output load: | |
| Pin 1 to pin | 4 | 169,4 | 336,0 | | | | 4,36A@55V0 | IC |
| Pin 2 to pin | 3 | 168,0 | 336,0 | | | | | |
| Pin 2 to pin | 4 | 168,1 | 336,0 | | | | | |
| Working voltage of Transformer T1 | | | | | | | | |
| Pin 1 to PE | | 169,4 | 344,0 | | | | Output load: | |
| Pin 2 to PE | | 164,6 | 344,0 | | | | | |
| Pin 4 to PE | | 222,4 | 392,0 | | | | | |
| Pin 5 to PE | | 220,7 | 392,0 | | | | | |
| Pin 4 to Pin | FL1 | 221,7 | 392,0 | | | | | |
| Pin 4 to Pin | FL2 | 202,7 | 376,0 | | | | | |
| Working voltage of Optical insulator U3 | | | | | | | | |

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| | | | | IEC 606 | 01-1 | | | |
| Clause | Require | ement + T | est | | | Result - Remark | (| Verdict |
| 8.4.2 | TABL | E: TABL | E: Working | g Voltage / Powe | er Measu | urement | | Р |
| Pin 1 to pir | n 3 | 168,7 | 336,0 | | | | Output load: | |
| Pin 1 to pir | า 4 | 166,6 | 336,0 | | | | 20A@12Vdc | |
| Pin 2 to pir | n 3 | 168,2 | 336,0 | | | | | |
| Pin 2 to pir | า 4 | 166,0 | 336,0 | | | | | |
| | | | Work | ing voltage of O | ptical in | sulator U4 | | |
| Pin 1 to pir | n 3 | 171,0 | 336,0 | | | | Output load: | |
| Pin 1 to pir | า 4 | 161,7 | 328,0 | | | | - 20A@12Vdc | |
| Pin 2 to pir | n 3 | 170,8 | 336,0 | | | | | |
| Pin 2 to pir | า 4 | 162,2 | 328,0 | | | | | |
| | | | Work | ing voltage of O | ptical in | sulator U5 | | |
| Pin 1 to pir | n 3 | 163,9 | 328,0 | | | | Output load: | |
| Pin 1 to pir | า 4 | 164,3 | 328,0 | | | | 20A@12Vdc | |
| Pin 2 to pir | n 3 | 163,4 | 328,0 | | | | | |
| Pin 2 to pir | า 4 | 163,4 | 328,0 | | | | | |
| Suppleme | ntary Inf | formatior | ו: | | | | | |
| 1. The voltage | input sup | oply voltag | ge to the Mi Ilts in the hi | E EQUIPMENT was | the RATI | ED voltage or the | voltage within the | e 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

Minus of the output, input N and PE were connected.

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| 8.4.2 | TABL | E: TABL | E: Working | g Voltage / Powe | er Measurem | ient | | Р |
|---|--------|-----------|---------------|-------------------------------------|---------------|---------------|--------------|------|
| Test supply | voltag | ge/freque | ncy (V/Hz) | 1 | | : | 320/dc | |
| Location | า | | | Measured value | ues | | | |
| From/To |) | Vrms | Vpk or Vdc | Peak-to-peak ripple ² | Power W/VA | Energy (J) | Rem | arks |
| | | | Wo | orking voltage of | Transforme | er T1 | | |
| Pin 1 to PE | | 1,43 | 5,12 | | | | Output load: | |
| Pin 2 to PE | | 15,49 | 23,60 | | | | 4,36A@55V0 | IC |
| Pin 4 to PE | | 255,9 | 392,0 | | | | | |
| Pin 5 to PE | | 252,0 | 392,0 | | | | | |
| Pin 4 to Pin | FL1 | 203,1 | 360,0 | | | | | |
| Pin 4 to Pin | FL2 | 255,7 | 396,0 | | | | | |
| | | | Work | ing voltage of O | ptical insula | tor U3 | | |
| Pin 1 to pin | 3 | 5,7 | 16,0 | | | | Output load: | la. |
| Pin 1 to pin | 4 | 8,4 | 20,0 | | | | 4,36A@55V0 | IC |
| Pin 2 to pin | 3 | 8,2 | 20,0 | | | | | |
| Pin 2 to pin | 4 | 6,5 | 16,0 | | | | | |
| Working voltage of Optical insulator U4 | | | | | | | | |
| Pin 1 to pin | 3 | 43,7 | 56,0 | | | | Output load: | |
| Pin 1 to pin | 4 | 29,0 | 40,0 | | | | 4,36A@55V0 | IC |
| Pin 2 to pin | 3 | 49,4 | 64,0 | | | | | |
| Pin 2 to pin | 4 | 35,3 | 52,0 | | | | | |
| | | | Work | ing voltage of O | ptical insula | tor U5 | | |
| Pin 1 to pin | 3 | 10,9 | 20,0 | | | | Output load: | |
| Pin 1 to pin | 4 | 11,2 | 24,0 | | | | 4,36A@55V0 | IC |
| Pin 2 to pin | 3 | 12,3 | 24,0 | | | | | |
| Pin 2 to pin | 4 | 12,1 | 24,0 | | | | | |
| Working voltage of Transformer T1 | | | | | | | | |
| Pin 1 to PE | | 11,35 | 24,0 | | | | Output load: | |
| Pin 2 to PE | | 18,14 | 40,0 | | | | 20A@12Vac | |
| Pin 4 to PE | | 252,3 | 392,0 | | | | | |
| Pin 5 to PE | | 253,0 | 396,0 | | | | | |
| Pin 5 to Pin | FL1 | 253,9 | 392,0 | | | | | |
| Pin 5 to Pin | FL2 | 270,7 | 452,0 | | | | | |
| | | | Work | ing voltage of O | ptical insula | tor U3 | | |

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| 8.4.2 | TAB | LE: TABL | E: Working | g Voltage / Powe | er Measu | urement | | Р |
| Pin 1 to pi | n 3 | 4,3 | 12,0 | | | | Output load: | |
| Pin 1 to pi | n 4 | 7,2 | 16,0 | | | | 20A@12Vdc | |
| Pin 2 to pi | n 3 | 5,5 | 16,0 | | | | | |
| Pin 2 to pi | n 4 | 8,1 | 16,0 | | | | | |
| | | | Work | ing voltage of O | ptical in | sulator U4 | • | |
| Pin 1 to pi | n 3 | 3,1 | 16,0 | | | | Output load: | |
| Pin 1 to pi | n 4 | 14,2 | 28,0 | | | | 20A@12Vdc | |
| Pin 2 to pi | n 3 | 3,2 | 12,0 | | | | | |
| Pin 2 to pi | n 4 | 13,9 | 24,0 | | | | | |
| | | | Work | ing voltage of O | ptical in | sulator U5 | | |
| Pin 1 to pi | n 3 | 10,9 | 20,0 | | | | Output load: | |
| Pin 1 to pi | n 4 | 11,0 | 20,0 | | | | 20A@12Vdc | |
| Pin 2 to pi | n 3 | 11,6 | 20,0 | | | | | |
| Pin 2 to pi | n 4 | 12,1 | 24,0 | | | | | |
| Suppleme | ntary In | formatior | ו: | | | | • | |
| 1. The voltage | input su range | upply voltage which resu | ge to the M Ilts in the hi | E EQUIPMENT was ghest measured | the RATE value. S | ED voltage or the ee clause 8.5.4. | voltage within the | RATED |

2. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2

Minus of the input, output minus and PE were connected.

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

| 8.4.2 | TABL | E: TABL | E: Working | g Voltage / Powe | er Measurem | ent | | Р |
|---|--------|-----------|---------------|-------------------------------------|---------------|---------------|--------------|------|
| Test supply v | /oltag | je/freque | ncy (V/Hz) | 1 | | : | 320/dc | 1 |
| Location | | | | Measured value | Jes | | | |
| From/To | - | Vrms | Vpk or Vdc | Peak-to-peak ripple ² | Power W/VA | Energy (J) | Rem | arks |
| | | | Wo | rking voltage of | Transforme | er T1 | | |
| Pin 1 to PE | | 308,3 | 320,0 | | | | Output load: | |
| Pin 2 to PE | | 309,5 | 336,0 | | | | 4,36A@55VC | IC |
| Pin 4 to PE | | 202,0 | 316,0 | | | | | |
| Pin 5 to PE | | 199,5 | 316,0 | | | | | |
| Pin 4 to Pin F | L1 | 325,3 | 544,0 | | | | | |
| Pin 4 to Pin F | L2 | 309,8 | 336,0 | | | | | |
| | | | Work | ing voltage of O | ptical insula | tor U3 | | |
| Pin 1 to pin 3 | | 316,7 | 328,0 | | | | Output load: | |
| Pin 1 to pin 4 | | 213,5 | 324,0 | | | | 4,36A@55VC | IC |
| Pin 2 to pin 3 | 5 | 315,6 | 328,0 | | | | | |
| Pin 2 to pin 4 | | 312,1 | 324,0 | | | | | |
| Working voltage of Optical insulator U4 | | | | | | | | |
| Pin 1 to pin 3 | 5 | 364,3 | 376,0 | | | | Output load: | |
| Pin 1 to pin 4 | | 349,0 | 360,0 | | | | 4,36A@55VC | IC |
| Pin 2 to pin 3 | 5 | 362,0 | 384,0 | | | | | |
| Pin 2 to pin 4 | | 352,5 | 368,0 | | | | | |
| | | | Work | ing voltage of O | ptical insula | tor U5 | | |
| Pin 1 to pin 3 | 5 | 310,4 | 320,0 | | | | Output load: | |
| Pin 1 to pin 4 | | 310,2 | 320,0 | | | | 4,36A@55VC | IC |
| Pin 2 to pin 3 | | 309,1 | 320,0 | | | | | |
| Pin 2 to pin 4 | | 308,9 | 320,0 | | | | | |
| | | | Wo | rking voltage of | Transforme | er T1 | | |
| Pin 1 to PE | | 308,7 | 320,0 | | | | Output load: | |
| Pin 2 to PE | | 309,6 | 340,0 | | | | 20A@12Vac | |
| Pin 4 to PE | | 198,7 | 320,0 | | | | | |
| Pin 5 to PE | | 196,0 | 312,0 | | | | | |
| Pin 5 to Pin F | L1 | 309,3 | 352,0 | | | | | |
| Pin 5 to Pin F | L2 | 308,9 | 336,0 | | | | | |
| | | | Work | ing voltage of O | ptical insula | tor U3 | | |

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| 8.4.2 | TABL | .E: TABL | E: Working | g Voltage / Powe | r Measu | urement | | Р |
| Pin 1 to pir | n 3 | 317,2 | 328,0 | | | | Output load: | |
| Pin 1 to pir | า 4 | 314,1 | 324,0 | | | | 20A@12Vdc | |
| Pin 2 to pir | n 3 | 316,2 | 328,0 | | | | | |
| Pin 2 to pir | า 4 | 312,9 | 324,0 | | | | | |
| | | | Work | ing voltage of O | ptical in | sulator U4 | | |
| Pin 1 to pir | n 3 | 320,5 | 332,0 | | | | Output load: | |
| Pin 1 to pir | า 4 | 305,9 | 316,0 | | | | 20A@12Vdc | |
| Pin 2 to pir | n 3 | 320,4 | 332,0 | | | | | |
| Pin 2 to pir | า 4 | 305,7 | 316,0 | | | | | |
| | | | Work | ing voltage of O | ptical in | sulator U5 | | |
| Pin 1 to pir | n 3 | 310,1 | 320,0 | | | | Output load: | |
| Pin 1 to pir | า 4 | 310,0 | 320,0 | | | | 20A@12Vdc | |
| Pin 2 to pir | n 3 | 309,0 | 320,0 | | | | | |
| Pin 2 to pir | า 4 | 308,5 | 320,0 | | | | | |
| Suppleme | ntary In | formatior | n: | | | | | |
| 1. The voltage | input su range v | pply voltag | ge to the M Ilts in the hi | E EQUIPMENT was ighest measured | the RATI value. S | ED voltage or the ee clause 8.5.4. | voltage within the | e RATED |

2. If the d.c peak-to-peak ripple >10%, waveform considered as a.c. See clause 8.4.2.2

Plus of the input, output minus and PE were connected.

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|--------|--------------------|-----------------|---------|
| Clause | Requirement + rest | Result - Remark | verdici |





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| | | | IEC 6 | 0601-1 | | | | | | |
| Clause | Requirement + Te | st | | | Resu | ılt - Rem | ark | | ١ | /erdict |
| Plug pin 2 a | and enclosure | | | | | | | | | |
| Supplemen | tary information: / | , | | | | | | | | |

| 8.4.4 | TABLE: Internal capaciti calculation of the stored capacitors or circuit par | ve circuits – measure charge in capacitive ts) after de-energizing | ement of residual vol circuits (i.e., accessi 9 ME EQUIPMENT | tage or ble | N/A |
|-----------------------------|--|--|--|----------------|-------|
| Maximum a | allowable residual voltage | (V): | | 60 V | |
| Maximum a | allowable stored charge w | hen residual voltage | exceeded 60 V : | 45 μC | |
| Description (i.e., acces | n of the capacitive circuit sible capacitor or circuit parts) | Measured residual voltage (V) | Calculated stored charge (μC) | Ren | narks |
| | | | | | |
| | | | | | |
| | | | | | |
| Supplemer | ntary information: | | | | |

| RM RESULTS TABLE: PATIENT Leads | N/A |
|--|---|
| | |
| TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies | N/A |
| · · · · · | |
| TABLE: defibrillation-proof applied parts – verification of recovery time | N/A |
| • | |
| TABLE: DEFIBRILLATION-PROOF APPLIED PARTS OF PATIENT CONNECTIONS OF DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load | N/A |
| • | |
| RM RESULTS TABLE: Protective earthing of moving parts | N/A |
| | RM RESULTS TABLE: PATIENT Leads TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies TABLE: defibrillation-proof applied parts – verification of recovery time TABLE: defibrillation-proof applied parts – verification of recovery time TABLE: defibrillation-proof applied parts – verification of recovery time RBLE: DEFIBRILLATION-PROOF APPLIED PARTS or PATIENT CONNECTIONS of DEFIBRILLATION-PROOF APPLIED PARTS - Energy reduction test –measurement of Energy delivered to a 100 Ω load RM RESULTS TABLE: Protective earthing of moving parts |

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| 8.6.4 TABLE: Impedance and current-carrying capability of PROTECTIVE EARTH CONNECTIONS | | | | | |
|--|---|--------------------------------------|--|--|---|
| Type o m | of ME EQUIPMENT & impedance neasured between parts | Test current (A) /Duration (s) | Voltage drop measured between parts (V) | Maximum calculated impedance (mΩ) | Maximum allowable impedance (mΩ) |
| Measured between input pin PE to metal | | 25,2 A | 365 mV | 14,5 | 100 |
| | | 10 sec. | | | |
| Measured b | etween input pin PE to metal | 40 Adc | 273 mV | 6,8 | 100 |
| P | | 120 sec. | | | |

Supplementary information:

PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 m Ω ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 m Ω

ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 m Ω

ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 m Ω

| 8.7 | TABLE: leakage current | | | | | Р |
|---------------------------|--|---|----|-------|--------------------|--------|
| Type o conditio | f leakage current and test on (including single faults) | skage current and test ncluding single faults) Supply Supply frequency (V) (Hz) (μA) Remarks | | ; | | |
| Fig. 13 - E | arth Leakage (ER) | | | | Maximum allowed va | alues: |
| 5 | 5 () | | | | 5 mA NC; 10 mA SF | С |
| Normal co before hu | ondition, normal polarity, midity treatment | 264 | 60 | 88,2 | 5 mA (NC) | |
| Normal co before hu | ondition, reverse polarity, midity treatment | 264 | 60 | 89,1 | 5 mA (NC) | |
| Single fau polarity, l | ult condition, normal before humidity treatment | 264 | 60 | 172,2 | 10 mA (SFC) | |
| Single fau polarity, l | ult I condition, reverse before humidity treatment | 264 | 60 | 172,2 | 10 mA (SFC) | |
| Normal co after hum | ondition, normal polarity, idity treatment | 264 | 60 | 90,3 | 5 mA (NC) | |
| Normal co after hum | ondition, reverse polarity, idity treatment | 264 | 60 | 91,6 | 5 mA (NC) | |
| Single fau polarity, a | ult condition, normal after humidity treatment | 264 | 60 | 176,3 | 10 mA (SFC) | |
| Single fau | ult I condition, reverse | 264 | 60 | 176,3 | 10 mA (SFC) | |

| S | I | Q |
|---|---|---|
| | | |

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Clause Requirement + Test

Result - Remark

Verdict

| polarity, after humidity treatment | | | | |
|---|-----|----|-------|---|
| | | | | Maximum allowed values: |
| Fig. 14 - Touch Current (TC) | _ | _ | — | 100 μΑ NC; 500 μΑ SFC |
| Normal condition, normal polarity, before humidity treatment | 264 | 60 | 229,6 | Measured on output connector. See summary of testing for details. |
| Normal condition, reverse polarity, before humidity treatment | 264 | 60 | 229,6 | Measured on output connector. See summary of testing for details. |
| Single fault condition (supply interruption), normal polarity, before humidity treatment | 264 | 60 | 327,6 | Measured on output connector. See summary of testing for details. |
| Single fault condition (supply interruption), reverse polarity, before humidity treatment | 264 | 60 | 327,8 | Measured on output connector. See summary of testing for details. |
| Single fault condition (protective earthling interruption), normal polarity, before humidity treatment | 264 | 60 | 232,4 | Measured on output connector. See summary of testing for details. |
| Single fault condition (protective earthling interruption), reverse polarity, before humidity treatment | 264 | 60 | 232,7 | Measured on output connector. See summary of testing for details. |
| Normal condition, normal polarity, after humidity treatment | 264 | 60 | 232,9 | Measured on output connector. See summary of testing for details. |
| Normal condition, reverse polarity, after humidity treatment | 264 | 60 | 233,0 | Measured on output connector. See summary of testing for details. |
| Single fault condition (supply interruption), normal polarity, after humidity treatment | 264 | 60 | 332,1 | Measured on output connector. See summary of testing for details. |
| Single fault condition (supply interruption), reverse polarity, after humidity treatment | 264 | 60 | 330,9 | Measured on output connector. See summary of testing for details. |
| Single fault condition (protective earthling interruption), normal polarity, after humidity treatment | 264 | 60 | 235,3 | Measured on output connector. See summary of testing for details. |
| Single fault condition (protective earthling interruption), reverse polarity, after humidity treatment | 264 | 60 | 235,1 | Measured on output connector. See summary of testing for details. |
| Function Earth Conductor Leakage | | | | Maximum allowed values: |
| Current (FECLC) | | | | 5 mA NC; 10 mA SFC |
| | | | | |

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;

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| Note 3: For Note 4: Tota same type. | 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 a humidity pro supply frequence overflow, sp | 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). | | | | | |
| | | ŀ | A - After humidity conditioning | | | |
| ER Earth | leakage current | E | 3 - Before humidity conditioning | | | |
| | | 1 | - Switch closed or set to normal | polarity | | |
| | | C |) - Switch open or set to reversed | l polarity | | |
| IND - Measi | uning device | ١ | NC - Normal condition | | | |
| | | S | SFC - Single fault condition | | | |

| 8.8.3 | TABLE: Dielectric strength test of solid insulating materials with safety function P - MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP) | | | | | | |
|--|---|-----------------------|--|---------------------------------------|--|--|--|
| | der to et | | Reference | Voltage | | Dielectric | |
| Insulation under test (area from insulation diagram) | | (1 or 2 MOOP/MOPP) | PEAK WORKING VOLTAGE (U) V _{peak} | PEAK WORKING VOLTAGE (U) V d.c. | A.C. test voltages in V r.m.s ¹ | breakdown after 1 minute Yes/No ² | |
| Area C (pr earth) | imary to | 1xMOOP | 392 (at 240 Vac supply) | - | 2220 Vdc | No | |
| Area C (pr earth) | imary to | 1xMOOP | 544 (at 320 Vac supply) | | 2594 Vdc | Νο | |
| Area D (pr secondary | imary to /) | 2xMOOP | 392 (at 240 Vac supply) | - | 4243 Vdc | No | |
| Area D (pr secondary | imary to /) | 2xMOOP | 544 (at 320 Vac supply) | - | 4243 Vdc | No | |
| Area E (primary to metal plate not connected to PE) | | 2xMOOP | 392 (at 240 Vac supply) | - | 4243 Vdc | Νο | |
| See 1) | | | | | | | |
| Area E (primary to metal plate not connected to PE) | | 2xMOOP | 544 (at 320 Vac supply) | | 3000 Vac | No | |
| See 1) | | | | | | | |

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| Clause | Requirement + Test | Result - Remark | | Verdict |
| | | • | | |

Supplementary information:

¹ Alternatively, per the Table (i.e., ___dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.

² A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

Based on Vpk measurement of T1.

1) Input to metal bottom plate (Capacitors CY1, CY2, CY3, CY4, CY5, CY6, CY7 and connecting wire marked with "B" removed from the equipment). Relevant for PSU without PE.

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| 8.8.4.1 | TABLE: Resistance to heat - Ball pressure test of thermoplastic parts | | | | |
|------------|---|------------|--------------------------|--------------|----------------------|
| | Allowed impression diameter (mm): | ≤ 2 | 2 mm | | _ |
| | Force (N): | 20 |) | _ | |
| Part/mater | ial | | Test temperature (°C) | Imp diame | ression eter (mm) |
| Insulating | material supporting un-insulated Mains Parts | | | | |
| | | | | | |
| Supplemer | ntary information: | | | | |
| Approved | thermoplastic materials used. See table 8.10. | | | | |

| 8.8.4.1 | RM RESULTS TABLE: Mechanical strength and resistance to heat | N/A |
|---------|--|-----|
|---------|--|-----|

| 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 OF 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 | | | | | |
| Sufficient creepage and clearance distances between parts of opposite polarity provided before mains fuses. After mains fuses, distances verified by short circuit. See Table 13.2 for details. | | | | | |

| 8.9.3.2 | Table: Thermal cycling tests on a solid insulation between conduction | mpound forming | N/A | |
|-------------------------|---|---|---|--|
| Test Sequence No. | Each test duration and temperature | Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6) | Dielectric streng humidity precond cl. 5.7 except for Breakdown: | th test after ditioning per r 48 h only, Yes/No |
| 1 | 68 h at T1 ± 2 °C =°C ¹ | | | |
| | 1 h at 25 °C ± 2 °C | | | |
| | 2 h at 0 °C ± 2 °C | | | |
| | 1 or more h at 25 °C ± 2 °C | | | |
| | 68 h at T1 ± 2 °C =°C ¹ | | | |
| 2 | 1 h at 25 °C ± 2 °C | | | |
| | 2 h at 0 °C ± 2 °C | | | |

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| 8.9.3.2 | Table: Thermal cycling tests on solid insulation between condu | one sample of insulating co ctive parts | ompound forming 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 or more h at 25 °C ± 2 °C | | |
| | 68 h at T1 ± 2 °C =°C ¹ | | |
| 3 | 1 h at 25 °C ± 2 °C | - | |
| | 2 h at 0 °C ± 2 °C | _ | |
| | 1 or more h at 25 °C ± 2 °C | _ | |
| | 68 h at T1 ± 2 °C =°C ¹ | | |
| 4 | 1 h at 25 °C ± 2 °C | - | |
| | 2 h at 0 °C ± 2 °C | _ | |
| | 1 or more h at 25 °C ± 2 °C | | |
| | | | |
| | | | |
| | | | |
| | | | |
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Supplementary information:

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

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| 8.9.3.4 | 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 streng humidity precond cl. 5.7 except fo Breakdown: | th test after ditioning per r 48 h only, Yes/No | | |
| | 68 h at T1 ± 2 °C =°C1 | | | | | |
| 4 | 1 h at 25 °C ± 2 °C | | | | | |
| | 2 h at 0 °C ± 2 °C | | | | | |
| | 1 or more h at 25 °C ± 2 °C | | | | | |
| | 68 h at T1 ± 2 °C =°C1 | | | | | |
| 2 | 1 h at 25 °C ± 2 °C | | | | | |
| 2 | 2 h at 0 °C ± 2 °C | | | | | |
| | 1 or more h at 25 °C ± 2 °C | | | | | |
| 3 | 68 h at T1 ± 2 °C =°C1 | | | | | |
| | 1 h at 25 °C ± 2 °C | | | | | |
| | 2 h at 0 °C ± 2 °C | | | | | |
| | 1 or more h at 25 °C ± 2 °C | | | | | |
| | 68 h at T1 ± 2 °C =°C1 | | | | | |
| | 1 h at 25 °C ± 2 °C | | | | | |
| 4 | 2 h at 0 °C ± 2 °C | | | | | |
| | 1 or more h at 25 °C ± 2 °C | | | | | |
| | | | | | | |
| | | | | | | |
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| | | | | | | |

Supplementary information:

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

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| 8.10 | TABI | E: List of critical | components | 5 | | Р |
|--|------------------|---|---------------------------|---|--------------------------------------|---|
| Compone Part No | ent/ o. | Manufacturer/ Trademark | Type No./model No./ | Technical data | Standard No./, Edition | Mark(s) & Certificates of conformity ¹ |
| Enclosure top | • | Sabic Innovative Plastics | C2950 | OD approx 140 by 87,6 mm Thickness 2,5 mm Min. UL94-V0 | (QMFZ2) IEC 60601-1 | UR E45329 Accepted |
| Enclosure top, altern 1 | e iate | Sabic Innovative plastics | SE1X, SE100X, CX741 | OD approx 140 by 87,6 mm Thickness 2,5 mm Min. UL94-V1 | (QMFZ2) IEC 60601-1 | UR E45329 Accepted |
| Enclosure top, altern 2 | e late | Sabic Innovative | SE1, SE100 | OD approx 140 by 87,6mm; Thickness 2,5 mm Min. UL94-V1 | (QMFZ2) IEC 60601-1 | UR E45329 Accepted |
| Insulation sheet on t bottom enclosure | he | +Formex | Formex GK | OD approx 133,8 by 81,4 mm Thickness min. 0,4 mm UL94-V0 Min RTI = 115°C | (QMFZ2) IEC 60601-1 | UR E121855 Accepted |
| Enclosure bottom |) | OD approx 140 by Thickness 0,6 mn Nickel plated | / 87,6 mm n | I | IEC 60601-1 | Accepted |
| Bonding w | vire | +HUESON CORP. | UL AWM Style 1569 | 300V; 105°C 18 AWG | (AVLV2) (AVLV8) IEC/EN 60601-1 | cURus E174416 Accepted |
| Input connector male (CON for -S vers Class I | r N1) sion | +Molex | KK 26-60- 4030 | UL94-V0 7 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURus E29179 TÜV R75108 |
| Input connector male (CON for -S vers Class II | r N1) sion | +Molex | КК 26-60- 4030 | UL94-V0 7 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURus E29179 TÜV R75108 |
| Input connector male (CON for –HOXX version Class I | r N1) KX | +Molex | KK 26-60- 4030 | UL94-V0 7 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURus E29179 TÜV R75108 |

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| | | | IEC 60601-1 | | | |
| Clause F | Requirement + Test | | | Result - Remark | | Verdict |
| Input connector male (CON1) for –HOXXX version Class II | +Molex | КК 26-60- 4030 | UL94-V0 7 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURu TÜV I | ıs E29179 R75108 |
| Input connector male (CON1) for –HIXXX version Class I | +Molex | КК 09-50- 3031 | UL94-V0 7 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURu TÜV I | is E29179 R75108 |
| Input connector male (CON1) for –HIXXX version Class II | +Molex | KK 09-50- 3031 | UL94-V0 7 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | CURu TÜV I | ls E29179 R75108 |

| Class II | | | | | |
|---|----------|----------------------|--|----------------------|----------------------------|
| Output connector male (CON2) for -S version | +Molex | KK 26-60- 4060 | UL94-V0 7 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURus E29179 TÜV R75108 |
| Output connector male (CON2) for –HOXXX version | +Molex | KK 09-50- 3061 | UL94-V0 7 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURus E29179 TÜV R75108 |
| Output connector male (CON2) for –HIXXX version | +Molex | KK 26-60- 4060 | UL94-V0 7 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURus E29179 TÜV R75108 |
| Output Connector Fan male (CON3) for -S version | +JST | B2B-PH- K-SLFSN | UL94-V0 4 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURus E60389 TÜV R75087 |
| Output Connector Fan male (CON3) for – HOXXX version | +JST | B2B-PH- K-SLFSN | UL94-V0 4 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURus E60389 TÜV R75087 |
| Output Connector Fan male (CON3) for – HIXXX version | +JST | B2B-PH- K-SLFSN | UL94-V0 4 A / 250 Vac 75°C max. | UL 1977 IEC 60947 | cURus E60389 TÜV R75087 |
| Earth quick connector (Faston | +Kanyang | PCH250 | Double crimped Uninsulated 6.35 x 0,8 | IEC 60950-1 | Accepted |

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| Class I units) | | | mm | | |
|-----------------------------|----------|-----------|------------------------------------|----------------|--------------|
| Input | +Molex | 09-50- | UL94-V0 | UL 1977 | cURus E29179 |
| connector | | 3031 | 5 A / 250 Vac | IEC 60947 | TÜV R75108 |
| (CON1) | | | 75°C max. | | |
| Output | +Molex | 09-50- | UL94-V0 | UL 1977 | cURus E29179 |
| connector | | 3061 | 7 A / 250 Vac | IEC 60947 | TÜV R75108 |
| (CON2) | | | (Phosphor Bronze) | | |
| . , | | | 75°C max. | | |
| Output | +JST | PHR-2; | UL94-V0 | UL 1977 | cURus E60389 |
| Fan female | | P0.5S | 4 A / 250 Vac | IEC 60947 | TÜV R75087 |
| (CON3) | | | 75°C max. | | |
| PCB Main | +Xinke | 530-0096 | Material: FR-4; | (ZPMV2) | UL E231590 |
| Board | | | UL94-V0 | IEC/EN 60601-1 | Accepted |
| | | | Min. 130°C | | |
| | | | Overall approx. 76,2 by 127 mm | | |
| PCB Control | +Xinke | 530-0097 | Material: FR-4 | (ZPMV2) | UL E231590 |
| Board | | | UL94-V0 | IEC/EN 60601-1 | Accepted |
| | | | Min. 130°C | | |
| | | | Overall approx. 23,8 by 31,3 mm | | |
| Heatsink | +GlobTek | 500-0189A | L-shaped | IEC/EN 60601-1 | Accepted |
| (Secondary) connected to | | | OD approx 44,5 by 24 by 36 mm | | |
| initiae output | | | Thick. 4mm | | |
| | | | Copper | | |
| Heatsink, | +GlobTek | 500-0189B | L-shaped | IEC/EN 60601-1 | Accepted |
| (Secondary) connected to | | | OD approx 44,5 by 24 by 36 mm | | |
| minus output | | | Thick. 4 mm | | |
| | | | Aluminium alloy | | |
| Heatsink | +GlobTek | 500-0184 | L-shaped | IEC/EN 60601-1 | Accepted |
| Primary | | | OD approx 76 by 36 by 30 mm | | |
| | | | Thick. 4mm | | |
| | | | Aluminium alloy | | |
| Heatsink | +GlobTek | 500-0183 | L-shaped | IEC/EN 60601-1 | Accepted |
| Primary (for BD1) | | | OD approx 33 by 31,5 by 35 mm | | |
| | | | Thick. 1,8 mm | | |
| | | | Copper | | |

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| Clamp semiconduct or on heatsink | +GlobTek | 500-0186 | L-shaped OD approx 12 by 22 1mm thick. | IEC/EN 60601-1 | Accepted |
|---|------------------------|-------------------------|--|------------------------|---------------|
| primary | | | Galvanized iron | | |
| Fuse (F1) | +Walter | ICP | 250 Vac / 5 A | (JDYX2) | UL E56092 |
| | | | Time delay | IEC 60127-4 | VDE |
| Fuse (F2) | LITTELFUSE | 392 | 250 Vac / 5 A | (YDYX2) | UL E67006 |
| | WERKE | | Time delay | (YDYX8) IEC 60127-3 | VDE |
| Fuse (F2) | | MST | 250 Vac / 5 A Time delay | (JDYX8) (JDYX2) | cURus E82636 |
| | | | | IEC 60127-3 | VDE |
| Fuse (F2) | BEL FUSE INC | RST | 250 Vac / 5 A Time delav | (JDYX2) (JDYX8) | cURus E20624 |
| | | | | IEC 60127-3 | VDE |
| Fuse (F2) | COOPER BUSSMANN | SS-5 | 250 Vac / 5 A Timo dolay | (YDYX2) (YDYX8) | URus E19180 |
| | INC. | | Time delay | IEC 60127-3 | VDE |
| Varistor MOV2 (Line | THINKING ELECTRONIC | TVR10471 -V | 300 Vrms; 385 Vdc, | (VZCA2) (VZCA8) | cURus E314979 |
| to Neutral) | | | Diamotor: 10 mm | IEC 61051-2 | VDE |
| | | | | IEC 60950-1 Annex Q | |
| Varistor MOV2 (Line | + JOYIN CO., LTD | JVR14S47 1K | 300 Vrms; 385 Vdc, | (VZCA2) (VZCA8) | cURus E325508 |
| to Neutral) | | | diameter: 14 mm | IEC 61051-2 | VDE |
| | | | | IEC 60950-1 Annex Q | |
| Varistor | + EPCOS | S(NF)14K | 300 Vrms; 385 Vdc, | (VZCA2) | URus E321126 |
| MOV2 (Line to Neutral) | | 300E2 | min. 3kA (8/20 us) | IEC 61051-2 | |
| | | | diameter: 14 mm | IEC 60950-1 Annex Q | VDE |
| Varistor MOV2 (Line | WALSIN TECHNOLOGY | SR471K14 D | 300 Vrms; 385 Vdc, | (VZCA2) (VZCA8) | cURus E309297 |
| to Neutral) | CORP | | diameter: 14 mm | IEC 61051-2 | VDE |
| | | | | IEC 60950-1 Annex Q | |
| Inductor (LF1) | GlobTek (Suzhou) | 321- 02176004(R) | Open type construction with tubing | IEC/EN 60601-1 | Accepted |
| | | | Overall approx. dimension: 30 by 10 mm | | |

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|-------------------|---------------------|-------------------------|--|--|----------------|------|---------|
| Clause | GlobTek (Suzhou) | 321- 02176003(R) | Rating: 60 mH M 1KHz / 0,25V Core: Ferrite Coil: Enamelled copper magnet w wound on core Temp. Class: Cla 2 Layers Myler ta after the copper is installed. Open type construction wit tubing Overall approx. dimension: 26 by mm Rating: 6 mH Min 1KHz / 0,25V Core: Ferrite Coil: Enamelled copper magnet w | Result in; wire ass B ape shield h y 12 n; wire | - Remark | Acce | verdict |
| Inductor (LF3) | GlobTek (Suzhou) | 321- 02171003(R) | wound on Core Temp. Class: Cla Epoxy fixing on bottom as a draw Open type construction wit outerwrap Myler overall Overall approx. dimension: 15 by mm Rating:1 to 1,5m 1KHz/0.25V Core: Ferrite Coil: Enamelled copper magnet w | ass B the ving. h tape y 8 H Min; vire | IEC/EN 60601-1 | Acce | pted |
| Inductor (LF4) | GlobTek (Suzhou) | 321- 02172802(| Temp. Class: Cla 2 Layers Myler ta after the copper is installed. Epos fixing on the bot as a drawing Open type construction wit | ass B ape shield xy tom h | IEC/EN 60601-1 | Acce | pted |

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| | | | IEC 60601-1 | | | |
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| | | R) | outerwrap Myler t | ape | | |
| | | | Overall approx. dimension: 12 by mm | 7,5 | | |
| | | | Rating: 280uH to 320uH; 1KHz/0,25 | v | | |
| | | | Core: Ferrite | | | |
| | | | Coil: Enamelled copper magnet wi wound on Core | ire | | |
| | | | Temp. Class: Clas | ss B | | |
| | | | Epoxy fixing on the bottom as a drawi | าe ing | | |
| PFC Inducto (L1) | or GlobTek | 405-0005 | Open type construction with tubing | | IEC/EN 60601-1 | Accepted |
| | | | Overall approx. dimension: 27 by mm | 21 | | |
| | | | Rating: 1.3uH to 1.8uH; 1KHz/0.25\ | v | | |
| | | | Core: Ferrite | | | |
| | | | Coil: Enamelled copper magnet wi wound on Core | ire | | |
| | | | Temp. Class: Clas | ss F | | |
| | | | Epoxy to hold wire the core. 1 Layer I tape, 18mm wide shield 1, than 2 La Myler tape, 18mm wide shield 2. | es to Myler ayers | | |
| Inductor (L100) | + GlobTek | 403-0056 for 48V to 55V | Open type construction with tubing | I | IEC/EN 60601-1 | Accepted |
| | | Output | Overall approx. dimension: 28 by mm | 14 | | |
| | | | Rating: 150uH to 170uH; 1KHz/0.25 | v | | |
| | | | Core: Ferrite | | | |
| | | | Coil: Enamelled copper magnet wi wound on Core | ire | | |
| | | | Temp. Class: Clas | ss B | | |
| L | | | Epoxy to hold wire | es to | | |

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| | | | the core. 1 Layer Myler tape, 14mm wide shield | | |
|--|--------------------------|---------------------|--|----------------|---------------|
| Capacitor | + ULTRA TECH | HQX | 250 Vac (UL) | (FOWX2) | cURus E183780 |
| (CX1) | | | 275 Vac (IEC) | (FOWX8) | |
| (X2 capacitor) | CO.,LTD. | | 1,0uF max. | IEC 60384-14 | VDE |
| capacitory | | | X2, 100°C | | |
| Capacitor | Various | Various | Rated: Min. 400V | IEC/EN 60601-1 | Accepted |
| Bulk | | | Min 105°C | | |
| (C1) | | | Min 120uF | | |
| Y-Capacitor | +SUCCESS | 5SE472MT | 250Vac | (FOWX2) | cURus E114280 |
| (CY8) | CO., LTD | 402A98 | Max. 4700pF | IEC 60384-14 | VDE |
| | | | Y1 type | | |
| Y-Capacitor | +WALSIN | YV0AH472 | 250Vac | (FOWX2) | cURus E146544 |
| (CY8) | TECHNOLOGY CORP. | M130 | Max. 4700pF | IEC 60384-14 | VDE |
| | | | Y1 type | | |
| Y-Capacitor | +MURATA MFG | Туре КХ | 250Vac | (FOWX2) | URus E37921 |
| (CY8) | CO., LTD. | | Max. 4700pF | IEC 60384-14 | VDE |
| | | | Y1 type | | |
| Y-Capacitor | +TDK-EPC | Type CD | 250Vac | (FOWX2) | URus E37861 |
| (CY8) | CORP. | | Max. 4700pF | IEC 60384-14 | VDE |
| | | | Y1 type | | |
| Y-Capacitor | +WELSON | Type WD | 250Vac | (FOWX2) | cURus E104572 |
| (CY8) | INDUSTRIAL | | Max. 4700pF | IEC 60484-14 | VDE |
| | | | Y1 type | | |
| Y-Capacitor | +JYA-NAY CO., | Type JN | 250Vac | (FOWX2) | cURus E201384 |
| (CY8) | LTD. | | Max. 4700pF | IEC 60484-14 | VDE |
| | | | Y1 type | | |
| Electrolytic Capacitor (C103, C104, C105) | Various | Various | Various, depending on power supply output voltage, | IEC/EN 60601-1 | Accepted |
| 0100) | | | Min. 105°C | | |
| NTC (RTH1) | + THINKING ELECTRONIC | SCK 153 | 240 Vac | (XGPU2) | cURus E138827 |
| | INDUSTRIAL | | 3 A | IEC 60950-1 | TUV |
| | CO., LTD. | DETERMINE | | | |
| (RTH2) | + Epcos | в57703M0 103G040 | Rated: 125°C | IEC/EN 60601-1 | Accepted |
| | | | heatsink by screw. | | |
| Transistor | +Toshiba | TK20A60U | Rated: 600 V / 20 A | IEC/EN 60601-1 | Accepted |

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|--------------------------------------|---------------------------------------|--------------------------------|--|---------------------------|------------------------|
| (Q1, Q2, Q3) | | | Mounted on Primary heatsink by clamp semiconductor secured by screw. | | |
| Optical insulator (U3, U4, U5) | +Vishay Semiconductor GmbH | TCLT1003 | Isolation voltage: 5000 Vac Ext. creepage: 7.9 mm | UL 1577 IEC/EN 60950-1 | cURus E76222 BSI |
| Optical insulator (U3, U4, U5) | +FAIRCHILD Semiconductor Corp. | FOD817C FOD817A (H11A817 | Isolation voltage: 5000 Vac Ext. creepage: 7,8 mm | UL 1577 IEC 60950-1 | cURus E90700 FIMKO |
| | | X) | | | |
| Optical insulator (U3, U4, U5) | +EVERLIGHT ELECTRONICS CO., LTD | EL817C | Isolation voltage: 5000 Vac Ext. creepage: 7,7 mm | UL 1577 IEC/EN 60950-1 | cURus E214129 SEMKO |
| Transformer (T1) Primary | GlobTek | 403- 0051(R) | Open type construction | IEC/EN 60601-1 | Accepted |
| to Secondary (Reinforced) | | | Overall dimension: 34 by 33 by 36 mm | | |
| | | | Rating: Output: 48V and 55V | | |
| | | | Switching frequency: 100 kHz Nominal | | |
| | | | Core: Ferrite PC44PQ32/30Z-12 or equivalent | | |
| | | | Coil: Polyurethane enamelled copper wire 130C and copper foil wound on bobbin | | |
| | | | Bobbin: FR PHENOL BPQ 32/32-1112CP or equivalent | | |
| | | | Phenolic T375J 94V0 150C | | |
| | | | (E59481(S) cURus (QMFZ2, QMFZ8)) | | |
| | | | Insulation: | | |
| | | | Pri/Pri 1 Layer; min. 0,025 mm Polyester tape | | |
| | | | Outerwrap: Myler type around the core, 2 Layers, 0,025mm; shield E3 and Myler type on top of shield E3, 3 Layers, 0,025mm | | |



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| • | | Result | - Remark | Verdict |
|---|-------------------|---|----------------|----------|
| | | Insulation between primary and secondary winding is achieved by triple insulation wire TEX-E or equiv and copper foil. All outlets are provided with Teflon- tube. Temp Class: Class B | | |
| Transformer (T1) Primary to Secondary (reinforced) | k 403- 0052(R) | Penip. Class. Class BOpen type constructionOverall dimension: 34 by 33 by 36 mmRating: Output: 24VSwitching frequency: 100 kHz nominalCore: Ferrite PC44PQ32/30Z-12 or equivalentCoil: Polyurethane enamelled copper wire 130C and copper foil wound on bobbinBobbin: FR PHENOL BPQ 32/32-1112CP or equivalentPhenolic T375J 94V0 150C(E59481(S) cURus (QMFZ2, QMFZ8))Insulation: Pri/Pri 1 Layer; min. 0,025 mm Polyester tapeOuterwrap: Myler type around the core before belly band is installed, than 3 Layers of Myler tape around the belly band.Insulation between primary and secondary winding is achieved by triple insulation wire TEX-E | IEC/EN 60601-1 | Accepted |

Clause

Requirement + Test

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| | | IE(|
|--|--|-----|
| | | |

IEC 60601-1

Result - Remark

| | | | foil. | | |
|------------------------------|---------|-----------------|--|----------------|----------|
| | | | All outlets are provided with Teflon- tube. | | |
| | | | Temp. Class: Class B | | |
| Transformer (T1) Primary | GlobTek | 403- 0053(R) | Open type construction | IEC/EN 60601-1 | Accepted |
| to Secondary (reinforced) | | | Overall dimension: 34 by 33 by 36 mm | | |
| | | | Rating: Output: 18V | | |
| | | | Switching frequency: 100 kHz, nominal | | |
| | | | Core: Ferrite PC44PQ32/30Z-12 or equivalent | | |
| | | | Coil: Polyurethane enamelled copper wire 130°C and copper foil wound on bobbin | | |
| | | | Bobbin: FR PHENOL BPQ 32/32-1112CP or equivalent | | |
| | | | Phenolic T375J 94V0 150C | | |
| | | | (E59481(S) cURus (QMFZ2, QMFZ8)) | | |
| | | | Insulation: | | |
| | | | Pri/Pri 1 Layer; min. 0,025 mm Polyester tape | | |
| | | | Outerwrap: Myler type around the core. After the shield is installed are 3 Layers of Myler tape (15mm). | | |
| | | | Insulation between primary and secondary winding is achieved by triple insulation wire TEX-E or equiv , and copper foil. | | |
| | | | All outlets are provided with Teflon- tube. | | |
| | | | Temp. Class: Class B | | |
| Transformer | GlobTek | 403- | Open type | IEC/EN 60601-1 | Accepted |

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Result - Remark

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Clause Requirement + Test

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| (T1) Primary | | 0054(R) | construction | | |
|------------------------------|---------|-------------------|---|----------------|----------|
| to Secondary (reinforced) | | | Overall dimension: 34 by 33 by 36 mm | | |
| | | | Rating: Output: 12V | | |
| | | | Switching frequency: 100 kHz nominal | | |
| | | | Core: Ferrite PC44PQ32/30Z-12 or equivalent | | |
| | | | Coil: Polyurethane enamelled copper wire 130°C and copper foil wound on bobbin | | |
| | | | Bobbin: FR PHENOL BPQ 32/32-1112CP | | |
| | | | Phenolic T375J 94V0 150C or equivalent | | |
| | | | (E59481(S) cURus (QMFZ2, QMFZ8)) | | |
| | | | Insulation: | | |
| | | | Pri/Pri 1 Layer; min. 0,025 mm Polyester tape | | |
| | | | Outerwrap: Myler type around the core. After the shield is installed are 3 Layers of Myler tape (15 mm). | | |
| | | | Insulation between primary and secondary winding is achieved by triple insulation wire TEX-E or equiv, and copper foil. | | |
| | | | All outlets are provided with Teflon- tube. | | |
| | | | Temp. Class: Class B | | |
| Drive Transformer | GlobTek | 320- 02320004(| Open type construction | IEC/EN 60601-1 | Accepted |
| (12) | | K) | Overall dimension: 16 by 7 mm | | |
| | | | Rating: 544 µH to 1011 µH | | |
| | | | Temp. Class: Class B | | |

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IEC 60601-1

| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|--------------------|-----------------|---------|

| PFC Diode (D1) | +CREE | C3D06060 A | Rated: 500V / min 5A Mounted on Primary heatsink by clamp semiconductor secured by screw. | IEC/EN 60601-1 | Accepted |
|--|--|----------------------------|---|------------------------------------|--|
| Rectifier Diode (D100, D101) | Various | Various | Rating varies depending on the output voltage and power of the power supply. | IEC/EN 60601-1 | Accepted |
| | | | Secured to Secondary heatsink. by screw. | | |
| Diode Bridge (BD1) | +DIODES INC | GBU1010 | Rated: 700V min, 10A min | (QQQX2) | URus E94661 |
| | | | Secured to Primary heatsink. by screw, and between is insulation foil | | |
| SMD Capacitor (CY1, CY2, CY3, CY4, CY5, CY6, CY7) (Primary - PE) SMD | +PANASONIC CORPORATION +MURATA MFG | ECCTFC2 20JG Type GC | 250 Vac 330 pF max Y2 Type 250 Vac | (FOWX2) IEC 60384-14 (FOWX2) | URus E62674 S, D, N, FI cURus E37921 |
| Capacitor (CY1, CY2, CY3, CY4, CY5, CY6, CY7) (Primary - | CO., LID. | | 330 рF max Ү2 Туре | (FOWX8) IEC 60384-14 | VDE |
| PE) | | | | | |
| Capacitor (C106, C107) Output to PE | + VISHAY ELECTRONIC GMBH | VY1 | 250 Vac 22 pF max | (FOWX8) (FOWX2) IEC 60384-14 | cURus E183844 VDE |
| | | | x1/Y1 type | - | |

Supplementary information:

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

8.10.1

RM RESULTS TABLE: Fixing of components

N/A

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|---|----------------------------|---------------------------|-----------------|--------------|------------------------|------|--|--|
| | | | IEC 60601-1 | | | | | |
| Clause Requirement + Test Result - Rema | | | Result - Remark | k Verdic | | | | |
| | | | | | | | | |
| 8.11.3.5 | TABLE: Cord a | nchorages | | | | N/A | | |
| Cord under test | | Mass of equipment (kg) | Pull (N) | Torque Nm) | Rem | arks | | |
| | | | | | | | | |
| | | | | | | | | |
| | | | | | | | | |
| Suppleme | Supplementary information: | | | | | | | |

| 8.11.3.6 | I1.3.6 TABLE: Cord guard | | | | | |
|----------------------------|--------------------------|-----------|--------------------|--------|-------|--|
| Cord under test | | Test mass | Measured curvature | Remark | narks | |
| | | | | | | |
| | | | | | | |
| | | | | | | |
| Supplementary information: | | | | | | |

Supplementary information:

| RM RESULTS TABLE: HAZARDS associated with moving parts - General | N/A |
|---|--|
| TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996) | N/A |
| | |
| TABLE: Over-travel End Stop Test | N/A |
| | |
| RM RESULTS TABLE: Emergency stopping devices | N/A |
| RM RESULTS TABLE: Release of patient | N/A |
| | T |
| TABLE: Instability—overbalance in transport position | N/A |
| TABLE: Instability—overbalance excluding transport position | N/A |
| TABLE: Instability—overbalance from horizontal and vertical forces | N/A |
| TABLE: Castors and wheels – Force for propulsion | N/A |
| TABLE: Castors and wheels - Movement over a threshold | N/A |
| | |
| TABLE: Instability from unwanted lateral movement (including sliding) in transport position | N/A |
| | RM RESULTS TABLE: HAZARDS associated with moving parts - General TABLE: Measurement of gap "a" according to Table 20 (ISO 13852: 1996) TABLE: Over-travel End Stop Test RM RESULTS TABLE: Emergency stopping devices RM RESULTS TABLE: Release of patient TABLE: Instability—overbalance in transport position TABLE: Instability—overbalance excluding transport position TABLE: Instability—overbalance from horizontal and vertical forces TABLE: Castors and wheels – Force for propulsion TABLE: Castors and wheels – Movement over a threshold TABLE: Instability from unwanted lateral movement (including sliding) in transport position |

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|---------|---|--------------------------------------|-------------|
| | IEC 60601-1 | | |
| Clause | Requirement + Test | Result - Remark | Verdict |
| 9.4.3.2 | TABLE: Instability from unwanted lateral mo excluding transport po | vement (including sliding) sition | N/A |
| 9.4.4 | TABLE: Grips and other handling devices | | N/A |
| 9.5.1 | RM RESULTS TABLE: Protective means | | N/A |
| 9.6.1 | RM RESULTS TABLE: Acoustic energy - Genera | al | N/A |
| 9.6.2.2 | RM RESULTS TABLE: Infrasound and ultrasour | nd energy | N/A |
| 9.7.2 | RM RESULTS TABLE: Pneumatic and hydraulic | parts | N/A |
| 9.7.5 | TABLE: Pressure vessels | | N/A |
| 9.7.7 | RM RESULTS TABLE: Pressure-relief device | | N/A |
| 9.8.1 | RM RESULTS TABLE: Hazards associated with | support systems - General | N/A |
| 9.8.2 | RM RESULTS TABLE: Tensile safety factor | | N/A |
| 9.8.3.1 | RM RESULTS TABLE: Strength of patient or op systems - General | perator support or suspension | N/A |
| 9.8.3.2 | TABLE: PATIENT support/suspension system - S | tatic forces | N/A |
| 9.8.3.3 | TABLE: Support/Suspension System – Dynam persons | ic forces due to loading from | N/A |
| 9.8.5 | RM RESULTS TABLE: Systems without mechan | ical protective devices | N/A |
| 10.1.1 | TABLE: Measurement of X - radiation | | N/A |
| 10.1.2 | RM RESULTS TABLE: ME equipment intended t therapeutic X-radiation | o produce diagnostic or | N/A |
| 10.2 | RM RESULTS TABLE: Alpha, beta, gamma, neu | tron & other particle radiation | N/A |
| 10.5 | RM RESULTS TABLE: Other visible electromage | netic radiation | N/A |
| 10.6 | RM RESULTS TABLE: RISK associated with emitted by lasers and LEDs | infrared radiation other than | N/A |

emitted by lasers and LEDs

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| | | - | | | | | |
|--------|--|-------------------------------|---------|--|--|--|--|
| | IEC 60601-1 | | | | | | |
| Clause | Requirement + Test | Result - Remark | Verdict | | | | |
| | | | | | | | |
| 10.7 | RM RESULTS TABLE: RISK associated with ult | raviolet radiation other than | N/A | | | | |

| 11.1.1 TABLE: Excessive temperatures in r | | | ME EQUIPMENT | | | | |
|---|--------------------------------|----------|--------------|------------------------|--------|-------|-------------------------|
| | Supply voltage (V~): | 90 | 90 | 100 | 100 | 200 | _ |
| | Frequency (Hz): | 50 | 60 | 50 | 60 | 50 | _ |
| | Ambient Tmin (°C): | 25,8 | 26,0 | 25,5 | 25,9 | 25,2 | _ |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | 40,0 | 40,0 | |
| Maximum measured temperature T of part/at:: | | т (°С) | | | | | Allowed Tmax (°C) |
| | GT(M)91110P24012-C(W)-S | or -HIOX | XX or -H | OXXX or · | -HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 82,2 | 82,2 | 78,7 | 79,1 | 69,7 | 130 |
| 2. | Input Choke LF2 (Winding) | 85,5 | 85,8 | 82,1 | 82,1 | 72,2 | 130 |
| 3. | Diode Bridge BD1 | 105,2 | 105,4 | 101,1 | 101,0 | 86,9 | 130 |
| 4. | PFC Choke L1 (Winding) | 115,6 | 115,6 | 113,9 | 113,8 | 108,6 | 155 |
| 5. | PFC Transistor Q1 | 121,2 | 121,2 | 119,0 | 118,9 | 108,2 | 130 |
| 6. | PFC Diode D1 | 111,5 | 111,4 | 109,3 | 109,2 | 101,8 | 130 |
| 7. | Bulk C1 | 96,4 | 96,5 | 94,9 | 94,9 | 90,4 | 105 |
| 8. | Switching Transistor Q3 | 109,9 | 109,7 | 108,2 | 108,1 | 101,5 | 130 |
| 9. | Power Transformer T1 (Core) | 98,4 | 98,2 | 97,7 | 97,8 | 95,6 | 130 |
| 10. | Power Transformer T1 (Winding) | 101,7 | 101,6 | 100,8 | 101,2 | 98,7 | 130 |
| 11. | Rectifier Diode D100 | 99,9 | 99,9 | 99,1 | 99,2 | 97,9 | 130 |
| 12. | Rectifier Diode D101 | 94,7 | 94,8 | 94,1 | 94,1 | 93,4 | 130 |
| 13. | Output Choke L100 (winding) | 98,8 | 98,7 | 97,9 | 97,8 | 97,2 | 130 |
| 14. | Output Bulk C105 | 75,2 | 75,3 | 74,5 | 74,3 | 74,5 | 105 |
| 15. | Thermistor RTH2 | 94,7 | 94,6 | 93,9 | 93,8 | 92,7 | 125 |
| Output load: | | | 6 | 6,7 <mark>A @12</mark> | V | | |

Supplementary information: The above temperatures are measured at Tmin. The values measured are subtracted with Tmin and Tmax (°C) added. Therefore above measured temperatures are the absolute temperatures in °C at maximum ambient.

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

Max temperature determined in accordance with 11.1.3e).

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

| 11.1.1 | 11.1.1 TABLE: Excessive temperatures in ME EQUIPMENT | | | | | | Р |
|---|--|--------------|----------|------------------------|-------|-------|-----|
| | Supply voltage (V~) | : 200 | 240 | 240 | 264 | 264 | — |
| | Frequency (Hz) | : 60 | 50 | 60 | 50 | 60 | _ |
| | Ambient Tmin (°C) | : 25,4 | 25,0 | 25,0 | 26,0 | 26,0 | _ |
| | Ambient Tmax (°C) | : 40,0 | 40,0 | 40,0 | 40,0 | 40,0 | _ |
| Maximum measured temperature T of part/at:: | | at:: | T (°C) | | | | |
| | GT(M)91110P24012-C(| W)-S or -HIO | XX or -H | OXXX or | HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 69,6 | 67,8 | 67,8 | 65,9 | 66,1 | 130 |
| 2. | Input Choke LF2 (Winding) | 72,0 | 70,0 | 70,2 | 67,6 | 68,1 | 130 |
| 3. | Diode Bridge BD1 | 86,9 | 83,0 | 83,1 | 79,7 | 80,1 | 130 |
| 4. | PFC Choke L1 (Winding) | 108,3 | 102,8 | 102,8 | 97,7 | 98,4 | 155 |
| 5. | PFC Transistor Q1 | 108,6 | 103,6 | 104,0 | 101,1 | 101,6 | 130 |
| 6. | PFC Diode D1 | 101,9 | 98,2 | 98,9 | 95,5 | 96,6 | 130 |
| 7. | Bulk C1 | 90,3 | 88,5 | 88,4 | 86,9 | 87,4 | 105 |
| 8. | Switching Transistor Q3 | 101,2 | 98,5 | 99,0 | 96,4 | 97,4 | 130 |
| 9. | Power Transformer T1 (Core) | 95,9 | 94,7 | 94,6 | 93,4 | 94,4 | 130 |
| 10. | Power Transformer T1 (Winding) | 98,1 | 97,7 | 97,6 | 96,4 | 96,7 | 130 |
| 11. | Rectifier Diode D100 | 98,0 | 97,4 | 97,6 | 96,3 | 96,8 | 130 |
| 12. | Rectifier Diode D101 | 93,6 | 92,9 | 93,4 | 92,2 | 92,8 | 130 |
| 13. | Output Choke L100 (winding) | 97,1 | 97,0 | 97,2 | 96,0 | 97,0 | 130 |
| 14. | Output Bulk C105 | 74,8 | 74,6 | 75,4 | 73,7 | 74,4 | 105 |
| 15. | Thermistor RTH2 | 92,6 | 92,5 | 93,3 | 91,8 | 93,1 | 125 |
| Output load: | | | 6 | 6,7 <mark>A @12</mark> | V | | |

Supplementary information: The above temperatures are measured at Tmin. The values measured are subtracted with Tmin and Tmax (°C) added. Therefore above measured temperatures are the absolute temperatures in °C at maximum ambient.

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

Max temperature determined in accordance with 11.1.3e).
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|---------------------------|--------------------|--|-----------------|--------------|-------------|--|--|--|
| | IEC 60601-1 | | | | | | | |
| Clause | Requirement + Test | | Result - Remark | | Verdict | | | |

| 11.1.1 | TABLE: Excessive temperatures in r | ME EQUIPN | IENT | | | | Р |
|--------|---|-----------|-----------|----------|-------|-------|-------------------------|
| | Supply voltage (V~): | 90 | 90 | 100 | 100 | 200 | _ |
| | Frequency (Hz): | 50 | 60 | 50 | 60 | 50 | |
| | Ambient Tmin (°C): | 25,8 | 26,0 | 25,5 | 25,9 | 25,2 | |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | 40,0 | 40,0 | |
| Maxir | num measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24012-F(W)-S | or -HIOX | XX or -HO | DXXX or | HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 97,1 | 96,9 | 90,7 | 91,1 | 70,7 | 130 |
| 2. | Input Choke LF2 (Winding) | 99,1 | 99,0 | 90,7 | 91,2 | 67,2 | 130 |
| 3. | Diode Bridge BD1 | 118,8 | 119,0 | 114,1 | 113,8 | 92,6 | 130 |
| 4. | PFC Choke L1 (Winding) | 139,1 | 139,0 | 134,9 | 135,1 | 123,6 | 155 |
| 5. | PFC Transistor Q1 | 120,8 | 120,7 | 118,3 | 118,0 | 108,8 | 130 |
| 6. | PFC Diode D1 | 118,0 | 117,9 | 115,0 | 115,0 | 105,8 | 130 |
| 7. | Bulk C1 | 89,7 | 89,7 | 88,0 | 87,8 | 104,8 | 105 |
| 8. | Switching Transistor Q3 | 119,6 | 119,4 | 116,4 | 116,4 | 107,2 | 130 |
| 9. | Power Transformer T1 (Core) | 99,6 | 99,5 | 98,0 | 98,1 | 95,7 | 120 |
| 10. | Power Transformer T1 (Winding) | 112,4 | 112,2 | 110,8 | 111,0 | 107,4 | 120 |
| 11. | Rectifier Diode D100 | 123,5 | 123,6 | 122,9 | 123,1 | 121,7 | 130 |
| 12. | Rectifier Diode D101 | 118,1 | 117,9 | 116,9 | 117,1 | 117,0 | 130 |
| 13. | Output Choke L100 (winding) | 121,4 | 121,3 | 120,7 | 120,9 | 119,6 | 130 |
| 14. | Output Bulk C105 | 91,1 | 91,1 | 90,4 | 90,8 | 89,8 | 105 |
| 15. | Thermistor RTH2 | 116,9 | 116,7 | 116,2 | 116,4 | 115,1 | 125 |
| Outp | ut load: | | 1: | 2,5A @12 | 2V | | |

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | | TABLE: Excessive temperatures in I | ME EQUIPM | IENT | | | | Р |
|---|--------|------------------------------------|------------|-----------|-----------|-------|-------|-------------------------|
| | | Supply voltage (V~): | 200 | 240 | 240 | 264 | 264 | _ |
| | | Frequency (Hz): | 60 | 50 | 60 | 50 | 60 | _ |
| | | Ambient Tmin (°C): | 25,4 | 25,0 | 25,0 | 26,0 | 26,0 | _ |
| | | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | 40,0 | 40,0 | _ |
| Maximum measured temperature T of part/at:: | | | | | T (°C) | | | Allowed Tmax (°C) |
| | | GT(M)91110P24012-F(W)-S | or -HIOX | XX or -HO | OXXX or - | HIXXX | | |
| 1. | Inpu | it Choke LF1 (Winding) | 70,5 | 66,4 | 66,9 | 64,6 | 64,4 | 130 |
| 2. Input Choke LF2 (Winding) | | 67,6 | 63,6 | 63,4 | 62,2 | 62,6 | 130 | |
| 3. Diode Bridge BD1 | | | 92,6 | 86,8 | 87,2 | 83,8 | 83,4 | 130 |
| 4. PFC Choke L1 (Winding) | | 123,6 | 115,9 | 116,5 | 110,6 | 110,7 | 155 | |
| 5. | PFC | Transistor Q1 | 109,2 | 104,4 | 105,1 | 102,2 | 102,6 | 130 |
| 6. | PFC | Diode D1 | 106,0 | 101,5 | 102,1 | 99,4 | 99,9 | 130 |
| 7. | Bull | « C1 | 83,7 | 82,2 | 82,9 | 81,2 | 81,3 | 105 |
| 8. | Swi | tching Transistor Q3 | 107,5 | 103,0 | 103,6 | 101,0 | 101,7 | 130 |
| 9. | Pow | ver Transformer T1 (Core) | 95,5 | 94,4 | 95,3 | 93,4 | 93,9 | 130 |
| 10. | Pow | ver Transformer T1 (Winding) | 107,4 | 106,2 | 106,2 | 104,8 | 105,0 | 130 |
| 11. | Rec | tifier Diode D100 | 121,6 | 121,0 | 121,2 | 120,0 | 121,1 | 130 |
| 12. | Rec | tifier Diode D101 | 117,2 | 116,8 | 116,9 | 115,0 | 116,2 | 130 |
| 13. | Out | put Choke L100 (winding) | 119,8 | 118,7 | 119,0 | 117,8 | 117,8 | 130 |
| 14. | Out | put Bulk C105 | 90,0 | 89,6 | 90,0 | 89,0 | 89,1 | 105 |
| 15. | The | rmistor RTH2 | 114,9 | 114,6 | 114,8 | 113,6 | 113,8 | 125 |
| Outpu | it loa | d: | 12,5A @12V | | | | | |

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | | Р |
|--------|---|------------|-----------|---------|----------|-------|-------------------------|
| | Supply voltage (V~): | 90 | 90 | 100 | 100 | 200 | _ |
| | Frequency (Hz): | 50 | 60 | 50 | 60 | 50 | _ |
| | Ambient Tmin (°C): | 25,8 | 26,0 | 25,5 | 25,9 | 25,2 | |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | 40,0 | 40,0 | |
| Maxii | mum measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-C(W) | -S or -HIC | OXXX or - | HOXXX o | r –HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 84,0 | 83,9 | 80,7 | 81,1 | 71,8 | 130 |
| 2. | Input Choke LF2 (Winding) | 88,4 | 88,3 | 85,3 | 85,8 | 75,6 | 130 |
| 3. | Diode Bridge BD1 | 114,8 | 114,7 | 111,6 | 111,8 | 97,1 | 130 |
| 4. | PFC Choke L1 (Winding) | 139,0 | 139,0 | 137,9 | 138,3 | 128,6 | 155 |
| 5. | PFC Transistor Q1 | 129,8 | 129,7 | 128,0 | 128,4 | 117,9 | 130 |
| 6. | PFC Diode D1 | 126,0 | 125,9 | 124,5 | 124,7 | 115,4 | 130 |
| 7. | Bulk C1 | 102,1 | 101,9 | 100,9 | 100,9 | 95,6 | 105 |
| 8. | Switching Transistor Q3 | 121,8 | 121,7 | 120,3 | 120,6 | 112,0 | 130 |
| 9. | Power Transformer T1 (Core) | 109,0 | 108,9 | 107,7 | 108,1 | 104,2 | 130 |
| 10. | Power Transformer T1 (Winding) | 111,4 | 111,2 | 110,1 | 110,5 | 106,3 | 130 |
| 11. | Rectifier Diode D100 | 94,4 | 94,2 | 93,7 | 93,9 | 92,2 | 130 |
| 12. | Rectifier Diode D101 | 92,0 | 91,6 | 91,3 | 91,1 | 89,9 | 130 |
| 13. | Output Choke L100 (winding) | 107,3 | 107,0 | 106,7 | 106,7 | 105,0 | 130 |
| 14. | Output Bulk C105 | 80,9 | 80,4 | 80,3 | 79,9 | 79,7 | 105 |
| 15. | Thermistor RTH2 | 89,2 | 88,9 | 88,5 | 88,4 | 87,1 | 125 |
| Outp | ut load: | | 1 | ,4A @55 | V | | |

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | TABLE: Excessive temperatures in | | IENT | | | | Р |
|---|----------------------------------|------------|----------|-----------------------|----------|-------|-------------------------|
| | Supply voltage (V~): | 200 | 240 | 240 | 264 | 264 | _ |
| | Frequency (Hz): | 60 | 50 | 60 | 50 | 60 | _ |
| | Ambient Tmin (°C): | 25,4 | 25,0 | 25,0 | 26,0 | 26,0 | _ |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | 40,0 | 40,0 | _ |
| Maximum measured temperature T of part/at:: | | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-C(W) | -S or -HIC | XXX or - | ΗΟΧΧΧ ο | r –HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 71,8 | 69,7 | 69,7 | 67,8 | 68,2 | 130 |
| 2. Input Choke LF2 (Winding) | | 75,6 | 72,7 | 72,9 | 70,4 | 70,8 | 130 |
| 3. Diode Bridge BD1 | | | 91,9 | 92,1 | 88,4 | 88,7 | 130 |
| 4. PFC Choke L1 (Winding) | | 128,7 | 119,7 | 119,8 | 114,0 | 114,6 | 155 |
| 5. | PFC Transistor Q1 | 117,9 | 112,7 | 112,7 | 109,5 | 109,9 | 130 |
| 6. | PFC Diode D1 | 115,3 | 110,5 | 110,7 | 107,2 | 107,6 | 130 |
| 7. | Bulk C1 | 95,2 | 93,1 | 93,3 | 91,0 | 91,3 | 105 |
| 8. | Switching Transistor Q3 | 112,2 | 107,8 | 108,0 | 104,9 | 105,3 | 130 |
| 9. | Power Transformer T1 (Core) | 103,6 | 102,6 | 102,6 | 100,5 | 101,2 | 130 |
| 10. | Power Transformer T1 (Winding) | 106,4 | 104,6 | 104,7 | 102,9 | 103,1 | 130 |
| 11. | Rectifier Diode D100 | 92,5 | 91,1 | 91,3 | 90,4 | 90,2 | 130 |
| 12. | Rectifier Diode D101 | 90,1 | 89,1 | 89,2 | 88,2 | 88,2 | 130 |
| 13. | Output Choke L100 (winding) | 105,1 | 104,0 | 104,2 | 103,2 | 103,3 | 130 |
| 14. | Output Bulk C105 | 79,7 | 78,7 | 79,0 | 78,3 | 78,4 | 105 |
| 15. | Thermistor RTH2 | 87,2 | 86,0 | 86,5 | 85,5 | 85,7 | 125 |
| Outpu | ut load: | | 1 | ,4A @ <mark>55</mark> | v | | |

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | | Р |
|---|------------------------------------|-----------|----------|----------|----------|-------|-------------------------|
| | Supply voltage (V~) | 90 | 90 | 100 | 100 | 200 | _ |
| | Frequency (Hz) | 50 | 60 | 50 | 60 | 50 | _ |
| | Ambient Tmin (°C): | 25,8 | 26,0 | 25,5 | 25,9 | 25,2 | |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | 40,0 | 40,0 | |
| Maximum measured temperature T of part/at:: | | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-F(W) | S or -HIC | XXX or - | ΗΟΧΧΧ ο | r –HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 94,3 | 94,4 | 86,3 | 86,5 | 66,0 | 130 |
| 2. | Input Choke LF2 (Winding) | 94,0 | 93,8 | 87,9 | 87,8 | 71,2 | 130 |
| 3. | Diode Bridge BD1 | 117,8 | 117,7 | 112,1 | 112,2 | 94,1 | 130 |
| 4. | PFC Choke L1 (Winding) | 136,2 | 136,1 | 133,4 | 133,7 | 125,3 | 155 |
| 5. | PFC Transistor Q1 | 122,9 | 122,9 | 120,2 | 120,2 | 111,6 | 130 |
| 6. | PFC Diode D1 | 121,4 | 121,1 | 119,0 | 119,0 | 109,8 | 130 |
| 7. | Bulk C1 | 88,4 | 88,5 | 87,1 | 87,3 | 82,9 | 105 |
| 8. | Switching Transistor Q3 | 121,4 | 121,4 | 119,3 | 119,4 | 111,0 | 130 |
| 9. | Power Transformer T1 (Core) | 104,3 | 104,3 | 102,5 | 102,5 | 99,5 | 130 |
| 10. | Power Transformer T1 (Winding) | 104,0 | 104,1 | 102,7 | 102,7 | 100,9 | 130 |
| 11. | Rectifier Diode D100 | 99,6 | 99,5 | 99,1 | 98,9 | 98,7 | 130 |
| 12. | Rectifier Diode D101 | 97,1 | 97,1 | 96,5 | 96,3 | 96,4 | 130 |
| 13. | Output Choke L100 (winding) | 108,4 | 108,1 | 107,8 | 107,6 | 107,8 | 130 |
| 14. | Output Bulk C105 | 73,9 | 74,1 | 73,9 | 73,7 | 74,0 | 105 |
| 15. | Thermistor RTH2 | 93,7 | 93,8 | 93,6 | 93,4 | 93,0 | 125 |
| Outp | ut load: | | 2 | ,72A @55 | SV . | | |

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | TAB | BLE: Excessive temperatures in | ME EQUIPM | IENT | | | | Р |
|---|-----------|--------------------------------|-----------|----------|----------|----------|-------|-------------------------|
| | Sup | ply voltage (V~): | 200 | 240 | 240 | 264 | 264 | _ |
| | Fred | quency (Hz): | 60 | 50 | 60 | 50 | 60 | _ |
| | Amb | pient Tmin (°C): | 25,4 | 25,0 | 25,0 | 26,0 | 26,0 | _ |
| | Aml | pient Tmax (°C): | 40,0 | 40,0 | 40,0 | 40,0 | 40,0 | _ |
| Maximum measured temperature T of part/at:: | | | | | T (°C) | | | Allowed Tmax (°C) |
| | | GT(M)91110P24055-X.X-F(W)- | S or -HIC | XXX or - | HOXXX o | r –HIXXX | | |
| 1. | Input Ch | oke LF1 (Winding) | 66,0 | 63,4 | 63,8 | 61,3 | 62,2 | 130 |
| 2. Input Choke LF2 (Winding) | | | 71,3 | 68,4 | 68,8 | 65,7 | 66,3 | 130 |
| 3. Diode Bridge BD1 | | | 94,2 | 88,8 | 89,2 | 85,1 | 85,7 | 130 |
| 4. PFC Choke L1 (Winding) | | 125,2 | 119,2 | 119,6 | 113,9 | 115,8 | 155 | |
| 5. | PFC Trar | nsistor Q1 | 111,8 | 107,7 | 108,1 | 105,6 | 106,7 | 130 |
| 6. | PFC Dioc | le D1 | 110,0 | 106,2 | 106,3 | 103,9 | 104,1 | 130 |
| 7. | Bulk C1 | | 82,8 | 80,8 | 80,8 | 80,4 | 79,1 | 105 |
| 8. | Switching | g Transistor Q3 | 111,2 | 107,1 | 107,3 | 105,8 | 106,0 | 130 |
| 9. | Power Tr | ansformer T1 (Core) | 99,6 | 97,6 | 98,1 | 96,8 | 96,9 | 130 |
| 10. | Power Tr | ansformer T1 (Winding) | 100,8 | 99,6 | 100,1 | 98,7 | 99,2 | 130 |
| 11. | Rectifier | Diode D100 | 98,5 | 97,6 | 98,1 | 98,0 | 98,8 | 130 |
| 12. | Rectifier | Diode D101 | 96,6 | 95,3 | 95,2 | 95,7 | 96,0 | 130 |
| 13. | Output C | hoke L100 (winding) | 107,9 | 106,8 | 106,9 | 106,7 | 106,6 | 130 |
| 14. | Output B | ulk C105 | 74,0 | 73,1 | 73,6 | 74,0 | 74,2 | 105 |
| 15. | Thermist | or RTH2 | 93,6 | 92,2 | 92,8 | 92,6 | 92,4 | 125 |
| Outpu | ut load: | | | 2 | ,72A @55 | V | | |

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | | Р |
|--|------------------------------------|-----------|----------|-------------------------|--------|-------|-----|
| | Supply voltage (V~): | 90 | 90 | 100 | 100 | 200 | _ |
| | Frequency (Hz): | 50 | 60 | 50 | 60 | 50 | _ |
| | Ambient Tmin (°C): | 52,7 | 52,7 | 52,7 | 52,7 | 52,7 | |
| | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | 55,0 | 55,0 | |
| Maximum measured temperature T of part/at:: T (°C) | | | | Allowed Tmax (°C) | | | |
| | GT(M)91110P24012-C(W)-S | or -HIOX | XX or -H | OXXX or | -HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 84,0 | 84,2 | 83,3 | 83,5 | 79,2 | 130 |
| 2. | Input Choke LF2 (Winding) | 85,9 | 86,1 | 85,1 | 85,2 | 80,3 | 130 |
| 3. | Diode Bridge BD1 | 100,1 | 100,3 | 98,9 | 98,9 | 90,4 | 130 |
| 4. | PFC Choke L1 (Winding) | 115,3 | 115,4 | 114,9 | 114,9 | 108,5 | 155 |
| 5. | PFC Transistor Q1 | 120,3 | 120,4 | 119,9 | 120,2 | 111,4 | 130 |
| 6. | PFC Diode D1 | 111,5 | 111,6 | 111,1 | 111,1 | 104,2 | 130 |
| 7. | Bulk C1 | 97,0 | 97,1 | 96,9 | 97,0 | 96,1 | 105 |
| 8. | Switching Transistor Q3 | 113,5 | 113,6 | 113,3 | 113,4 | 107,1 | 130 |
| 9. | Power Transformer T1 (Core) | 99,6 | 99,6 | 99,3 | 99,6 | 98,2 | 130 |
| 10. | Power Transformer T1 (Winding) | 101,6 | 101,5 | 101,5 | 101,5 | 99,8 | 130 |
| 11. | Rectifier Diode D100 | 96,0 | 96,0 | 96,0 | 95,9 | 95,8 | 130 |
| 12. | Rectifier Diode D101 | 92,4 | 92,5 | 92,1 | 92,3 | 91,6 | 130 |
| 13. | Output Choke L100 (winding) | 99,1 | 99,0 | 99,0 | 99,0 | 98,5 | 130 |
| 14. | Output Bulk C105 | 83,6 | 83,6 | 83,4 | 83,5 | 82,6 | 105 |
| 15. | Thermistor RTH2 | 92,1 | 92,1 | 92,1 | 92,0 | 91,6 | 125 |
| Outp | ut load: | | 3 | ,3 <mark>5A @12</mark> | 2V | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | 1 TABLE: Excessive temperatures i | 1 ME EQUIPN | MENT | | | | Р |
|--------|--|-------------|-----------|----------|-------------------------|-------|-----|
| | Supply voltage (V~) | : 200 | 240 | 240 | 264 | 264 | _ |
| | Frequency (Hz) | : 60 | 50 | 60 | 50 | 60 | _ |
| | Ambient Tmin (°C) | : 52,7 | 52,7 | 52,7 | 53,5 | 52,8 | _ |
| | Ambient Tmax (°C) | : 55,0 | 55,0 | 55,0 | 55,0 | 55,0 | _ |
| Maxir | Maximum measured temperature T of part/at:: T (°C) | | | | Allowed Tmax (°C) | | |
| | GT(M)91110P24012-C(W) | S or -HIOX | (XX or -H | OXXX or | -HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 79,3 | 78,8 | 78,7 | 77,6 | 76,2 | 130 |
| 2. | Input Choke LF2 (Winding) | 80,5 | 79,8 | 79,9 | 78,3 | 79,3 | 130 |
| 3. | Diode Bridge BD1 | 90,4 | 89,5 | 89,5 | 87,2 | 87,4 | 130 |
| 4. | PFC Choke L1 (Winding) | 108,7 | 107,5 | 107,4 | 103,4 | 103,5 | 155 |
| 5. | PFC Transistor Q1 | 111,8 | 109,3 | 109,4 | 107,5 | 107,7 | 130 |
| 6. | PFC Diode D1 | 104,3 | 103,4 | 103,6 | 101,2 | 101,1 | 130 |
| 7. | Bulk C1 | 96,3 | 93,1 | 93,2 | 91,4 | 91,4 | 105 |
| 8. | Switching Transistor Q3 | 107,3 | 106,1 | 106,3 | 104,5 | 104,5 | 130 |
| 9. | Power Transformer T1 (Core) | 98,5 | 97,1 | 97,3 | 95,7 | 95,8 | 130 |
| 10. | Power Transformer T1 (Winding) | 99,8 | 99,0 | 99,2 | 97,8 | 98,2 | 130 |
| 11. | Rectifier Diode D100 | 95,9 | 94,5 | 94,7 | 93,5 | 93,7 | 130 |
| 12. | Rectifier Diode D101 | 91,8 | 91,0 | 91,0 | 90,4 | 90,5 | 130 |
| 13. | Output Choke L100 (winding) | 98,6 | 97,8 | 97,9 | 96,4 | 96,2 | 130 |
| 14. | Output Bulk C105 | 82,7 | 82,5 | 82,5 | 81,7 | 81,1 | 105 |
| 15. | Thermistor RTH2 | 91,8 | 90,9 | 90,8 | 90,4 | 90,3 | 125 |
| Outpu | ut load: | | 3 | ,35A @12 | 2V | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | | Р |
|--------|---|--|-----------|-------------------------|-------------------------|-------|-----|
| | Supply voltage (V~): | 90 | 90 | 100 | 100 | 200 | _ |
| | Frequency (Hz): | 50 | 60 | 50 | 60 | 50 | |
| | Ambient Tmin (°C): | 53,5 | 53,5 | 53,5 | 53,5 | 53,5 | |
| | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | 55,0 | 55,0 | |
| Maxir | mum measured temperature T of part/at:: | m measured temperature T of part/at:: T (°C) | | | Allowed Tmax (°C) | | |
| | GT(M)91110P24012-F(W)-S | or -HIOX | XX or -HO | DXXX or | HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 78,5 | 78,6 | 77,0 | 77,3 | 70,3 | 130 |
| 2. | Input Choke LF2 (Winding) | 76,6 | 76,9 | 74,9 | 75,0 | 68,0 | 130 |
| 3. | Diode Bridge BD1 | 96,9 | 97,2 | 95,4 | 95,5 | 85,0 | 130 |
| 4. | PFC Choke L1 (Winding) | 121,3 | 121,3 | 121,7 | 121,7 | 116,0 | 155 |
| 5. | PFC Transistor Q1 | 106,2 | 106,0 | 105,8 | 105,8 | 99,3 | 130 |
| 6. | PFC Diode D1 | 106,6 | 106,8 | 106,4 | 106,4 | 99,6 | 130 |
| 7. | Bulk C1 | 84,8 | 84,1 | 84,3 | 84,3 | 81,7 | 105 |
| 8. | Switching Transistor Q3 | 106,9 | 107,1 | 106,6 | 106,8 | 100,0 | 130 |
| 9. | Power Transformer T1 (Core) | 99,2 | 93,2 | 92,8 | 92,9 | 90,1 | 130 |
| 10. | Power Transformer T1 (Winding) | 99,3 | 99,4 | 99,1 | 99,2 | 96,0 | 130 |
| 11. | Rectifier Diode D100 | 100,7 | 100,9 | 100,9 | 101,0 | 99,6 | 130 |
| 12. | Rectifier Diode D101 | 98,1 | 98,1 | 98,2 | 98,2 | 97,3 | 130 |
| 13. | Output Choke L100 (winding) | 102,1 | 102,2 | 102,2 | 102,2 | 100,9 | 130 |
| 14. | Output Bulk C105 | 86,4 | 86,3 | 86,4 | 86,5 | 85,8 | 105 |
| 15. | Thermistor RTH2 | 97,9 | 98,0 | 97,9 | 98,1 | 96,7 | 125 |
| Outp | ut load: | | 6 | ,2 <mark>5A @1</mark> 2 | 2V | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | TABLE: Excessive temperatures in | | IENT | | | | Р |
|--------|--|----------|----------|-----------|-------------------------|-------|-----|
| | Supply voltage (V~): | 200 | 240 | 240 | 264 | 264 | — |
| | Frequency (Hz): | 60 | 50 | 60 | 50 | 60 | _ |
| | Ambient Tmin (°C): | 53,5 | 53,5 | 53,5 | 54,0 | 53,5 | |
| | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | 55,0 | 55,0 | _ |
| Maxim | Maximum measured temperature T of part/at:: T (°C) | | | | Allowed Tmax (°C) | | |
| | GT(M)91110P24012-F(W)-S | or -HIOX | XX or -H | OXXX or · | HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 70,3 | 68,1 | 68,3 | 66,0 | 66,3 | 130 |
| 2. | Input Choke LF2 (Winding) | 68,1 | 66,5 | 66,6 | 65,1 | 65,5 | 130 |
| 3. | Diode Bridge BD1 | 85,3 | 81,2 | 81,2 | 77,4 | 77,5 | 130 |
| 4. | PFC Choke L1 (Winding) | 116,1 | 107,1 | 107,3 | 101,1 | 101,5 | 155 |
| 5. | PFC Transistor Q1 | 99,5 | 95,5 | 95,7 | 92,5 | 92,8 | 130 |
| 6. | PFC Diode D1 | 99,8 | 95,2 | 95,2 | 92,0 | 92,2 | 130 |
| 7. | Bulk C1 | 81,7 | 79,8 | 79,9 | 78,8 | 78,7 | 105 |
| 8. | Switching Transistor Q3 | 100,2 | 95,7 | 95,8 | 93,2 | 93,4 | 130 |
| 9. | Power Transformer T1 (Core) | 90,1 | 88,5 | 88,6 | 87,6 | 87,7 | 130 |
| 10. | Power Transformer T1 (Winding) | 96,1 | 94,0 | 94,0 | 92,7 | 92,9 | 130 |
| 11. | Rectifier Diode D100 | 99,6 | 98,6 | 98,7 | 96,8 | 97,1 | 130 |
| 12. | Rectifier Diode D101 | 97,3 | 96,0 | 96,1 | 94,3 | 94,5 | 130 |
| 13. | Output Choke L100 (winding) | 101,0 | 100,0 | 100,0 | 98,1 | 98,3 | 130 |
| 14. | Output Bulk C105 | 85,9 | 85,2 | 85,5 | 83,2 | 83,4 | 105 |
| 15. | Thermistor RTH2 | 96,7 | 95,7 | 95,8 | 94,1 | 94,5 | 125 |
| Outpu | it load: | | 6 | ,25A @12 | V | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1. | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | | Р |
|-------|---|-----------|----------|---------|----------|-------|-------------------------|
| | Supply voltage (V~) | 90 | 100 | 100 | 200 | 200 | _ |
| | Frequency (Hz) | 50 | 50 | 60 | 50 | 60 | |
| | Ambient Tmin (°C): | 52,7 | 52,7 | 52,7 | 52,7 | 52,6 | |
| | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | 55,0 | 55,0 | |
| Maxii | mum measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-C(W)· | S or -HIC | XXX or - | ΗΟΧΧΧ ο | r –HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 84,5 | 83,2 | 83,9 | 78,2 | 78,2 | 130 |
| 2. | Input Choke LF2 (Winding) | 88,4 | 87,5 | 87,8 | 81,2 | 81,3 | 130 |
| 3. | Diode Bridge BD1 | 108,6 | 107,3 | 107,7 | 95,4 | 95,6 | 130 |
| 4. | PFC Choke L1 (Winding) | 130,6 | 131,2 | 131,6 | 115,6 | 115,6 | 155 |
| 5. | PFC Transistor Q1 | 121,5 | 119,6 | 120,9 | 105,5 | 105,5 | 130 |
| 6. | PFC Diode D1 | 117,8 | 116,4 | 117,8 | 104,0 | 104,0 | 130 |
| 7. | Bulk C1 | 96,7 | 96,7 | 96,9 | 91,3 | 91,3 | 105 |
| 8. | Switching Transistor Q3 | 120,5 | 115,7 | 120,2 | 103,5 | 103,5 | 130 |
| 9. | Power Transformer T1 (Core) | 98,5 | 98,3 | 98,8 | 95,0 | 95,0 | 130 |
| 10. | Power Transformer T1 (Winding) | 100,6 | 100,4 | 100,9 | 96,9 | 96,9 | 130 |
| 11. | Rectifier Diode D100 | 86,7 | 87,8 | 88,1 | 86,6 | 86,6 | 130 |
| 12. | Rectifier Diode D101 | 85,0 | 86,1 | 86,3 | 85,1 | 85,2 | 130 |
| 13. | Output Choke L100 (winding) | 100,2 | 101,8 | 102,2 | 100,7 | 100,8 | 130 |
| 14. | Output Bulk C105 | 82,5 | 83,2 | 83,5 | 82,7 | 82,7 | 105 |
| 15. | Thermistor RTH2 | 83,8 | 84,3 | 84,9 | 83,3 | 83,3 | 125 |
| Outp | ut load: | | 0, | 7A@55V | dc | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | 1 TABLE: Excessive temperatures in | | IENT | | | Р |
|--------|---|------------|-----------|---------|-----------|-------------------------|
| | Supply voltage (V~): | 240 | 240 | 264 | 264 | _ |
| | Frequency (Hz): | 50 | 60 | 50 | 60 | _ |
| | Ambient Tmin (°C): | 52,7 | 52,8 | 52,8 | 52,8 | |
| | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | 55,0 | |
| Maxii | mum measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-C(W) | -S or -HIC | OXXX or - | HOXXX o | or –HIXXX | |
| 1. | Input Choke LF1 (Winding) | 78,9 | 78,9 | 77,9 | 78,0 | 130 |
| 2. | Input Choke LF2 (Winding) | 81,9 | 81,8 | 80,6 | 80,7 | 130 |
| 3. | Diode Bridge BD1 | 96,1 | 96,3 | 93,9 | 93,9 | 130 |
| 4. | PFC Choke L1 (Winding) | 118,1 | 118,1 | 113,6 | 113,7 | 155 |
| 5. | PFC Transistor Q1 | 110,1 | 110,1 | 107,7 | 107,9 | 130 |
| 6. | PFC Diode D1 | 108,0 | 108,0 | 105,7 | 105,9 | 130 |
| 7. | Bulk C1 | 93,2 | 93,2 | 92,1 | 92,2 | 105 |
| 8. | Switching Transistor Q3 | 107,2 | 107,2 | 105,0 | 105,0 | 130 |
| 9. | Power Transformer T1 (Core) | 96,5 | 96,5 | 95,4 | 95,5 | 130 |
| 10. | Power Transformer T1 (Winding) | 98,4 | 98,5 | 97,3 | 97,5 | 130 |
| 11. | Rectifier Diode D100 | 87,2 | 87,3 | 86,9 | 87,0 | 130 |
| 12. | Rectifier Diode D101 | 85,6 | 85,7 | 85,3 | 85,5 | 130 |
| 13. | Output Choke L100 (winding) | 101,3 | 101,4 | 101,0 | 101,0 | 130 |
| 14. | Output Bulk C105 | 83,0 | 82,9 | 83,0 | 82,9 | 105 |
| 15. | Thermistor RTH2 | 83,9 | 83,6 | 83,6 | 83,7 | 125 |
| Outp | ut load: | | 0, | 7A@55V | dc | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1. | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | | Р |
|-------|---|------------|----------|---------|----------|-------|-------------------------|
| | Supply voltage (V~): | 90 | 90 | 100 | 100 | 200 | _ |
| | Frequency (Hz) | 50 | 60 | 50 | 60 | 50 | _ |
| | Ambient Tmin (°C): | 52,8 | 53,0 | 53,0 | 52,9 | 53,0 | |
| | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | 55,0 | 55,0 | |
| Maxi | mum measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-F(W) | -S or -HIC | XXX or - | ΗΟΧΧΧ ο | r –HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 79,7 | 79,6 | 77,2 | 77,4 | 71,0 | 130 |
| 2. | Input Choke LF2 (Winding) | 85,7 | 85,8 | 83,4 | 83,7 | 77,2 | 130 |
| 3. | Diode Bridge BD1 | 105,3 | 105,3 | 103,5 | 103,6 | 94,0 | 130 |
| 4. | PFC Choke L1 (Winding) | 124,2 | 124,0 | 123,9 | 124,1 | 118,9 | 155 |
| 5. | PFC Transistor Q1 | 112,4 | 112,4 | 111,2 | 111,6 | 105,2 | 130 |
| 6. | PFC Diode D1 | 110,8 | 110,8 | 109,6 | 109,8 | 104,0 | 130 |
| 7. | Bulk C1 | 85,4 | 85,3 | 84,7 | 84,8 | 81,6 | 105 |
| 8. | Switching Transistor Q3 | 113,4 | 113,2 | 112,4 | 112,5 | 106,3 | 130 |
| 9. | Power Transformer T1 (Core) | 97,2 | 97,2 | 96,3 | 96,5 | 93,6 | 130 |
| 10. | Power Transformer T1 (Winding) | 97,2 | 97,1 | 96,4 | 96,4 | 94,6 | 130 |
| 11. | Rectifier Diode D100 | 90,5 | 90,3 | 90,2 | 90,5 | 89,7 | 130 |
| 12. | Rectifier Diode D101 | 88,6 | 88,4 | 88,2 | 88,3 | 87,9 | 130 |
| 13. | Output Choke L100 (winding) | 104,1 | 104,0 | 104,0 | 104,1 | 103,6 | 130 |
| 14. | Output Bulk C105 | 79,1 | 79,0 | 79,0 | 79,1 | 78,9 | 105 |
| 15. | Thermistor RTH2 | 86,7 | 86,6 | 86,4 | 86,6 | 86,1 | 125 |
| Outp | ut load: | | 1,3 | 36A@55V | /dc | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | TABLE: Excessive temperatures in | | IENT | | | | Р |
|---|----------------------------------|------------|----------|---------|----------|-------|-------------------------|
| | Supply voltage (V~): | 200 | 240 | 240 | 264 | 264 | _ |
| | Frequency (Hz): | 60 | 50 | 60 | 50 | 60 | _ |
| | Ambient Tmin (°C): | 52,9 | 52,9 | 53,0 | 52,8 | 52,9 | _ |
| | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | 55,0 | 55,0 | |
| Maximum measured temperature T of part/at:: | | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-F(W) | -S or -HIC | XXX or - | HOXXX o | r –HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 71,1 | 69,3 | 69,3 | 67,6 | 68,1 | 130 |
| 2. | Input Choke LF2 (Winding) | 77,5 | 74,4 | 74,7 | 72,2 | 73,0 | 130 |
| 3. | Diode Bridge BD1 | 94,2 | 89,4 | 89,4 | 86,0 | 86,6 | 130 |
| 4. | PFC Choke L1 (Winding) | 119,3 | 111,2 | 111,0 | 106,5 | 107,1 | 155 |
| 5. | PFC Transistor Q1 | 105,4 | 101,5 | 101,8 | 99,8 | 100,0 | 130 |
| 6. | PFC Diode D1 | 104,2 | 100,4 | 100,2 | 98,3 | 99,1 | 130 |
| 7. | Bulk C1 | 82,1 | 80,2 | 80,5 | 79,9 | 80,0 | 105 |
| 8. | Switching Transistor Q3 | 106,5 | 102,7 | 102,7 | 100,9 | 101,3 | 130 |
| 9. | Power Transformer T1 (Core) | 93,7 | 92,1 | 92,0 | 91,2 | 92,1 | 130 |
| 10. | Power Transformer T1 (Winding) | 94,9 | 93,3 | 93,1 | 92,2 | 92,6 | 130 |
| 11. | Rectifier Diode D100 | 89,9 | 89,3 | 89,1 | 89,0 | 89,0 | 130 |
| 12. | Rectifier Diode D101 | 87,9 | 87,5 | 87,7 | 87,2 | 87,4 | 130 |
| 13. | Output Choke L100 (winding) | 103,7 | 103,4 | 103,6 | 103,1 | 103,4 | 130 |
| 14. | Output Bulk C105 | 78,9 | 78,8 | 78,8 | 78,6 | 78,6 | 105 |
| 15. | Thermistor RTH2 | 86,3 | 85,7 | 85,6 | 85,2 | 85,5 | 125 |
| Outpu | ut load: | | 1,3 | 86A@55V | dc | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | | Р |
|--------|---|-----------|-----------|----------|--------|-------|-------------------------|
| | Supply voltage (V~): | 90 | 90 | 100 | 200 | 200 | _ |
| | Frequency (Hz): | 50 | 60 | 60 | 50 | 60 | |
| | Ambient Tmin (°C): | 27,8 | 27,7 | 28,3 | 27,8 | 28,1 | |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | 40,0 | 40,0 | |
| Maxir | mum measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24012-CA(W)- | S or -HIO | XXX or -H | OXXX or | -HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 106,8 | 107,8 | 94,9 | 61,2 | 61,3 | 130 |
| 2. | Input Choke LF2 (Winding) | 91,1 | 91,9 | 83,1 | 57,7 | 56,5 | 130 |
| 3. | Diode Bridge BD1 | 88,6 | 87,7 | 83,3 | 61,9 | 61,5 | 130 |
| 4. | PFC Choke L1 (Winding) | 73,3 | 73,0 | 71,5 | 63,7 | 64,1 | 155 |
| 5. | PFC Transistor Q1 | 81,4 | 81,6 | 78,7 | 68,4 | 68,4 | 130 |
| 6. | PFC Diode D1 | 58,8 | 58,5 | 57,9 | 54,3 | 55,1 | 130 |
| 7. | Bulk C1 | 56,8 | 56,9 | 56,3 | 53,5 | 54,7 | 105 |
| 8. | Switching Transistor Q3 | 70,9 | 71,5 | 69,9 | 64,5 | 64,5 | 130 |
| 9. | Power Transformer T1 (Core) | 80,5 | 81,3 | 80,5 | 78,6 | 78,0 | 130 |
| 10. | Power Transformer T1 (Winding) | 85,0 | 85,8 | 85,0 | 83,1 | 82,4 | 130 |
| 11. | Rectifier Diode D100 | 82,3 | 83,3 | 82,2 | 80,9 | 80,2 | 130 |
| 12. | Rectifier Diode D101 | 101,7 | 102,5 | 101,8 | 100,4 | 101,0 | 130 |
| 13. | Output Choke L100 (winding) | 90,1 | 89,4 | 90,3 | 89,0 | 89,1 | 130 |
| 14. | Output Bulk C105 | 74,8 | 74,7 | 74,8 | 73,6 | 73,5 | 105 |
| 15. | Thermistor RTH2 | 95,6 | 95,8 | 95,5 | 94,6 | 95,6 | 125 |
| Outp | ut load: | | 16 | 6,67A @1 | 2V | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1. | 1 TABLE: Excessive temperatures in | | IENT | | | Р |
|---|------------------------------------|----------------|-----------|----------|--------|-------------------------|
| | Supply voltage (V~): | 264 | 264 | | | _ |
| | Frequency (Hz): | 50 | 60 | | | _ |
| | Ambient Tmin (°C): | 26,8 | 27,2 | | | |
| | Ambient Tmax (°C): | 40,0 | 40,0 | | | |
| Maximum measured temperature T of part/at:: | | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24012-CA(W)- | S or -HIO | XXX or -H | IOXXX or | -HIXXX | |
| 1. | Input Choke LF1 (Winding) | 55,5 | 55,2 | | | 130 |
| 2. | Input Choke LF2 (Winding) | 52,9 | 51,0 | | | 130 |
| 3. | Diode Bridge BD1 | 56,4 | 57,6 | | | 130 |
| 4. | PFC Choke L1 (Winding) | 57,8 | 57,8 | | | 155 |
| 5. | PFC Transistor Q1 | 65,0 | 65,8 | | | 130 |
| 6. | PFC Diode D1 | 52,6 | 51,3 | | | 130 |
| 7. | Bulk C1 | 52,5 | 50,9 | | | 105 |
| 8. | Switching Transistor Q3 | 62,4 | 61,6 | | | 130 |
| 9. | Power Transformer T1 (Core) | 77,8 | 78,4 | | | 130 |
| 10. | Power Transformer T1 (Winding) | 82,3 | 83,1 | | | 130 |
| 11. | Rectifier Diode D100 | 80,6 | 81,9 | | | 130 |
| 12. | Rectifier Diode D101 | 100,1 | 101,4 | | | 130 |
| 13. | Output Choke L100 (winding) | 88,6 | 87,6 | | | 130 |
| 14. | Output Bulk C105 | 73,4 | 71,0 | | | 105 |
| 15. | Thermistor RTH2 | 94,6 | 96,1 | | | 125 |
| Outp | ut load: | 16,67 <i>A</i> | @12V | | | |
| | | | | | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1. | 1 TABLE: Excessive temperatures in | ME EQUIP | IENT | | | | Р |
|-------|---|-----------|-----------|----------|--------|---|-------------------------|
| | Supply voltage (V~) | 90 | 90 | 200 | 200 | | |
| | Frequency (Hz) | 50 | 60 | 50 | 60 | | |
| | Ambient Tmin (°C) | 24,7 | 24,5 | 24,8 | 24,8 | | |
| | Ambient Tmax (°C) | 40,0 | 40,0 | 40,0 | 40,0 | | |
| Maxi | mum measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24012-FA(W)- | S or -HIO | XXX or -H | OXXX or | -HIXXX | • | |
| 1. | Input Choke LF1 (Winding) | 107,9 | 108,5 | 62,9 | 62,8 | | 130 |
| 2. | Input Choke LF2 (Winding) | 112,8 | 113,4 | 59,3 | 59,2 | | 130 |
| 3. | Diode Bridge BD1 | 128,9 | 129,0 | 85,7 | 85,3 | | 130 |
| 4. | PFC Choke L1 (Winding) | 120,5 | 120,6 | 96,7 | 96,5 | | 155 |
| 5. | PFC Transistor Q1 | 86,6 | 86,7 | 74,5 | 75,0 | | 130 |
| 6. | PFC Diode D1 | 91,1 | 91,2 | 77,1 | 77,2 | | 130 |
| 7. | Bulk C1 | 78,6 | 78,6 | 74,5 | 74,6 | | 105 |
| 8. | Switching Transistor Q3 | 81,3 | 81,4 | 69,5 | 69,5 | | 130 |
| 9. | Power Transformer T1 (Core) | 52,6 | 52,7 | 51,5 | 51,5 | | 130 |
| 10. | Power Transformer T1 (Winding) | 65,5 | 65,6 | 64,2 | 64,0 | | 130 |
| 11. | Rectifier Diode D100 | 100,3 | 101,0 | 100,1 | 101,1 | | 130 |
| 12. | Rectifier Diode D101 | 95,4 | 95,7 | 95,2 | 96,2 | | 130 |
| 13. | Output Choke L100 (winding) | 123,7 | 123,8 | 121,9 | 123,2 | | 130 |
| 14. | Output Bulk C105 | 90,2 | 90,3 | 89,9 | 90,1 | | 105 |
| 15. | Thermistor RTH2 | 107,9 | 108,5 | 85,8 | 86,0 | | 125 |
| Outp | ut load: | | 2 | 0,0A @12 | 2V | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | 1 TABLE: Excessive temperatures in | ME EQUIPI | IENT | | | | Р |
|--------|---|------------|-----------|---------|--------|---|-------------------------|
| | Supply voltage (V~) | 264 | 264 | | | | _ |
| | Frequency (Hz) | : 50 | 60 | | | | _ |
| | Ambient Tmin (°C) | 24,6 | 24,6 | | | | _ |
| | Ambient Tmax (°C) | 40,0 | 40,0 | | | | _ |
| Maxir | num measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24012-FA(W) | -S or -HIO | XXX or -H | OXXX or | -HIXXX | • | |
| 1. | Input Choke LF1 (Winding) | 57,4 | 57,3 | | | | 130 |
| 2. | Input Choke LF2 (Winding) | 54,0 | 54,2 | | | | 130 |
| 3. | Diode Bridge BD1 | 75,8 | 75,7 | | | | 130 |
| 4. | PFC Choke L1 (Winding) | 86,5 | 86,5 | | | | 155 |
| 5. | PFC Transistor Q1 | 71,8 | 72,0 | | | | 130 |
| 6. | PFC Diode D1 | 73,6 | 73,6 | | | | 130 |
| 7. | Bulk C1 | 72,8 | 72,8 | | | | 105 |
| 8. | Switching Transistor Q3 | 66,8 | 66,7 | | | | 130 |
| 9. | Power Transformer T1 (Core) | 51,3 | 51,2 | | | | 130 |
| 10. | Power Transformer T1 (Winding) | 63,6 | 63,3 | | | | 130 |
| 11. | Rectifier Diode D100 | 98,6 | 98,1 | | | | 130 |
| 12. | Rectifier Diode D101 | 94,0 | 94,1 | | | | 130 |
| 13. | Output Choke L100 (winding) | 119,9 | 120,2 | | | | 130 |
| 14. | Output Bulk C105 | 88,7 | 88,6 | | | | 105 |
| 15. | Thermistor RTH2 | 85,6 | 85,3 | | | | 125 |
| Outpu | ut load: | 20,0A | @12V | | | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1. | 1 TABLE: Excessive temperatures in | ME EQUIPM | IENT | | | | Р |
|---|------------------------------------|-------------|---------|---------|----------|------|-------------------------|
| | Supply voltage (V~) | 90 | 90 | 100 | 200 | 200 | _ |
| | Frequency (Hz) | 50 | 60 | 60 | 50 | 60 | _ |
| | Ambient Tmin (°C) | 27,7 | 27,5 | 27,5 | 27,8 | 27,4 | |
| | Ambient Tmax (°C) | 40,0 | 40,0 | 40,0 | 40,0 | 40,0 | |
| Maximum measured temperature T of part/at:: | | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-CA(V | /)-S or -HI | OXXX or | -HOXXX | or –HIXX | x | |
| 1. | Input Choke LF1 (Winding) | 106,1 | 106,5 | 80,7 | 64,5 | 64,8 | 130 |
| 2. | Input Choke LF2 (Winding) | 92,9 | 93,6 | 74,1 | 60,7 | 60,8 | 130 |
| 3. | Diode Bridge BD1 | 79,0 | 79,8 | 69,2 | 59,5 | 59,8 | 130 |
| 4. | PFC Choke L1 (Winding) | 86,1 | 86,7 | 81,4 | 76,1 | 76,7 | 155 |
| 5. | PFC Transistor Q1 | 68,5 | 68,6 | 64,7 | 61,2 | 60,8 | 130 |
| 6. | PFC Diode D1 | 50,9 | 50,9 | 49,5 | 48,1 | 48,2 | 130 |
| 7. | Bulk C1 | 48,9 | 48,9 | 47,9 | 46,6 | 47,9 | 105 |
| 8. | Switching Transistor Q3 | 73,9 | 73,8 | 70,2 | 66,7 | 67,8 | 130 |
| 9. | Power Transformer T1 (Core) | 77,8 | 77,5 | 76,5 | 75,0 | 76,2 | 130 |
| 10. | Power Transformer T1 (Winding) | 81,9 | 82,2 | 80,5 | 79,1 | 80,1 | 130 |
| 11. | Rectifier Diode D100 | 80,9 | 80,8 | 80,2 | 79,1 | 80,3 | 130 |
| 12. | Rectifier Diode D101 | 84,5 | 85,0 | 83,8 | 82,5 | 83,2 | 130 |
| 13. | Output Choke L100 (winding) | 77,4 | 78,0 | 76,8 | 75,8 | 76,5 | 130 |
| 14. | Output Bulk C105 | 69,3 | 69,9 | 68,7 | 67,6 | 67,8 | 105 |
| 15. | Thermistor RTH2 | 78,1 | 78,5 | 77,5 | 76,2 | 76,8 | 125 |
| Outp | ut load: | | 3,6 | 64A@55V | /dc | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | TABLE: Excessive temperatures in | | IENT | | | | Р |
|--------|---|------------|---------|--------|----------|---|-------------------------|
| | Supply voltage (V~): | 264 | 264 | | | | _ |
| | Frequency (Hz): | 50 | 60 | | | | |
| | Ambient Tmin (°C): | 26,7 | 27,1 | | | | |
| | Ambient Tmax (°C): | 40,0 | 40,0 | | | | |
| Maxin | num measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-CA(W |)-S or -HI | OXXX or | -HOXXX | or –HIXX | X | |
| 1. | Input Choke LF1 (Winding) | 60,7 | 59,9 | | | | 130 |
| 2. | Input Choke LF2 (Winding) | 56,9 | 55,7 | | | | 130 |
| 3. | Diode Bridge BD1 | 55,5 | 55,8 | | | | 130 |
| 4. | PFC Choke L1 (Winding) | 69,2 | 68,4 | | | | 155 |
| 5. | PFC Transistor Q1 | 59,0 | 56,8 | | | | 130 |
| 6. | PFC Diode D1 | 47,4 | 47,5 | | | | 130 |
| 7. | Bulk C1 | 46,3 | 46,9 | | | | 105 |
| 8. | Switching Transistor Q3 | 64,5 | 65,1 | | | | 130 |
| 9. | Power Transformer T1 (Core) | 74,7 | 74,2 | | | | 130 |
| 10. | Power Transformer T1 (Winding) | 78,5 | 78,6 | | | | 130 |
| 11. | Rectifier Diode D100 | 78,7 | 80,4 | | | | 130 |
| 12. | Rectifier Diode D101 | 82,3 | 83,9 | | | | 130 |
| 13. | Output Choke L100 (winding) | 75,5 | 75,2 | | | | 130 |
| 14. | Output Bulk C105 | 67,2 | 66,6 | | | | 105 |
| 15. | Thermistor RTH2 | 76,1 | 77,0 | | | | 125 |
| Ou | tput load: | 3,64A@ | 055Vdc | | | | |
| | | | | | | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | TABLE: Excessive temperatures in | ME EQUIPI | IENT | | | | Р |
|--------|---|-----------|---------|----------|-----------|---|-------------------------|
| | Supply voltage (V~): | 90 | 90 | 200 | 200 | | |
| | Frequency (Hz) | 50 | 60 | 50 | 60 | | |
| | Ambient Tmin (°C): | 23,7 | 23,7 | 23,6 | 23,7 | | |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | 40,0 | | |
| Maxim | Maximum measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-FA(W) | -S or -HI | OXXX or | -HOXXX (| or –HIXXX | x | |
| 1. | Input Choke LF1 (Winding) | 80,5 | 80,9 | 50,3 | 50,7 | | 130 |
| 2. | Input Choke LF2 (Winding) | 78,8 | 79,0 | 53,9 | 54,3 | | 130 |
| 3. | Diode Bridge BD1 | 97,1 | 97,4 | 69,7 | 69,7 | | 130 |
| 4. | PFC Choke L1 (Winding) | 100,7 | 100,8 | 84,6 | 84,6 | | 155 |
| 5. | PFC Transistor Q1 | 74,5 | 74,8 | 66,1 | 66,0 | | 130 |
| 6. | PFC Diode D1 | 79,2 | 79,2 | 69,7 | 70,0 | | 130 |
| 7. | Bulk C1 | 67,7 | 67,9 | 63,0 | 62,9 | | 105 |
| 8. | Switching Transistor Q3 | 65,8 | 66,0 | 59,8 | 59,8 | | 130 |
| 9. | Power Transformer T1 (Core) | 63,5 | 63,6 | 61,0 | 61,4 | | 130 |
| 10. | Power Transformer T1 (Winding) | 65,3 | 65,3 | 64,3 | 64,9 | | 130 |
| 11. | Rectifier Diode D100 | 75,1 | 75,4 | 74,5 | 74,5 | | 130 |
| 12. | Rectifier Diode D101 | 80,2 | 80,2 | 79,4 | 79,3 | | 130 |
| 13. | Output Choke L100 (winding) | 99,0 | 99,2 | 97,4 | 97,3 | | 130 |
| 14. | Output Bulk C105 | 65,3 | 65,3 | 64,9 | 65,0 | | 105 |
| 15. | Thermistor RTH2 | 80,5 | 80,9 | 67,1 | 67,2 | | 125 |
| Outpu | it load: | | 4,3 | 36A@55V | /dc | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | | TABLE: Excessive temperatures in r | ME EQUIPN | IENT | | | | Р |
|---|--------|------------------------------------|-----------|---------|----------|-----------|-------------------------|-----|
| | | Supply voltage (V~): | 264 | 264 | | | | |
| | | Frequency (Hz): | 50 | 60 | | | | |
| | | Ambient Tmin (°C): | 24,0 | 24,0 | | | | |
| | | Ambient Tmax (°C): | 40,0 | 40,0 | | | | |
| Maximum measured temperature T of part/at:: | | | | T (°C) | | | Allowed Tmax (°C) | |
| | | GT(M)91110P24055-X.X-FA(W) | -S or -HI | OXXX or | -HOXXX (| or –HIXXX | (| |
| 1. | Inpu | it Choke LF1 (Winding) | 47,7 | 47,7 | | | | 130 |
| 2. | Inpu | it Choke LF2 (Winding) | 51,0 | 51,0 | | | | 130 |
| 3. | Diod | de Bridge BD1 | 63,9 | 64,1 | | | | 130 |
| 4. | PFC | Choke L1 (Winding) | 77,3 | 77,5 | | | | 155 |
| 5. | PFC | Transistor Q1 | 64,3 | 64,3 | | | | 130 |
| 6. | PFC | Diode D1 | 67,3 | 67,5 | | | | 130 |
| 7. | Bull | « C1 | 61,7 | 61,8 | | | | 105 |
| 8. | Swit | tching Transistor Q3 | 58,6 | 58,9 | | | | 130 |
| 9. | Pow | ver Transformer T1 (Core) | 60,6 | 60,6 | | | | 130 |
| 10. | Pow | ver Transformer T1 (Winding) | 63,9 | 63,9 | | | | 130 |
| 11. | Rec | tifier Diode D100 | 74,1 | 74,2 | | | | 130 |
| 12. | Rec | tifier Diode D101 | 79,4 | 79,4 | | | | 130 |
| 13. | Out | put Choke L100 (winding) | 97,3 | 97,3 | | | | 130 |
| 14. | Out | put Bulk C105 | 65,0 | 65,2 | | | | 105 |
| 15. | The | rmistor RTH2 | 67,0 | 66,8 | | | | 125 |
| Outpu | ut loa | d: | | 4,3 | 36A@55V | dc | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1. | TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | Р |
|-------|---|-----------|-----------|----------|--------|-------------------------|
| | Supply voltage (V~): | 90 | 90 | 200 | 200 | |
| | Frequency (Hz): | 50 | 60 | 50 | 60 | |
| | Ambient Tmin (°C): | 59,8 | 59,8 | 59,9 | 59,9 | |
| | Ambient Tmax (°C): | 70,0 | 70,0 | 70,0 | 70,0 | |
| Maxii | Maximum measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24012-CA(W)-S | or -HIO | XXX or -H | OXXX or | -HIXXX | |
| 1. | Input Choke LF1 (Winding) | 103,9 | 104,2 | 89,8 | 89,8 | 130 |
| 2. | Input Choke LF2 (Winding) | 106,1 | 106,2 | 92,3 | 92,4 | 130 |
| 3. | Diode Bridge BD1 | 119,3 | 119,6 | 103,9 | 103,9 | 130 |
| 4. | PFC Choke L1 (Winding) | 117,6 | 117,6 | 112,8 | 112,8 | 155 |
| 5. | PFC Transistor Q1 | 112,6 | 112,8 | 104,2 | 104,4 | 130 |
| 6. | PFC Diode D1 | 107,2 | 107,2 | 101,3 | 101,4 | 130 |
| 7. | Bulk C1 | 102,3 | 102,5 | 98,1 | 98,1 | 105 |
| 8. | Switching Transistor Q3 | 99,2 | 99,3 | 95,7 | 95,7 | 130 |
| 9. | Power Transformer T1 (Core) | 86,4 | 86,4 | 86,1 | 86,3 | 130 |
| 10. | Power Transformer T1 (Winding) | 91,2 | 91,2 | 90,9 | 91,1 | 130 |
| 11. | Rectifier Diode D100 | 104,6 | 104,7 | 103,8 | 104,0 | 130 |
| 12. | Rectifier Diode D101 | 103,2 | 103,3 | 102,8 | 102,9 | 130 |
| 13. | Output Choke L100 (winding) | 117,6 | 118,0 | 116,4 | 116,7 | 130 |
| 14. | Output Bulk C105 | 101,2 | 101,4 | 100,7 | 101,0 | 105 |
| 15. | Thermistor RTH2 | 98,4 | 98,6 | 98,3 | 98,3 | 125 |
| Outp | ut load: | | 8 | ,34A @12 | V | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1. | 1 TABLE: Excessive temperatures in | | IENT | | | Р |
|-------|---|-----------|-----------|----------|--------|-------------------------|
| | Supply voltage (V~): | 264 | 264 | | | |
| | Frequency (Hz): | 50 | 60 | | | |
| | Ambient Tmin (°C): | 59,8 | 59,8 | | | |
| | Ambient Tmax (°C): | 70,0 | 70,0 | | | |
| Maxi | mum measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24012-CA(W)-\$ | S or -HIO | XXX or -H | IOXXX or | -HIXXX | |
| 1. | Input Choke LF1 (Winding) | 86,8 | 86,8 | | | 130 |
| 2. | Input Choke LF2 (Winding) | 88,6 | 88,7 | | | 130 |
| 3. | Diode Bridge BD1 | 98,0 | 98,2 | | | 130 |
| 4. | PFC Choke L1 (Winding) | 104,3 | 104,5 | | | 155 |
| 5. | PFC Transistor Q1 | 99,5 | 100,0 | | | 130 |
| 6. | PFC Diode D1 | 97,5 | 97,7 | | | 130 |
| 7. | Bulk C1 | 96,0 | 96,2 | | | 105 |
| 8. | Switching Transistor Q3 | 93,1 | 93,2 | | | 130 |
| 9. | Power Transformer T1 (Core) | 85,7 | 85,7 | | | 130 |
| 10. | Power Transformer T1 (Winding) | 90,4 | 90,6 | | | 130 |
| 11. | Rectifier Diode D100 | 103,7 | 103,7 | | | 130 |
| 12. | Rectifier Diode D101 | 103,1 | 103,2 | | | 130 |
| 13. | Output Choke L100 (winding) | 116,3 | 117,0 | | | 130 |
| 14. | Output Bulk C105 | 100,5 | 100,8 | | | 105 |
| 15. | Thermistor RTH2 | 98,7 | 98,9 | | | 125 |
| Outp | ut load: | 8,34A | @12V | | | |
| | | | | | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | TABLE: Excessive temperatures in r | ME EQUIPN | IENT | | | | Р |
|--------|---|-----------|-----------|----------|--------|---|-------------------------|
| | Supply voltage (V~): | 90 | 90 | 200 | 200 | | _ |
| | Frequency (Hz): | 50 | 60 | 50 | 60 | | _ |
| | Ambient Tmin (°C): | 60,0 | 60,0 | 60,0 | 60,0 | | |
| | Ambient Tmax (°C): | 70,0 | 70,0 | 70,0 | 70,0 | | _ |
| Maxir | num measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24012-FA(W)-S | or -HIO | XXX or -H | OXXX or | -HIXXX | - | |
| 1. | Input Choke LF1 (Winding) | 95,0 | 95,1 | 82,0 | 82,0 | | 130 |
| 2. | Input Choke LF2 (Winding) | 95,9 | 95,9 | 81,0 | 81,1 | | 130 |
| 3. | 3. Diode Bridge BD1 | | 108,5 | 93,0 | 93,0 | | 130 |
| 4. | PFC Choke L1 (Winding) | 114,4 | 114,4 | 111,6 | 111,7 | | 155 |
| 5. | PFC Transistor Q1 | 95,7 | 95,8 | 91,8 | 92,0 | | 130 |
| 6. | PFC Diode D1 | 96,9 | 96,9 | 92,7 | 92,7 | | 130 |
| 7. | Bulk C1 | 82,6 | 82,6 | 81,0 | 81,0 | | 105 |
| 8. | Switching Transistor Q3 | 94,4 | 94,5 | 91,0 | 91,3 | | 130 |
| 9. | Power Transformer T1 (Core) | 78,6 | 78,6 | 78,2 | 78,2 | | 130 |
| 10. | Power Transformer T1 (Winding) | 84,3 | 84,4 | 83,8 | 83,9 | | 130 |
| 11. | Rectifier Diode D100 | 95,0 | 95,0 | 94,7 | 94,8 | | 130 |
| 12. | Rectifier Diode D101 | 95,4 | 95,4 | 95,0 | 95,0 | | 130 |
| 13. | Output Choke L100 (winding) | 104,8 | 104,8 | 104,1 | 104,2 | | 130 |
| 14. | Output Bulk C105 | 92,2 | 92,2 | 92,0 | 92,0 | | 105 |
| 15. | Thermistor RTH2 | 89,9 | 89,9 | 89,7 | 89,8 | | 125 |
| Outpu | ıt load: | | 1 | 0,0A @12 | V | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| | | | | | | | 1 |
|---|--------|------------------------------------|-----------|-----------|---------|--------|-------------------------|
| 11.1.1 | I | TABLE: Excessive temperatures in I | ME EQUIPM | IENT | | | Р |
| | | Supply voltage (V~): | 264 | 264 | | | _ |
| | | Frequency (Hz): | 50 | 60 | | | _ |
| | | Ambient Tmin (°C): | 60,0 | 60,0 | | | _ |
| | | Ambient Tmax (°C): | 70,0 | 70,0 | | | |
| Maximum measured temperature T of part/at:: | | | | | T (°C) | | Allowed Tmax (°C) |
| | | GT(M)91110P24012-FA(W)-S | or -HIO | (XX or -H | OXXX or | -HIXXX | |
| 1. | Inpu | it Choke LF1 (Winding) | 79,1 | 79,1 | | | 130 |
| 2. | Inpu | it Choke LF2 (Winding) | 78,6 | 78,6 | | | 130 |
| 3. | Diod | de Bridge BD1 | 87,5 | 87,5 | | | 130 |
| 4. | PFC | Choke L1 (Winding) | 101,8 | 101,9 | | | 155 |
| 5. | PFC | Transistor Q1 | 89,0 | 89,0 | | | 130 |
| 6. | PFC | Diode D1 | 89,3 | 89,4 | | | 130 |
| 7. | Bulk | (C1 | 80,0 | 80,0 | | | 105 |
| 8. | Swit | tching Transistor Q3 | 88,1 | 88,3 | | | 130 |
| 9. | Pow | ver Transformer T1 (Core) | 78,0 | 78,1 | | | 130 |
| 10. | Pow | ver Transformer T1 (Winding) | 83,3 | 83,4 | | | 130 |
| 11. | Rec | tifier Diode D100 | 94,1 | 94,3 | | | 130 |
| 12. | Rec | tifier Diode D101 | 94,7 | 94,9 | | | 130 |
| 13. | Out | put Choke L100 (winding) | 103,3 | 103,5 | | | 130 |
| 14. | Out | put Bulk C105 | 91,4 | 91,4 | | | 105 |
| 15. | The | rmistor RTH2 | 89,4 | 89,5 | | | 125 |
| Outpu | ut loa | d: | 10,0A | @12V | | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1. | 1 TABLE: Excessive temperatures in | | IENT | | | | Р |
|-------|---|-------------|---------|--------|----------|---|-------------------------|
| | Supply voltage (V~): | 90 | 90 | 200 | 200 | | |
| | Frequency (Hz): | 50 | 60 | 50 | 60 | | |
| | Ambient Tmin (°C): | 60,1 | 60,2 | 60,2 | 60,2 | | _ |
| | Ambient Tmax (°C): | 70,0 | 70,0 | 70,0 | 70,0 | | _ |
| Maxii | mum measured temperature T of part/at:: | | 1 | T (°C) | 1 | 1 | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-CA(W | /)-S or -HI | OXXX or | -HOXXX | or –HIXX | X | |
| 1. | Input Choke LF1 (Winding) | 102,1 | 102,3 | 89,9 | 90,1 | | 130 |
| 2. | Input Choke LF2 (Winding) | 105,7 | 105,9 | 93,2 | 93,5 | | 130 |
| 3. | 3. Diode Bridge BD1 | | 119,4 | 103,8 | 104,4 | | 130 |
| 4. | PFC Choke L1 (Winding) | 128,5 | 128,7 | 122,7 | 123,2 | | 155 |
| 5. | PFC Transistor Q1 | 111,1 | 111,2 | 104,9 | 105,2 | | 130 |
| 6. | PFC Diode D1 | 105,8 | 105,9 | 100,7 | 100,9 | | 130 |
| 7. | Bulk C1 | 97,2 | 97,2 | 93,8 | 93,9 | | 105 |
| 8. | Switching Transistor Q3 | 101,5 | 101,7 | 97,4 | 97,7 | | 130 |
| 9. | Power Transformer T1 (Core) | 89,0 | 89,0 | 88,0 | 88,1 | | 130 |
| 10. | Power Transformer T1 (Winding) | 96,1 | 96,0 | 94,7 | 94,7 | | 130 |
| 11. | Rectifier Diode D100 | 100,9 | 100,9 | 99,8 | 100,0 | | 130 |
| 12. | Rectifier Diode D101 | 102,7 | 102,6 | 101,6 | 101,8 | | 130 |
| 13. | Output Choke L100 (winding) | 121,8 | 121,9 | 120,2 | 120,3 | | 130 |
| 14. | Output Bulk C105 | 104,9 | 104,8 | 103,8 | 103,8 | | 105 |
| 15. | Thermistor RTH2 | 96,6 | 96,6 | 95,7 | 95,6 | | 125 |
| Outp | ut load: | 1,82A@55Vdc | | | | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| | | | | | | | - |
|--------|---|------------|---------|--------|-----------|---|-------------------------|
| 11.1.1 | TABLE: Excessive temperatures in | | IENT | | | | Р |
| | Supply voltage (V~): | 264 | 264 | | | | |
| | Frequency (Hz): | 50 | 60 | | | | _ |
| | Ambient Tmin (°C): | 60,1 | 60,1 | | | | |
| | Ambient Tmax (°C): | 70,0 | 70,0 | | | | |
| Maxim | num measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-CA(W) |)-S or -HI | OXXX or | -HOXXX | or –HIXXX | X | |
| 1. | Input Choke LF1 (Winding) | 77,2 | 77,3 | | | | 130 |
| 2. | Input Choke LF2 (Winding) | 79,4 | 49,7 | | | | 130 |
| 3. | Diode Bridge BD1 | 87,4 | 87,8 | | | | 130 |
| 4. | PFC Choke L1 (Winding) | 101,4 | 101,7 | | | | 155 |
| 5. | PFC Transistor Q1 | 90,4 | 90,7 | | | | 130 |
| 6. | PFC Diode D1 | 86,9 | 87,2 | | | | 130 |
| 7. | Bulk C1 | 82,0 | 82,2 | | | | 105 |
| 8. | Switching Transistor Q3 | 84,4 | 84,6 | | | | 130 |
| 9. | Power Transformer T1 (Core) | 77,6 | 77,8 | | | | 130 |
| 10. | Power Transformer T1 (Winding) | 84,1 | 84,3 | | | | 130 |
| 11. | Rectifier Diode D100 | 89,4 | 89,6 | | | | 130 |
| 12. | Rectifier Diode D101 | 91,4 | 91,4 | | | | 130 |
| 13. | Output Choke L100 (winding) | 109,5 | 109,5 | | | | 130 |
| 14. | Output Bulk C105 | 93,5 | 93,5 | | | | 105 |
| 15. | Thermistor RTH2 | 85,4 | 85,4 | | | | 125 |
| Ou | tput load: | 1,82A@ | 055Vdc | | | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | | Р |
|--------|---|-------------|---------|---------|-----------|---|-------------------------|
| | Supply voltage (V~): | 90 | 90 | 200 | 200 | | |
| | Frequency (Hz): | 50 | 60 | 50 | 60 | | _ |
| | Ambient Tmin (°C): | 60,0 | 60,0 | 60,3 | 60,3 | | |
| | Ambient Tmax (°C): | 70,0 | 70,0 | 70,0 | 70,0 | | _ |
| Maxim | num measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-FA(W) | -S or -HI | OXXX or | HOXXX o | or –HIXXX | K | |
| 1. | Input Choke LF1 (Winding) | 89,6 | 89,9 | 77,8 | 89,6 | | 130 |
| 2. | Input Choke LF2 (Winding) | 88,7 | 89,0 | 80,8 | 88,7 | | 130 |
| 3. | 3. Diode Bridge BD1 | | 104,8 | 95,8 | 104,2 | | 130 |
| 4. | PFC Choke L1 (Winding) | 109,7 | 110,1 | 110,9 | 109,7 | | 155 |
| 5. | PFC Transistor Q1 | 94,7 | 95,0 | 91,5 | 94,7 | | 130 |
| 6. | PFC Diode D1 | 96,7 | 97,0 | 93,6 | 96,7 | | 130 |
| 7. | Bulk C1 | 83,9 | 84,5 | 81,1 | 83,9 | | 105 |
| 8. | Switching Transistor Q3 | 95,5 | 95,8 | 92,7 | 95,5 | | 130 |
| 9. | Power Transformer T1 (Core) | 84,2 | 84,6 | 82,7 | 84,2 | | 130 |
| 10. | Power Transformer T1 (Winding) | 85,1 | 85,6 | 84,2 | 85,1 | | 130 |
| 11. | Rectifier Diode D100 | 87,2 | 87,6 | 87,0 | 87,2 | | 130 |
| 12. | Rectifier Diode D101 | 90,2 | 90,6 | 90,2 | 90,2 | | 130 |
| 13. | Output Choke L100 (winding) | 106,0 | 106,3 | 105,9 | 106,0 | | 130 |
| 14. | Output Bulk C105 | 86,5 | 86,8 | 87,1 | 86,5 | | 105 |
| 15. | Thermistor RTH2 | 83,9 | 84,2 | 83,4 | 83,9 | | 125 |
| Outpu | it load: | 2,18A@55Vdc | | | | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

| SI Page 138 of 233 F | | | Report No. T | 221-0013/17 | | |
|----------------------|--------------------|-----------------|--------------|-------------|--|--|
| IEC 60601-1 | | | | | | |
| Clause | Requirement + Test | Result - Remark | | Verdict | | |

| 11.1.1 | I | TABLE: Excessive temperatures in | ME EQUIPM | IENT | | | | Р |
|--------|---|----------------------------------|-------------|---------|----------|-----------|---|-------------------------|
| | | Supply voltage (V~): | 264 | 264 | | | | _ |
| | | Frequency (Hz): | 50 | 60 | | | | _ |
| | | Ambient Tmin (°C): | 60,2 | 60,2 | | | | _ |
| | | Ambient Tmax (°C): | 70,0 | 70,0 | | | | _ |
| Maxir | Maximum measured temperature T of part/at:: | | | | T (°C) | | | Allowed Tmax (°C) |
| | | GT(M)91110P24055-X.X-FA(W) |)-S or -HI | OXXX or | -HOXXX (| or –HIXXX | (| |
| 1. | Inpu | t Choke LF1 (Winding) | 76,0 | 76,3 | | | | 130 |
| 2. | Inpu | t Choke LF2 (Winding) | 78,0 | 78,6 | | | | 130 |
| 3. | Dioc | le Bridge BD1 | 89,6 | 89,7 | | | | 130 |
| 4. | PFC | Choke L1 (Winding) | 101,1 | 101,2 | | | | 155 |
| 5. | PFC | Transistor Q1 | 88,5 | 88,7 | | | | 130 |
| 6. | PFC | Diode D1 | 90,3 | 90,3 | | | | 130 |
| 7. | Bulk | « C1 | 80,0 | 80,0 | | | | 105 |
| 8. | Swit | ching Transistor Q3 | 89,8 | 90,3 | | | | 130 |
| 9. | Pow | er Transformer T1 (Core) | 81,6 | 81,8 | | | | 130 |
| 10. | Pow | er Transformer T1 (Winding) | 83,6 | 83,6 | | | | 130 |
| 11. | Rec | tifier Diode D100 | 86,8 | 86,9 | | | | 130 |
| 12. | Rec | tifier Diode D101 | 90,0 | 90,0 | | | | 130 |
| 13. | Out | out Choke L100 (winding) | 105,6 | 105,5 | | | | 130 |
| 14. | Out | out Bulk C105 | 86,9 | 87,4 | | | | 105 |
| 15. | The | rmistor RTH2 | 83,2 | 83,3 | | | | 125 |
| Outp | ut load | d: | 2,18A@55Vdc | | | | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | I TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | Р |
|--------|---|-----------|-------------------|---------|--------|-------------------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | |
| | Ambient Tmin (°C): | 25,7 | 25,0 | 25,0 | | |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | | |
| Maxir | num measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24012-C(W)-S | or -HIOX | XX or -H | OXXX or | -HIXXX | |
| 1. | Input Choke LF1 (Winding) | 77,3 | 73,3 | 69,3 | | 130 |
| 2. | Input Choke LF2 (Winding) | 81,0 | 76,6 | 70,4 | | 130 |
| 3. | Diode Bridge BD1 | 100,7 | 93,5 | 82,4 | | 130 |
| 4. | PFC Choke L1 (Winding) | 118,9 | 119,2 | 101,7 | | 155 |
| 5. | PFC Transistor Q1 | 120,1 | 117,6 | 111,0 | | 130 |
| 6. | PFC Diode D1 | 110,1 | 108,6 | 101,9 | | 130 |
| 7. | Bulk C1 | 95,6 | 94,3 | 90,5 | | 105 |
| 8. | Switching Transistor Q3 | 109,7 | 108,2 | 102,5 | | 130 |
| 9. | Power Transformer T1 (Core) | 98,3 | 97,8 | 95,8 | | 130 |
| 10. | Power Transformer T1 (Winding) | 101,7 | 101,1 | 98,8 | | 130 |
| 11. | Rectifier Diode D100 | 100,1 | 99,8 | 98,5 | | 130 |
| 12. | Rectifier Diode D101 | 95,1 | 95,1 | 93,7 | | 130 |
| 13. | Output Choke L100 (winding) | 99,4 | 99,2 | 97,9 | | 130 |
| 14. | Output Bulk C105 | 75,7 | 75,7 | 74,4 | | 105 |
| 15. | Thermistor RTH2 | 95,1 | 94,9 | 93,9 | | 125 |
| Outp | ut load: | (| 6,7 A@12 \ | V | | |

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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|--------------------|--------------------|-------------|-------------------------|
| | | IEC 60601-1 | |
| Clause | Requirement + Test | Result - R | emark Verdict |

| 11.1.1 | TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | Р |
|--------|---|-----------|----------|---------|-------|-------------------------|
| | Supply voltage (V===): | 130 | 200 | 320 | | _ |
| | Ambient Tmin (°C): | 25,7 | 25,0 | 25,0 | | _ |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | | _ |
| Maxir | num measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24012-F(W)-S | or -HIOX | XX or -H | OXXX or | HIXXX | |
| 1. | Input Choke LF1 (Winding) | 82,5 | 74,2 | 66,3 | | 130 |
| 2. | Input Choke LF2 (Winding) | 80,1 | 70,4 | 64,0 | | 130 |
| 3. | Diode Bridge BD1 | 108,5 | 98,9 | 84,9 | | 130 |
| 4. | PFC Choke L1 (Winding) | 135,5 | 134,1 | 112,3 | | 155 |
| 5. | PFC Transistor Q1 | 114,7 | 111,7 | 104,8 | | 130 |
| 6. | PFC Diode D1 | 113,1 | 110,0 | 101,7 | | 130 |
| 7. | Bulk C1 | 86,1 | 84,6 | 82,0 | | 105 |
| 8. | Switching Transistor Q3 | 115,7 | 112,5 | 104,5 | | 130 |
| 9. | Power Transformer T1 (Core) | 99,1 | 97,9 | 95,2 | | 130 |
| 10. | Power Transformer T1 (Winding) | 111,0 | 110,0 | 107,2 | | 130 |
| 11. | Rectifier Diode D100 | 124,1 | 123,6 | 122,2 | | 130 |
| 12. | Rectifier Diode D101 | 120,1 | 119,8 | 117,7 | | 130 |
| 13. | Output Choke L100 (winding) | 122,1 | 121,7 | 120,0 | | 130 |
| 14. | Output Bulk C105 | 94,5 | 94,5 | 93,2 | | 105 |
| 15. | Thermistor RTH2 | 117,5 | 117,0 | 115,9 | | 125 |
| Outpu | ut load: | 1 | 2,5A@12 | V | | |

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | Р |
|--------|---|------------|-----------|---------|----------|-------------------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | _ |
| | Ambient Tmin (°C): | 25,5 | 25,0 | 25,0 | | _ |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | | _ |
| Maxir | num measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-C(W) | -S or -HIC |)XXX or - | HOXXX o | r –HIXXX | |
| 1. | Input Choke LF1 (Winding) | 79,8 | 76,2 | 71,5 | | 130 |
| 2. | Input Choke LF2 (Winding) | 85,1 | 81,3 | 74,4 | | 130 |
| 3. | Diode Bridge BD1 | 111,7 | 106,2 | 93,0 | | 130 |
| 4. | PFC Choke L1 (Winding) | 145,3 | 145,7 | 123,1 | | 155 |
| 5. | PFC Transistor Q1 | 129,9 | 127,8 | 118,9 | | 130 |
| 6. | PFC Diode D1 | 125,8 | 123,4 | 114,6 | | 130 |
| 7. | Bulk C1 | 101,7 | 99,9 | 95,2 | | 105 |
| 8. | Switching Transistor Q3 | 122,8 | 120,7 | 112,9 | | 130 |
| 9. | Power Transformer T1 (Core) | 108,3 | 106,8 | 103,9 | | 130 |
| 10. | Power Transformer T1 (Winding) | 112,1 | 110,6 | 107,3 | | 130 |
| 11. | Rectifier Diode D100 | 95,9 | 95,3 | 93,5 | | 130 |
| 12. | Rectifier Diode D101 | 93,1 | 92,8 | 90,5 | | 130 |
| 13. | Output Choke L100 (winding) | 108,4 | 107,8 | 105,8 | | 130 |
| 14. | Output Bulk C105 | 81,2 | 80,5 | 79,5 | | 105 |
| 15. | Thermistor RTH2 | 90,6 | 90,1 | 88,7 | | 125 |
| Outp | ut load: | | 1,4A@55\ | / | | |

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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|---------------------------|--------------------|-------------|-------------------------|
| | | IEC 60601-1 | |
| Clause | Requirement + Test | Result - R | emark Verdict |

| 11.1.1 | TABLE: Excessive temperatures in | | IENT | | | Р |
|--------|---|------------|----------|---------|----------|-------------------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | _ |
| | Ambient Tmin (°C): | 25,7 | 25,0 | 25,0 | | _ |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | | _ |
| Maxir | num measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-F(W) | -S or -HIC | XXX or - | HOXXX o | r –HIXXX | |
| 1. | Input Choke LF1 (Winding) | 78,8 | 69,6 | 63,4 | | 130 |
| 2. | Input Choke LF2 (Winding) | 83,7 | 75,5 | 67,5 | | 130 |
| 3. | Diode Bridge BD1 | 109,4 | 100,8 | 86,8 | | 130 |
| 4. | PFC Choke L1 (Winding) | 133,7 | 131,8 | 112,9 | | 155 |
| 5. | PFC Transistor Q1 | 118,4 | 115,3 | 108,3 | | 130 |
| 6. | PFC Diode D1 | 117,0 | 113,4 | 105,6 | | 130 |
| 7. | Bulk C1 | 86,5 | 85,1 | 81,6 | | 105 |
| 8. | Switching Transistor Q3 | 118,5 | 115,7 | 108,7 | | 130 |
| 9. | Power Transformer T1 (Core) | 101,9 | 100,8 | 98,0 | | 130 |
| 10. | Power Transformer T1 (Winding) | 102,5 | 101,6 | 99,6 | | 130 |
| 11. | Rectifier Diode D100 | 99,9 | 100,0 | 98,9 | | 130 |
| 12. | Rectifier Diode D101 | 96,9 | 97,2 | 96,1 | | 130 |
| 13. | Output Choke L100 (winding) | 108,4 | 108,4 | 107,2 | | 130 |
| 14. | Output Bulk C105 | 74,9 | 75,6 | 74,8 | | 105 |
| 15. | Thermistor RTH2 | 94,5 | 94,8 | 93,7 | | 125 |
| Outp | ut load: | 2 | ,72A@55 | V | | |

Tests were performed with 100% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | Р |
|--------|---|-----------|----------|---------|--------|-------------------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | _ |
| | Ambient Tmin (°C): | 47,8 | 47,9 | 49,7 | | |
| | Ambient Tmax (°C): | 50,0 | 50,0 | 50,0 | | |
| Maxir | Maximum measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24012-C(W)-S | or -HIOX | XX or -H | OXXX or | -HIXXX | |
| 1. | Input Choke LF1 (Winding) | 75,7 | 71,9 | 71,1 | | 130 |
| 2. | Input Choke LF2 (Winding) | 77,7 | 73,1 | 70,4 | | 130 |
| 3. | Diode Bridge BD1 | 91,8 | 84,0 | 78,1 | | 130 |
| 4. | PFC Choke L1 (Winding) | 113,6 | 104,5 | 93,3 | | 155 |
| 5. | PFC Transistor Q1 | 114,2 | 99,3 | 98,5 | | 130 |
| 6. | PFC Diode D1 | 105,3 | 95,1 | 93,0 | | 130 |
| 7. | Bulk C1 | 89,9 | 85,2 | 84,1 | | 105 |
| 8. | Switching Transistor Q3 | 107,6 | 98,4 | 96,8 | | 130 |
| 9. | Power Transformer T1 (Core) | 93,2 | 90,0 | 89,3 | | 130 |
| 10. | Power Transformer T1 (Winding) | 95,1 | 91,9 | 91,1 | | 130 |
| 11. | Rectifier Diode D100 | 89,6 | 88,0 | 87,1 | | 130 |
| 12. | Rectifier Diode D101 | 86,0 | 84,5 | 84,3 | | 130 |
| 13. | Output Choke L100 (winding) | 92,2 | 90,7 | 90,3 | | 130 |
| 14. | Output Bulk C105 | 86,2 | 86,1 | 76,1 | | 105 |
| 15. | Thermistor RTH2 | 85,9 | 84,7 | 84,0 | | 125 |
| Outp | ut load: | 3 | ,35A@12 | V | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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|---------------------------|--------------------|-------------|-------------------------|-------------------------|
| | | IEC 60601-1 | | |
| Clause | Requirement + Test | Result - R | emark Verdict | Verdict |

| 11.1.1 | 1 TABLE: Excessive temperatures in | | IENT | | | Р |
|--------|---|----------|----------|---------|--------|-----------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | _ |
| | Ambient Tmin (°C): | 47,8 | 47,9 | 49,7 | | _ |
| | Ambient Tmax (°C): | 50,0 | 50,0 | 50,0 | | _ |
| Maxir | mum measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax |
| | | | | | | (°C) |
| | GT(M)91110P24012-F(W)-S | or -HIOX | XX or -H | OXXX or | -HIXXX | |
| 1. | Input Choke LF1 (Winding) | 69,2 | 68,0 | 62,9 | | 130 |
| 2. | Input Choke LF2 (Winding) | 66,2 | 64,1 | 61,6 | | 130 |
| 3. | Diode Bridge BD1 | 90,0 | 86,2 | 76,1 | | 130 |
| 4. | PFC Choke L1 (Winding) | 124,7 | 124,5 | 104,3 | | 155 |
| 5. | PFC Transistor Q1 | 101,0 | 100,3 | 94,6 | | 130 |
| 6. | PFC Diode D1 | 102,0 | 100,8 | 94,4 | | 130 |
| 7. | Bulk C1 | 79,9 | 79,9 | 77,6 | | 105 |
| 8. | Switching Transistor Q3 | 102,5 | 101,2 | 95,6 | | 130 |
| 9. | Power Transformer T1 (Core) | 87,7 | 87,8 | 85,8 | | 130 |
| 10. | Power Transformer T1 (Winding) | 94,1 | 93,7 | 91,3 | | 130 |
| 11. | Rectifier Diode D100 | 95,6 | 95,0 | 94,2 | | 130 |
| 12. | Rectifier Diode D101 | 93,0 | 92,2 | 91,1 | | 130 |
| 13. | Output Choke L100 (winding) | 96,8 | 96,0 | 95,3 | | 130 |
| 14. | Output Bulk C105 | 80,8 | 80,3 | 80,0 | | 105 |
| 15. | Thermistor RTH2 | 92,5 | 91,9 | 91,3 | | 125 |
| Outp | ut load: | 6 | ,25A@12 | 2V | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).
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|-------------------------|--------------------|--|-----------------|-------------|---------|--|--|--|
| | IEC 60601-1 | | | | | | | |
| Clause | Requirement + Test | | Result - Remark | | Verdict | | | |

| 11.1.1 | TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | Р | |
|--------|---|------------|----------|----------|----------|-------------------------|--|
| | Supply voltage (V==): | 130 | 200 | 320 | | | |
| | Ambient Tmin (°C): | 47,8 | 47,9 | 49,7 | | _ | |
| | Ambient Tmax (°C): | 50,0 | 50,0 | 50,0 | | _ | |
| Maxir | num measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) | |
| | GT(M)91110P24055-X.X-C(W) | -S or -HIC | XXX or - | ноххх о | r –HIXXX | | |
| 1. | Input Choke LF1 (Winding) | 76,9 | 74,4 | 72,5 | | 130 | |
| 2. | Input Choke LF2 (Winding) | 81,3 | 77,5 | 73,7 | | 130 | |
| 3. | Diode Bridge BD1 | 101,5 | 93,7 | 85,2 | | 130 | |
| 4. | PFC Choke L1 (Winding) | 131,6 | 119,4 | 104,0 | | 155 | |
| 5. | PFC Transistor Q1 | 114,5 | 106,6 | 100,7 | | 130 | |
| 6. | PFC Diode D1 | 111,5 | 104,2 | 98,5 | | 130 | |
| 7. | Bulk C1 | 90,9 | 88,3 | 85,8 | | 105 | |
| 8. | Switching Transistor Q3 | 110,3 | 104,2 | 98,8 | | 130 | |
| 9. | Power Transformer T1 (Core) | 93,2 | 91,9 | 89,9 | | 130 | |
| 10. | Power Transformer T1 (Winding) | 95,0 | 93,4 | 91,7 | | 130 | |
| 11. | Rectifier Diode D100 | 82,3 | 82,4 | 81,7 | | 130 | |
| 12. | Rectifier Diode D101 | 80,6 | 80,5 | 80,1 | | 130 | |
| 13. | Output Choke L100 (winding) | 96,2 | 96,2 | 95,5 | | 130 | |
| 14. | Output Bulk C105 | 78,1 | 78,2 | 77,5 | | 105 | |
| 15. | Thermistor RTH2 | 78,8 | 78,9 | 78,3 | | 125 | |
| Outp | ut load: | (|),7A@55\ | 0,7A@55V | | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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|--------------------|--------------------|------------|-------------------------|---------------|------|
| | | | | | |
| Clause | Requirement + Test | Result - R | emark Verdict | - Remark | ct |

| 11.1.1 | TABLE: Excessive temperatures in | | IENT | | | Р |
|--------|---|------------|----------|---------|----------|-------------------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | _ |
| | Ambient Tmin (°C): | 48,2 | 47,9 | 49,7 | | _ |
| | Ambient Tmax (°C): | 50,0 | 50,0 | 50,0 | | _ |
| Maxir | Maximum measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-F(W) | -S or -HIC | XXX or - | HOXXX o | r –HIXXX | |
| 1. | Input Choke LF1 (Winding) | 83,4 | 69,3 | 66,8 | | 130 |
| 2. | Input Choke LF2 (Winding) | 87,4 | 76,5 | 71,2 | | 130 |
| 3. | Diode Bridge BD1 | 109,7 | 97,1 | 86,1 | | 130 |
| 4. | PFC Choke L1 (Winding) | 130,4 | 129,0 | 108,9 | | 155 |
| 5. | PFC Transistor Q1 | 108,3 | 106,4 | 101,3 | | 130 |
| 6. | PFC Diode D1 | 107,2 | 105,0 | 99,3 | | 130 |
| 7. | Bulk C1 | 84,0 | 78,3 | 76,6 | | 105 |
| 8. | Switching Transistor Q3 | 109,0 | 108,7 | 103,7 | | 130 |
| 9. | Power Transformer T1 (Core) | 95,3 | 93,0 | 90,3 | | 130 |
| 10. | Power Transformer T1 (Winding) | 97,4 | 92,8 | 91,3 | | 130 |
| 11. | Rectifier Diode D100 | 86,7 | 85,4 | 84,7 | | 130 |
| 12. | Rectifier Diode D101 | 85,3 | 83,1 | 82,9 | | 130 |
| 13. | Output Choke L100 (winding) | 104,8 | 98,3 | 97,7 | | 130 |
| 14. | Output Bulk C105 | 86,5 | 73,7 | 73,6 | | 105 |
| 15. | Thermistor RTH2 | 83,8 | 81,5 | 80,9 | | 125 |
| Outp | ut load: | 1 | ,36A@55 | SV . | | |

Tests were performed with 50% output load with air convention cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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

| 11.1.1 | TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | Р |
|--------|---|--------------|-----------|----------|----------|-------------------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | |
| | Ambient Tmin (°C): | 31,5 | 30,0 | 26,7 | | _ |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | | _ |
| Maxir | Maximum measured temperature T of part/at:: | | | T (°C) | <u> </u> | Allowed Tmax (°C) |
| | GT(M)91110P24012-CA(W)- | S or -HIO | XXX or -H | IOXXX or | -HIXXX | |
| 1. | Input Choke LF1 (Winding) | 70,6 | 57,2 | 54,3 | | 130 |
| 2. | Input Choke LF2 (Winding) | 58,8 | 51,4 | 52,1 | | 130 |
| 3. | Diode Bridge BD1 | 64,3 | 56,8 | 55,4 | | 130 |
| 4. | PFC Choke L1 (Winding) | 71,1 | 69,1 | 57,1 | | 155 |
| 5. | PFC Transistor Q1 | 73,4 | 68,1 | 65,4 | | 130 |
| 6. | PFC Diode D1 | 58,4 | 56,2 | 52,8 | | 130 |
| 7. | Bulk C1 | 58,8 | 57,0 | 49,9 | | 105 |
| 8. | Switching Transistor Q3 | 72,1 | 69,0 | 63,1 | | 130 |
| 9. | Power Transformer T1 (Core) | 86,8 | 83,0 | 75,8 | | 130 |
| 10. | Power Transformer T1 (Winding) | 91,9 | 87,8 | 79,9 | | 130 |
| 11. | Rectifier Diode D100 | 106,3 | 103,6 | 72,4 | | 130 |
| 12. | Rectifier Diode D101 | 115,7 | 111,9 | 95,1 | | 130 |
| 13. | Output Choke L100 (winding) | 107,7 | 104,2 | 81,4 | | 130 |
| 14. | Output Bulk C105 | 87,1 | 85,0 | 68,7 | | 105 |
| 15. | Thermistor RTH2 | 109,9 | 106,4 | 90,7 | | 125 |
| Outp | ut load: | 16,67A@12Vdc | | | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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|------------------------|--------------------|-------------------------|---------------|--|--|--|--|--|
| | IEC 60601-1 | | | | | | | |
| Clause | Requirement + Test | Result - Re | emark Verdict | | | | | |

| 11.1.1 | TABLE: Excessive | e temperatures in r | ME EQUIPM | IENT | | | Р |
|--------|---|---------------------|-----------|-------------------------|---------|--------|-------------------------|
| | Supply voltage (V: | ==): | 130 | 200 | 320 | | — |
| | Ambient Tmin (°C) | : | 23,7 | 23,4 | 24,0 | | _ |
| | Ambient Tmax (°C |): | 40,0 | 40,0 | 40,0 | | _ |
| Maxir | Maximum measured temperature T of part/at:: | | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)911 ² | 10P24012-FA(W)-S | or -HIO | (XX or -H | OXXX or | -HIXXX | |
| 1. | Input Choke LF1 (Wind | ing) | 84,0 | 67,6 | 56,7 | | 130 |
| 2. | Input Choke LF2 (Wind | ing) | 81,5 | 62,6 | 53,5 | | 130 |
| 3. | Diode Bridge BD1 | | 110,5 | 92,2 | 74,2 | | 130 |
| 4. | PFC Choke L1 (Winding | 3) | 110,9 | 104,6 | 83,8 | | 155 |
| 5. | PFC Transistor Q1 | | 81,7 | 77,6 | 72,7 | | 130 |
| 6. | PFC Diode D1 | | 84,4 | 79,6 | 73,6 | | 130 |
| 7. | Bulk C1 | | 78,7 | 76,8 | 73,4 | | 105 |
| 8. | Switching Transistor Q | 3 | 76,7 | 72,7 | 67,8 | | 130 |
| 9. | Power Transformer T1 | (Core) | 53,4 | 53,2 | 52,6 | | 130 |
| 10. | Power Transformer T1 | (Winding) | 67,1 | 66,4 | 65,6 | | 130 |
| 11. | Rectifier Diode D100 | | 103,3 | 102,3 | 101,5 | | 130 |
| 12. | Rectifier Diode D101 | | 97,7 | 96,9 | 96,6 | | 130 |
| 13. | Output Choke L100 (with | nding) | 129,2 | 125,1 | 126,0 | | 130 |
| 14. | Output Bulk C105 | | 93,6 | 92,4 | 92,0 | | 105 |
| 15. | Thermistor RTH2 | | 88,5 | 88,0 | 87,4 | | 125 |
| Outpu | ut load: | | 20 |),0 <mark>@12V</mark> d | dc | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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| 11.1.* | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | Р |
|--------|---|------------|---------|----------|-----------|-------------------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | |
| | Ambient Tmin (°C): | 24,0 | 24,6 | 24,3 | | |
| | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | | _ |
| Maxii | Maximum measured temperature T of part/at:: | | | T (°C) | <u> </u> | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-CA(W |)-S or -HI | OXXX or | -HOXXX (| or –HIXXX | |
| 1. | Input Choke LF1 (Winding) | 90,2 | 74,6 | 64,8 | | 130 |
| 2. | Input Choke LF2 (Winding) | 94,6 | 79,4 | 67,6 | | 130 |
| 3. | Diode Bridge BD1 | 119,3 | 106,0 | 85,8 | | 130 |
| 4. | PFC Choke L1 (Winding) | 128,2 | 120,8 | 97,0 | | 155 |
| 5. | PFC Transistor Q1 | 99,7 | 93,9 | 84,7 | | 130 |
| 6. | PFC Diode D1 | 95,8 | 90,4 | 81,7 | | 130 |
| 7. | Bulk C1 | 83,0 | 79,7 | 74,8 | | 105 |
| 8. | Switching Transistor Q3 | 83,0 | 79,2 | 73,0 | | 130 |
| 9. | Power Transformer T1 (Core) | 71,3 | 70,5 | 68,2 | | 130 |
| 10. | Power Transformer T1 (Winding) | 79,4 | 78,2 | 75,3 | | 130 |
| 11. | Rectifier Diode D100 | 89,6 | 88,4 | 85,6 | | 130 |
| 12. | Rectifier Diode D101 | 94,4 | 93,1 | 90,5 | | 130 |
| 13. | Output Choke L100 (winding) | 109,1 | 106,9 | 103,6 | | 130 |
| 14. | Output Bulk C105 | 82,7 | 80,6 | 79,4 | | 105 |
| 15. | Thermistor RTH2 | 82,0 | 80,9 | 78,8 | | 125 |
| Outp | ut load: | 3,0 | 64A@55V | /dc | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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| | | | | |
| Clause | Requirement + Test | Result - R | emark Verdict | lt - Remark Verdi |

| 11.1.1 | | TABLE: Excessive temperatures in | | IENT | | | | Р |
|--------|--------|-------------------------------------|-----------|---------|----------|-----------|---|---------|
| | | Supply voltage (V=) | 130 | 200 | 320 | | | |
| | | Ambient Tmin (°C) | 23.7 | 23.7 | 23.7 | | | |
| | | Ambient Turou (20) | 40.0 | 40.0 | 40.0 | | | |
| | | Ambient Tmax (°C): | 40,0 | 40,0 | 40,0 | | | |
| Maxin | num I | measured temperature T of part/at:: | | | T (°C) | | | Allowed |
| | | | | | | | | (°C) |
| | | GT(M)91110P24055-X.X-FA(W) | -S or -HI | OXXX or | -HOXXX (| or –HIXX) | (| |
| 1. | Inpu | it Choke LF1 (Winding) | 66,9 | 54,9 | 48,7 | | | 130 |
| 2. | Inpu | it Choke LF2 (Winding) | 74,3 | 61,8 | 53,2 | | | 130 |
| 3. | Diod | de Bridge BD1 | 101,1 | 85,7 | 69,9 | | | 130 |
| 4. | PFC | Choke L1 (Winding) | 102,3 | 97,7 | 79,0 | | | 155 |
| 5. | PFC | Transistor Q1 | 71,8 | 68,5 | 64,9 | | | 130 |
| 6. | PFC | Diode D1 | 76,9 | 72,9 | 68,2 | | | 130 |
| 7. | Bull | « C1 | 64,1 | 61,8 | 59,3 | | | 105 |
| 8. | Swi | tching Transistor Q3 | 69,1 | 66,3 | 62,5 | | | 130 |
| 9. | Pow | ver Transformer T1 (Core) | 60,8 | 59,6 | 58,1 | | | 130 |
| 10. | Pow | ver Transformer T1 (Winding) | 64,0 | 63,3 | 62,6 | | | 130 |
| 11. | Rec | tifier Diode D100 | 70,1 | 69,7 | 69,7 | | | 130 |
| 12. | Rec | tifier Diode D101 | 74,6 | 75,2 | 75,0 | | | 130 |
| 13. | Out | put Choke L100 (winding) | 92,1 | 91,6 | 91,3 | | | 130 |
| 14. | Out | put Bulk C105 | 61,8 | 61,6 | 60,9 | | | 105 |
| 15. | The | rmistor RTH2 | 63,7 | 63,5 | 63,2 | | | 125 |
| Outpu | ut loa | d: | 4,3 | 86A@55V | dc | | | |

Tests were performed with 100% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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| 11.1.1 | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | Р |
|---|------------------------------------|-----------|-----------|----------|--------|-------------------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | |
| | Ambient Tmin (°C): | 44,4 | 44,6 | 44,6 | | |
| | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | | |
| Maximum measured temperature T of part/at:: | | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24012-CA(W)- | S or -HIO | XXX or -H | IOXXX or | -HIXXX | |
| 1. | Input Choke LF1 (Winding) | 76,6 | 72,2 | 68,6 | | 130 |
| 2. | Input Choke LF2 (Winding) | 80,6 | 75,8 | 70,4 | | 130 |
| 3. | Diode Bridge BD1 | 94,3 | 87,2 | 77,9 | | 130 |
| 4. | PFC Choke L1 (Winding) | | 98,4 | 85,3 | | 155 |
| 5. | PFC Transistor Q1 | 89,5 | 87,2 | 84,0 | | 130 |
| 6. | PFC Diode D1 | 85,6 | 84,0 | 80,2 | | 130 |
| 7. | Bulk C1 | 83,5 | 81,9 | 79,5 | | 105 |
| 8. | Switching Transistor Q3 | 80,2 | 79,1 | 76,7 | | 130 |
| 9. | Power Transformer T1 (Core) | 70,4 | 70,1 | 69,8 | | 130 |
| 10. | Power Transformer T1 (Winding) | 75,4 | 75,0 | 74,6 | | 130 |
| 11. | Rectifier Diode D100 | 88,7 | 88,0 | 87,2 | | 130 |
| 12. | Rectifier Diode D101 | 88,5 | 87,9 | 87,4 | | 130 |
| 13. | Output Choke L100 (winding) | 102,0 | 101,1 | 100,1 | | 130 |
| 14. | Output Bulk C105 | 87,5 | 86,8 | 86,2 | | 105 |
| 15. | Thermistor RTH2 | 83,3 | 82,9 | 82,4 | | 125 |
| Outp | ut load: | 8, | 34A@12V | /dc | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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| | | | | | | р | | |
|--------|--------|-------------------------------------|---------|-----------|---------|--------|---|-------------------------|
| 11.1.1 | | TABLE: Excessive temperatures in | | IENT | 1 | [| 1 | F |
| | | Supply voltage (V==): | 130 | 200 | 320 | | | — |
| | | Ambient Tmin (°C): | 45,8 | 45,8 | 46,0 | | | — |
| | | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | | | |
| Maxir | num ı | neasured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | | GT(M)91110P24012-FA(W)-S | or -HIO | XXX or -H | OXXX or | -HIXXX | | |
| 1. | Inpu | it Choke LF1 (Winding) | 68,6 | 65,1 | 61,7 | | | 130 |
| 2. | Inpu | It Choke LF2 (Winding) | 63,7 | 61,0 | 59,2 | | | 130 |
| 3. | Diod | de Bridge BD1 | 86,1 | 80,2 | 71,4 | | | 130 |
| 4. | PFC | Choke L1 (Winding) | 99,1 | 100,6 | 84,7 | | | 155 |
| 5. | PFC | Transistor Q1 | 74,9 | 73,9 | 71,6 | | | 130 |
| 6. | PFC | Diode D1 | 76,3 | 75,2 | 72,1 | | | 130 |
| 7. | Bull | « C1 | 68,4 | 67,9 | 67,0 | | | 105 |
| 8. | Swi | tching Transistor Q3 | 72,0 | 71,3 | 68,8 | | | 130 |
| 9. | Pow | ver Transformer T1 (Core) | 60,6 | 60,5 | 60,2 | | | 130 |
| 10. | Pow | ver Transformer T1 (Winding) | 67,0 | 66,9 | 66,4 | | | 130 |
| 11. | Rec | tifier Diode D100 | 79,4 | 79,1 | 79,6 | | | 130 |
| 12. | Rec | tifier Diode D101 | 78,3 | 77,9 | 78,4 | | | 130 |
| 13. | Out | put Choke L100 (winding) | 86,6 | 86,4 | 87,2 | | | 130 |
| 14. | Out | put Bulk C105 | 74,0 | 73,8 | 74,5 | | | 105 |
| 15. | The | rmistor RTH2 | 74,1 | 73,7 | 74,0 | | | 125 |
| Outpu | ut loa | d: | 1 | 0,0@12Vo | dc | | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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| 11.1.1 | .1 TABLE: Excessive temperatures in ME EQUIPMENT | | | | | |
|--------|--|------------|---------|----------|-----------|-------------------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | _ |
| | Ambient Tmin (°C): | 46,0 | 46,0 | 46,0 | | |
| | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | | _ |
| Maxir | num measured temperature T of part/at:: | | | T (°C) | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-CA(W |)-S or -HI | OXXX or | -HOXXX (| or –HIXXX | |
| 1. | Input Choke LF1 (Winding) | 83,4 | 78,9 | 74,4 | | 130 |
| 2. | Input Choke LF2 (Winding) | 87,4 | 82,6 | 75,9 | | 130 |
| 3. | Diode Bridge BD1 | 109,7 | 102,4 | 89,1 | | 130 |
| 4. | PFC Choke L1 (Winding) | 123,0 | 123,9 | 103,5 | | 155 |
| 5. | PFC Transistor Q1 | 98,8 | 97,4 | 91,1 | | 130 |
| 6. | PFC Diode D1 | 94,3 | 93,0 | 87,4 | | 130 |
| 7. | Bulk C1 | 84,0 | 82,9 | 80,2 | | 105 |
| 8. | Switching Transistor Q3 | 88,1 | 87,2 | 82,8 | | 130 |
| 9. | Power Transformer T1 (Core) | 77,6 | 77,4 | 76,3 | | 130 |
| 10. | Power Transformer T1 (Winding) | 81,3 | 81,0 | 79,8 | | 130 |
| 11. | Rectifier Diode D100 | 83,4 | 83,3 | 82,7 | | 130 |
| 12. | Rectifier Diode D101 | 85,3 | 85,3 | 84,9 | | 130 |
| 13. | Output Choke L100 (winding) | 104,8 | 104,3 | 103,4 | | 130 |
| 14. | Output Bulk C105 | 86,5 | 86,3 | 85,9 | | 105 |
| 15. | Thermistor RTH2 | 78,7 | 78,6 | 78,1 | | 125 |
| Outp | ut load: | 1,8 | 32A@55V | /dc | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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| 11.1.1 | 1 TABLE: Excessive temperatures in | ME EQUIPN | IENT | | | | Р |
|--------|---|------------|------------------------|----------|-----------|---|-------------------------|
| | Supply voltage (V==): | 130 | 200 | 320 | | | — |
| | Ambient Tmin (°C): | 45,0 | 45,3 | 45,0 | | | |
| | Ambient Tmax (°C): | 55,0 | 55,0 | 55,0 | | | _ |
| Maxir | num measured temperature T of part/at:: | | | T (°C) | | | Allowed Tmax (°C) |
| | GT(M)91110P24055-X.X-FA(W |)-S or -HI | OXXX or | -HOXXX (| or –HIXXX | Ζ | |
| 1. | Input Choke LF1 (Winding) | 64,6 | 61,8 | 60,1 | | | 130 |
| 2. | Input Choke LF2 (Winding) | 70,0 | 66,6 | 63,0 | | | 130 |
| 3. | Diode Bridge BD1 | 87,3 | 81,8 | 73,1 | | | 130 |
| 4. | PFC Choke L1 (Winding) | 99,9 | 101,5 | 86,1 | | | 155 |
| 5. | PFC Transistor Q1 | 76,6 | 75,5 | 73,1 | | | 130 |
| 6. | PFC Diode D1 | 79,0 | 77,7 | 74,6 | | | 130 |
| 7. | Bulk C1 | 70,3 | 69,1 | 67,8 | | | 105 |
| 8. | Switching Transistor Q3 | 74,2 | 73,5 | 71,3 | | | 130 |
| 9. | Power Transformer T1 (Core) | 67,9 | 67,4 | 66,6 | | | 130 |
| 10. | Power Transformer T1 (Winding) | 69,0 | 68,7 | 68,3 | | | 130 |
| 11. | Rectifier Diode D100 | 71,1 | 70,7 | 70,7 | | | 130 |
| 12. | Rectifier Diode D101 | 72,7 | 72,4 | 72,3 | | | 130 |
| 13. | Output Choke L100 (winding) | 91,1 | 90,8 | 90,6 | | | 130 |
| 14. | Output Bulk C105 | 69,8 | 69,5 | 69,5 | | | 105 |
| 15. | Thermistor RTH2 | 67,8 | 67,5 | 67,4 | | | 125 |
| Outp | ut load: | 2, | 18 <mark>A@55</mark> V | /dc | | | |

Tests were performed with 50% output load with 20 CFM airflow cooling.

The printed circuit board is rated 130°C.

Temperature rise measured on the power transformer T1 windings was measured directly on the transformer windings by thermocouple; therefore reduction of the temperature limit for 10°C not required (temperature limit of T1: 130°C – Class B transformer).

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| 11.1.1 | RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24) | N/A |
|----------|--|-----|
| | | |
| 11.1.2.1 | RM RESULTS TABLE: Applied parts intended to supply heat to patient | N/A |

| 11.1.2.2 | RM RESULTS TABLE: Applied parts not intended to supply heat to patient | N/A |
|----------|--|-----|
| | The second secon | |

| 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)AllowedTmax (°C) | | | | Insulatio n class | | | | |
| | | | | | | | | |

Supplementary information:

Switch mode transformer incorporated. Temperature rise measured was measured on the transformer windings by thermocouple.

| 11.1.3 | RM RESULTS TABLE: Measurements | N/A |
|----------|--|-----|
| | | |
| 11.2.2.1 | RM RESULTS TABLE: Risk of fire in an oxygen rich environment | N/A |
| | TT | |
| 11.2.2.1 | TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source | N/A |
| | | |
| 11.3 | RM RESULTS TABLE: Constructional requirements for fire enclosures of ME equipment | N/A |
| | | |
| 11.5 | RM RESULTS TABLE: ME equipment and ME systems intended for use in conjunction with flammable agents | N/A |
| | | |
| 11.6.1 | TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances | N/A |

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| 11.6.3 | RM RESULTS TABLE: Spillage on ME equipment and ME system | N/A |
|----------|---|-----|
| | | |
| 11.6.5 | RM RESULTS TABLE: Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS | N/A |
| | | |
| 11.6.7 | RM RESULTS TABLE: Sterilization of ME equipment and ME systems | N/A |
| | | |
| 11.6.8 | RM RESULTS TABLE: Compatibility with substances used | N/A |
| | | |
| 12.1 | RM RESULTS TABLE: Accuracy of controls and equipment | N/A |
| | | |
| 12.4.1 | RM RESULTS TABLE: Intentional exceeding of safety limits | N/A |
| | 1 | |
| 12.4.2 | RM RESULTS TABLE: Indication of parameters relevant to safety | N/A |
| | | |
| 12.4.3 | RM RESULTS TABLE: Accidental selection of excessive output values | N/A |
| 1244 | RM RESULTS TABLE: Incorrect output | N/A |
| 12.4.4 | | N/A |
| 12.4.5.3 | RM RESULTS TABLE: Radiotherapy equipment | N/A |
| | | |
| 12.4.5.4 | RM RESULTS TABLE: Other ME equipment producing diagnostic or therapeutic radiation | N/A |
| | | |
| 12.4.6 | RM RESULTS TABLE: Diagnostic or therapeutic acoustic pressure | N/A |

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| Clause | Requirement + Test | Result - Remark | Verdict | | |

| 13.1.2 | 13.1.2TABLE: 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 | | | | ts to N/A | |
|--------------------------------------|--|-------------------------------------|----------------------------------|---|--|---------|
| Power dissipated less than (W): 15 | | | | · | | |
| Energy dissipated less than (J): 900 | | | | | | |
| Part or component tested | | Measured power dissipated (W) | Calculated energy dissipated (J) | | SINGLE FAULT CONDITIONS waived (Yes/No) | Remarks |
| | | | | | | |
| Supplementary information: | | | | | | |

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Clause Requirement + Test

Result - Remark

Verdict

| 13.2 | TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive | | |
|---------------|--|---|------------------------------------|
| Clause No. | Description of SINGLE FAULT CONDITION | Results observed | Hazardous situation (Yes/No) |
| 13.2.2 | Electrical SINGLE FAULT CONDITIONS per Clause 8.1: | — | _ |
| | Diode D100 short circuit (no load) | Output switched off | No |
| | Supply voltage: 264 Vac | immediately. | |
| | Duration: 10 min | No defect, no hazard. | |
| | Diode D100 short circuit (rated load) | Output switched off | No |
| | Supply voltage: 264 Vac | immediately. | |
| | Duration: 10 min | No defect, no hazard. | |
| | Choke L100 short circuit (no load) | Output switched on/off. | No |
| | Supply voltage: 264 Vac | No defect, no hazard | |
| | Duration: 10 min | | |
| | Choke L100 short circuit (rated load) | Output switched on/off. | No |
| | Supply voltage: 264 Vac | No defect, no hazard | |
| | Duration: 10 min | | |
| | Optocoupler U3 pin 1 to pin 2 short circuit (no load) | Output switched off immediately. | No |
| | Supply voltage: 264 Vac | No defect, no hazard. | |
| | Duration: 10 min | | |
| | Optocoupler U3 pin 1 to pin 2 short circuit (rated load) | Output voltage increased from 54,4 Vdc to 59,2 Vdc | No |
| | Supply voltage: 264 Vac | No defect, no hazard. | |
| | Duration: 10 min | | |
| | Optocoupler U3 pin 3 to pin 4 short circuit (no load) | Output switched off immediately. | No |
| | Supply voltage: 264 Vac | No defect, no hazard. | |
| | Duration: 10 min | | |
| | Optocoupler U3 pin 3 to pin 4 short circuit (rated load) | Output switched off immediately. | No |
| | Supply voltage: 264 Vac | No defect, no hazard. | |
| | Duration: 10 min | | |
| | Optocoupler U4 pin 1 to pin 2 short circuit (no load) | No effect on function. | No |
| | Supply voltage: 264 Vac | | |
| | Duration: 10 min | | |



| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|--|----------------------------------|---------|
| | Optocoupler U4 pin 1 to pin 2 short circuit (rated load) | No effect on function. | No |
| | Supply voltage: 264 Vac | | |
| | Duration: 10 min | | |
| | Optocoupler U4 pin 3 to pin 4 short circuit (no load) | Output switched off immediately. | No |
| | Supply voltage: 264 Vac | No defect, no hazard. | |
| | Duration: 10 min | | |
| | Optocoupler U4 pin 3 to pin 4 short circuit (rated load) | Output switched off immediately. | No |
| | Supply voltage: 264 Vac | No defect, no hazard. | |
| | Duration: 10 min | | |
| | Optocoupler U5 pin 1 to pin 2 short circuit (no load) | Output switched on/off. | No |
| | Supply voltage: 264 Vac | No defect, no hazard. | |
| | Duration: 10 min | | |
| | Optocoupler U5 pin 1 to pin 2 short circuit (rated | Output switched on/off. | No |
| | load) | No defect, no hazard. | |
| | Supply voltage: 264 Vac | | |
| | Duration: 10 min | | |
| | Optocoupler U5 pin 3 to pin 4 short circuit (no load) | No effect on function. | No |
| | Supply voltage: 264 Vac | | |
| | Duration: 10 min | | |
| | Optocoupler U5 pin 3 to pin 4 short circuit (rated load) | No effect on function. | No |
| | Supply voltage: 264 Vac | | |
| | Duration: 10 min | | |
| | Voltage regulation disabled (no load) | Output voltage decreased | No |
| | IC101 pin 4 open | from 56,0 vac to 48,0 vac. | |
| | Supply voltage: 264 Vac | No defect, no nazard. | |
| | Duration: 10 min | | |
| | Voltage regulation disabled (rated load) | Output switched on/off. | No |
| | IC101 pin 4 open | No defect, no hazard. | |
| | Supply voltage: 264 Vac | | |
| | Duration: 10 min | | |
| | Varistor MOV2 short circuit | Fuse F1 and external circuit | No |
| | Supply voltage: 264 Vac | breaker opened immediately. | |
| | | No hazard. | |

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| Clause | Requirement + Test | Result - Remark | Verdict | | |
| | Diode bridge DB1 short circuit plus to minus Supply voltage:264 Vac | Fuse F1 and external circuit breaker opened immediately. | No | | |
| | | No hazard. | | | |
| | Plus output to earth short circuit | No effect on function. | No | | |
| | Suppry voltage. 204 vac | No offect on function | No | | |
| | Minus output to earth short circuit | No effect on function. | NO | | |
| | Supply voltage: 264 vac | Output outtaked on/off | No | | |
| | Plus output to minus output short circuit | Output switched on/off. | NO | | |
| | Supply voltage: 264 vac | No defect, no nazaro. | Na | | |
| | Supply voltage: 264 Vac | Fuse F1, F2 and external circuit breaker opened immediately. | NO | | |
| | | No hazard. | | | |
| | PFC transistor Q1 short circuit (D to S) Supply voltage: 264 Vac | Fuse F1, F2 and external circuit breaker opened immediately. | No | | |
| | | No hazard. | | | |
| | PFC transistor Q1 short circuit (D to G) Supply voltage: 264 Vac | Fuse F1, F2 and external circuit breaker opened immediately. | No | | |
| | | No hazard. | | | |
| | Switching transistor Q3 short circuit (D to S) Supply voltage: 264 Vac | External circuit breaker opened immediately. | No | | |
| | | No hazard. | | | |
| | Switching transistor Q3 short circuit (D to G) Supply voltage: 264 Vac | External circuit breaker opened immediately. | No | | |
| | | No hazard. | | | |
| | Transformer T2 pin 3 to pin 4 short circuit Supply voltage: 264 Vac | External circuit breaker opened immediately. | No | | |
| | | No hazard. | | | |
| | Transformer T2 pin 1 to pin 6 short circuit | External circuit breaker opened immediately. | No | | |
| | | No hazard. | | | |
| | Transformer T2 pin 2 to pin 5 short circuit Supply voltage: 264 Vac | External circuit breaker opened immediately. | No | | |
| | | No hazard. | | | |
| | Transformer T1 pin 1 to pin 2 short circuit | Output switched on/off. | No | | |
| | Supply voltage: 264 Vac | No defect, no hazard. | | | |
| | | No excessive temperature rises. | | | |



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|--------|---|--|---------|--|
| Clause | Requirement + Test | Result - Remark | Verdict | |
| | Transformer T1 pin 4 to pin 5 short circuit Supply voltage: 264 Vac | Output switched off immediately. No defect, no hazard. No excessive temperature | No | |
| | Output short circuit Supply voltage: 264 Vac Duration: 60 min. | No defect, no hazard. No excessive temperature rises. | No | |
| | Output overload Supply voltage: 264 Vac Duration: 60 min. | Additional load at T1: 12,24 Vdc@27,2 A. The measured temperature on T1 was 98,7°C at ambient of 25,2°C. Calculated temperature at maximum ambient specified is 143,5°C. Limit is 175°C – 10°C= 165°C (10°C were subtracted because of the measurement with the thermo probes). No defect. No hazard. | No | |
| | External fan blocked (not part of the investigation) Supply voltage: 264 Vac Duration: 30 min. | After 20 min external circuit breaker opened. No hazard. No excessive temperature rise | No | |
| | Air holes closed. Supply voltage: 264 Vac Duration: 30 min. | After 20 min external circuit breaker opened. No hazard. No excessive temperature rise | Νο | |
| | Diode D100 short circuit (no load) Supply voltage: 320 Vdc Duration: 10 min | Output switched off immediately. No defect, no hazard. | No | |
| | Diode D100 short circuit (rated load) Supply voltage: 320 Vdc Duration: 10 min | Output switched off immediately. No defect, no hazard. | No | |
| | Choke L100 short circuit (no load) Supply voltage: 320 Vdc Duration: 10 min | Output switched on/off. No defect, no hazard | No | |

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| Requirement + Test | | Result - Remark | Verdict |
|--|------------------------|---|---|
| Choke I 100 short circuit (rat | ed load) | Output switched on/off | No |
| Supply voltage: 320 Vdc | eu loauj | No defect no bazard | NO |
| Duration: 10 min | | | |
| Optocoupler U3 pin 1 to pin 2 load) | 2 short circuit (no | Output switched off immediately. | No |
| Supply voltage: 320 Vdc | | No defect, no hazard. | |
| Duration: 10 min | | | |
| Optocoupler U3 pin 1 to pin 2 load) | 2 short circuit (rated | Output voltage increased from 54,4 Vdc to 59,2 Vdc | No |
| Supply voltage: 320 Vdc | | No defect, no hazard. | |
| Duration: 10 min | | | |
| Optocoupler U3 pin 3 to pin 4 load) | 4 short circuit (no | Output switched off immediately. | No |
| Supply voltage: 320 Vdc | | No defect, no hazard. | |
| Duration: 10 min | | | |
| Optocoupler U3 pin 3 to pin 4 load) | 4 short circuit (rated | Output switched off immediately. | No |
| Supply voltage: 320 Vdc | | No defect, no hazard. | |
| Duration: 10 min | | | |
| Optocoupler U4 pin 1 to pin 2 load) | 2 short circuit (no | No effect on function. | No |
| Supply voltage: 320 Vdc | | | |
| Duration: 10 min | | | |
| Optocoupler U4 pin 1 to pin 2 load) | 2 short circuit (rated | No effect on function. | No |
| Supply voltage: 320 Vdc | | | |
| Duration: 10 min | | | |
| Optocoupler U4 pin 3 to pin 4 load) | 4 short circuit (no | Output switched off immediately. | No |
| Supply voltage: 320 Vdc | | No defect, no hazard. | |
| Duration: 10 min | | | |
| Optocoupler U4 pin 3 to pin 4 load) | 4 short circuit (rated | Output switched off immediately. | No |
| Supply voltage: 320 Vdc | | No defect, no hazard. | |
| Duration: 10 min | | | Joint - Iverifiait No Vertifiait No tput switched on/off. No defect, no hazard No tput switched off No tput voltage increased No tput voltage increased No tput voltage increased No tput switched off No defect, no hazard. No tput switched off No defect, no hazard. No tput switched off No effect on function. No effect on function. No effect on function. No tput switched off No effect, no hazard. No tput switched off No effect, no hazard. No tput switched off No nediately. defect, no hazard. tput switched off No nediately. defect, no hazard. tput switched off No defect, no hazard. No tput switched off No defect, no hazard. No tput switched on/off. No <t< td=""></t<> |
| Optocoupler U5 pin 1 to pin 2 load) | 2 short circuit (no | Output switched on/off. No defect. no hazard. | No |
| Supply voltage: 320 Vdc | | | |
| Duration: 10 min | | | |



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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|--|---|---------|
| | Optocoupler U5 pin 1 to pin 2 short circuit (rated load) | Output switched on/off. | No |
| | Supply voltage: 320 Vdc | | |
| | Duration: 10 min | | |
| | Optocoupler U5 pin 3 to pin 4 short circuit (no load) | No effect on function. | No |
| | Supply voltage: 320 Vdc | | |
| | Duration: 10 min | | |
| | Optocoupler U5 pin 3 to pin 4 short circuit (rated load) | No effect on function. | No |
| | Supply voltage: 320 Vdc | | |
| | Duration: 10 min | | |
| | Voltage regulation disabled (no load) | Output voltage decreased from 56,0 Vdc to 48,0 Vdc. | No |
| | | No defect, no hazard. | |
| | Supply voltage: 320 vdc | | |
| | | | Na |
| | Voltage regulation disabled (rated load) | Output switched on/off. | NO |
| | | No defect, no hazard. | |
| | Supply voltage: 320 Vdc | | |
| | Duration: 10 min | | |
| | Varistor MOV2 short circuit | External DC fuse 3 A | No |
| | Supply voltage: 320 Vdc | No hazard | |
| | Diada bridga DB1 short circuit plus to minus | Extornal DC fueo 3 A | No |
| | Supply voltage: 220 Vda | opened immediately. | NO |
| | Supply voltage. 320 vuc | No hazard. | |
| | Plus output to earth short circuit | No effect on function. | No |
| | Supply voltage: 320 Vdc | | |
| | Minus output to earth short circuit | No effect on function. | No |
| | Supply voltage: 320 Vdc | | |
| | Plus output to minus output short circuit | Output switched on/off. | No |
| | Supply voltage: 320 Vdc | No defect, no hazard. | |
| | PFC regulation disabled (resistor R7 open) | External DC fuse 3 A | No |
| | Supply voltage: 320 Vdc | opened immediately. | |
| | | No hazard. | |
| | PFC transistor Q1 short circuit (D to S) | External DC fuse 3 A | No |
| | Supply voltage: 320 Vdc | opened immediately. | |
| | | No hazard. | |

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| | | IEC 60601-1 | | |
| Clause | Requirement + Test | | Result - Remark | Verdict |
| | PFC transistor Q1 short circuit Supply voltage: 320 Vdc | (D to G) | External DC fuse 3 A opened immediately. | No |
| | | | No hazard. | |
| | Switching transistor Q3 short of Supply voltage: 320 Vdc | circuit (D to S) | External DC fuse 3 A opened immediately. | No |
| | | | No hazard. | |
| | Switching transistor Q3 short of Supply voltage: 320 Vdc | circuit (D to G) | External DC fuse 3 A opened immediately. | No |
| | | | No hazard. | |
| | Transformer T2 pin 3 to pin 4 s Supply voltage: 320 Vdc | hort circuit | External DC fuse 3 A opened immediately. | No |
| | | | No hazard. | |
| | Transformer T2 pin 1 to pin 6 s Supply voltage: 320 Vdc | hort circuit | External DC fuse 3 A opened immediately. | No |
| | | | No hazard. | |
| | Transformer T2 pin 2 to pin 5 s Supply voltage: 320 Vdc | hort circuit | External DC fuse 3 A opened immediately. | No |
| | Supply Voltage. 520 Vac | | No hazard. | |
| | Transformer T1 pin 1 to pin 2 s | hort circuit | Output switched on/off. | No |
| | Supply voltage: 320 Vdc | | No defect, no hazard. | |
| | | | No excessive temperature rises. | |
| | Transformer T1 pin 4 to pin 5 s | hort circuit | Output switched off immediately. | No |
| | | | No defect, no hazard. | |
| | | | No excessive temperature rises. | |
| | Output short circuit | | Output switched on/off. | No |
| | Supply voltage: 320 Vdc | | No defect, no hazard. | |
| | Duration: 60 min. | | No excessive temperature rises. | |



| IEC 60601-1 | | | | | |
|-------------|---|---|---------|--|--|
| Clause | Requirement + Test | Result - Remark | Verdict | | |
| | Output overload Supply voltage: 320 Vdc Duration: 60 min. | Additional load at T1: 12,24 Vdc@27,2 A. The measured temperature on T1 was 98,7°C at ambient of 25,2°C. Calculated temperature at maximum ambient specified is 143,5°C. Limit is 175°C – 10°C= 165°C (10°C were subtracted because of the measurement with the thermo probes). No defect. No hazard. | Νο | | |
| | External fan blocked (not part of the investigation) Supply voltage: 320 Vdc Duration: 30 min. | No hazard. No excessive temperature rises. | No | | |
| | Air holes closed. Supply voltage: 320 Vdc Duration: 30 min. | No hazard. No excessive temperature rises. | No | | |
| 13.2.3 | Overheating of transformers per Clause 15.5: | — | — | | |
| | Transformer T1 pin FL1 to pin FL2 short circuit. Supply voltage: 264 Vac Duration: 60 min. | Output switched on/off. No defect, no hazard. No excessive temperature rises. | Νο | | |
| | Transformer T1 pin FL1 to pin FL2 overload. Supply voltage: 264 Vac Duration: 60 min. | Additional load at T1: 11,67 Vdc@20,1 A. The measured temperature on T1 was 101,9°C at ambient of 24,2°C. Calculated temperature at maximum ambient specified is 147,7°C. Limit is 175°C – 10°C= 165°C (10°C were subtracted because of the measurement with the thermo probes). No defect. No hazard. | No | | |
| | Transformer T1 pin FL1 to pin FL2 short circuit. Supply voltage: 320 Vdc Duration: 60 min. | Output switched on/off. No defect, no hazard. No excessive temperature rises. | No | | |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | Transformer T1 pin FL1 to pin FL2 overload. Supply voltage: 320 Vdc | Additional load at T1: 11,67 Vdc@20,1 A. The measured temperature | No |
| | Duration: 60 min. | on T1 was 101,9°C at ambient of 24,2°C. | |
| | | Calculated temperature at maximum ambient specified is 147,7°C. | |
| | | Limit is 175°C – 10°C= 165°C (10°C were subtracted because of the measurement with the thermo probes). | |
| | | No defect. No hazard. | |
| 13.2.4 | Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two: | | _ |
| | | | |
| 13.2.5 | Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two: | | _ |
| | | | |
| 13.2.7 | Impairment of cooling that could result in a HAZARD using test method of 11.1: | | - |
| | Single ventilation fans locked consecutively | External fan blocked (not part of the investigation). | No |
| | | No excessive temperature rises were observed. No hazard. | |
| | Ventilation openings on top and sides impaired | Air holes closed | No |
| | by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls | No excessive temperature rises were observed. | |
| | | No hazard. | |
| | Simulated blocking of filters | No such filter used. | — |
| | Flow of a cooling agent interrupted | No cooling agent provided. | — |
| | | | |
| 13.2.8 | Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below: | _ | _ |
| | | | |
| 13.2.9 | Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited ¹ – Also see 13.10 | _ | - |
| | No motor provided. | | |

| S | I | Q |
|---|---|---|
| | | |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|--------------------|-----------------|---------|

| 13.2.10 | Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9: | _ | — |
|---------|--|---------------------|---|
| | For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or upper limit of RATED voltage range for specified time: | No motors provided. | _ |
| | 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 | No motors provided. | _ |
| | Temperatures measured as specified in 11.1.3 d) | No motors provided. | _ |
| | Temperatures did not exceed limits of Table 26 | No motors provided. | — |
| | | | |
| 13.2.12 | Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3): | _ | — |
| | No such parts. | | |

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.

There was no flame, extensive smoke or melted metal.

| 13.2.6 | RM RESULTS TABLE: Leakage of liquid | N/A |
|--------|---|-----|
| 14.1 | RM RESULTS TABLE: Programmable electrical medical systems - General | N/A |
| 14.6.1 | RM RESULTS TABLE: Identification of known and foreseeable hazards | N/A |
| 14.6.2 | RM RESULTS TABLE: Risk control | N/A |
| 14.7 | RM RESULTS TABLE: Requirement specification | N/A |
| 14.8 | RM RESULTS TABLE: Architecture | N/A |
| 14.10 | RM RESULTS TABLE: Verification | N/A |
| 14 11 | RM RESULTS TABLE: PEMS validation | N/A |
| 44.42 | | |
| 14.13 | to other equipment | N/A |

Clause

Requirement + Test

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Result - Remark

| 15.3 | TABLE: Mechanical Strength tests ¹⁾ | | | | | | |
|--|--|--|--|--|--|--|--|
| Clause | Name of Test Test conditions Observed results/ | | | | | | |
| 15.3.2 | Push Test | Force = 250 N ± 10 N for 5 s | | | | | |
| 15.3.3 | Impact Test | Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m | | | | | |
| 15.3.4.1 | Drop Test (hand- held) | Free fall height (m) = | | | | | |
| 15.3.4.2 | Drop Test (portable) | Drop height (cm) = | | | | | |
| 15.3.5 | Rough handling test | Travel speed (m/s) = | | | | | |
| 15.3.6 | Mould Stress Relief | 7 h in oven at temperature (°C) = | | | | | |
| | | | | | | | |
| Supplementary information: ¹⁾ As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows). | | | | | | | |
| EUT is in tests are | EUT is intended for building-in. It is provided without external enclosure; therefore above mentioned ests are not applicable. | | | | | | |
| | | | | | | | |

| 15.4.1 | RM RESULTS TABLE: Construction of connectors | | | | |
|------------|--|------|--|--|--|
| | | | | | |
| 15.4.2.1 a | RM RESULTS TABLE: THERMAL CUT-OUTS and OVER-CURRENT RELEASES | N/A | | | |
| r | | | | | |
| 15.4.2.1 c | RM RESULTS TABLE: Independent non-SELF-RESETTING THERMAL CUT-OUT | N/A | | | |
| 15 4 2 1 4 | DM DESULTS TABLE: Loss of function of ME FOURMENT | N/A | | | |
| 15.4.2.1 U | RW RESULTS TABLE. LOSS OF TURCTION OF ME EQUIPMENT | IN/A | | | |
| 15.4.2.1 h | RM RESULTS TABLE: ME EQUIPMENT with tubular heating elements | N/A | | | |
| 15 4 3 1 | | N/A | | | |
| 15.4.5.1 | NW RESULTS TABLE. Housing | IN/A | | | |
| 15.4.3.2 | RM RESULTS TABLE: Connection | N/A | | | |
| | | | | | |
| 15.4.3.3 | RM RESULTS TABLE: Protection against overcharging | N/A | | | |
| 1544 | RM RESULTS TABLE: Indicators | N/A | | | |
| 10.4.4 | | 197 | | | |
| 15.4.5 | RM RESULTS TABLE: Pre-set controls | N/A | | | |
| | | | | | |
| 15.4.6 | TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests | N/A | | | |

| C | 0 |
|---|-----|
| 3 | 120 |
| | |

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| 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 | | | | | | | | Ρ |
|--|---|--|--|--|-----------------------------------|-----------------------------------|--|-----------------|---------------------|
| Primary voltage (most adverse value from 90 % to 110 % of RATED 264 Vac voltage)(V) ¹ | | | | | | | | — | |
| RATED inpu | t frequency (| Hz) | | | : | 50 |) 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) | Maxi allo temp Tab (° | mum wed from le 31 C) | Maximu windin temp measur (°C) | ım Ig Ied | Ambien t (°C) |
| T1: Pin FL1 to pin FL2 | Class B | Primary fuse | No | 60 min. | 10 | 65 | See 1 |) | 24,2 |
| Supplemen | tary information | tion: | • | | | | | | • |

¹Loads 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.

1) Output switched on/off. No defect, no hazard, no excessive temperature rises.

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| Clause | Requirement + Test | Result - Remark | Verdict |
|--------|--------------------|-----------------|---------|
|--------|--------------------|-----------------|---------|

| 15.5.1.3 TABLE: transformer overload test – conducted only when protective device under short-circuit test operated | | |
|---|---|---------|
| Primary vo | Itage, most adverse value between 90 % to 110 % of RATED voltage (V) ¹ : | 264 Vac |
| RATED input frequency (Hz): | | |
| Test current just below minimum current that would activate protective device & achieve THERMAL STABILITY under method a) (A) | | |
| Test currents external | nt based on Table 32 when protective device that operated under method a) to transformer, and it was shunted (A) | |

| Winding tested | Class of insulation (A, B, E, F, H) | Type of protective device used (fuse, circuit breaker)/Ratings | Maximum allowed temp from Table 31 (°C) | Maximum winding temp measured (°C) | Ambient (°C) |
|-----------------------------|---|---|--|--|-----------------|
| T1: Pin FL2 to D100 cathode | Class B | Primary fuse | 165 | 147,7 | 24,2 |

Supplementary information:

¹Loads 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.

Protective device not operated.

Additional load at T1: 11,67Vdc @ 20,1. The measured temperature on T1 was 101,9°C at an ambient of 24,2°C.

Calculated temperature at maximum ambient specified is 147,7°C. Limit in accordance to Annex C is 175°C – 10°C= 165°C. 10°C were subtracted because of the measurement with the thermo probes.

| 15.5.2 | TABLE | ABLE: Transformer dielectric strength after humidity preconditioning of 5.7 | | | | |
|---------------------------------------|-------|---|-------------------------|---------------------------|---------------------|--------------------------|
| Transformer Model/Type/ Part No | | Test voltage applied between | Test voltage, (V) | Test frequency (Hz) | Breakdown Yes/No | Deterioratio n Yes/No |
| T1 | | Primary & secondary windings | 4243Vdc | | No | No |
| | | Primary winding & frame | | | | |
| | | Secondary winding & frame | | | | |

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

Switch mode transformer incorporated within the power supply unit.

Reinforced insulation between primary and secondary windings provided (triple insulated wire used for primary windings).

| 16.1 | RM RESULTS TABLE: General requirements for ME Systems | N/A |
|------|---|-----|
|------|---|-----|

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| Clause | Requirement + Test | Result - Remark | Verdict |
| 16.6.1 | TABLE: LEAKAGE CURRENTS IN ME SYSTE | M_TOUCH CURRENT MEASUREMENTS | N/A |
| 16.9.1 | RM RESULTS TABLE: Connection te | rminals and connectors | N/A |

| 17 | RM RESULTS TABLE: Electromagnetic compatibility of ME equipment and | N/A |
|----|---|-----|
| | ME systems | |

| SP | TABLE: Additional or special tests conducted | | | | |
|--|--|-------------------------|------------------|--|--|
| Clause and Name of Test | | Test type and condition | Observed results | | |
| Evaluation of voltage limiting components in SELV circuits | | See tables below | See tables below | | |
| Limited current circuit | | See tables below | See tables below | | |
| Distance through insulation measurements | | See tables below | See tables below | | |
| Supplementary information: | | | | | |

| TABLE: evaluation of voltage limiting of | TABLE: evaluation of voltage limiting components in SELV circuits | | | Р |
|--|---|--------------------------|--------------------------------|-----------|
| Component (measured between) | max. vo (normal | oltage (V) operation) | Voltage Limiting Components | |
| | V peak | V d.c. | | |
| Input | 240 Vac | | | |
| GT(M)91110P24055-X.X-FA(W)-S or -HIOXX or -HOX | (XX or –HI) | XX | | |
| Transformer T1 (FL1 to FL2) | 276,0 | 119,5 Vrms | | |
| Diode D100 (Cathode to FL2) | 264,0 | 87,6 Vrms | D100 | |
| Choke L100 (FL2 to S1) | | 55,6 | L100 (pin F1 to pin S1) | |
| Choke L100 (FL2 to F2) | 20,4 | 11,6 Vrms | L100 (pin F2 to pin S2) | |
| GT(M)91110P24012-FA(W)-S or -HIOXX or -HOXXX | or -HIXXX | | | |
| Transformer T1 (FL1 to FL2) | 64,0 | 20,7 Vrms | | |
| Diode D100 (Cathode to FL2) | 14,4 | 12,0 Vrms | D100 | |
| Choke L100 (FL2 to S1) | | 11,5 | L100 (pin F1 t | o pin S1) |
| Choke L100 (FL2 to F2) | 19,6 | 11,5 Vrms | L100 (pin F2 t | o pin S2) |
| Input 3 | 320 Vac | | | |
| GT(M)91110P24055-X.X-FA(W)-S or -HIOXX or -HOXXX or -HIXXX | | | | |
| Transformer T1 (FL1 to FL2) | 272,0 | 125,0 Vrms | | |
| Diode D100 (Cathode to FL2) | 260,0 | 93,1 Vrms | D100 | |
| Choke L100 (FL2 to S1) | | 57,8 | L100 (pin F1 t | o pin S1) |

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| Clause | Requirement + Test | | Result - Remark | | Verdict |
| | · | | | | |

| | TABLE: evaluation of voltage limiting c | component | Р | | |
|--|---|--|-----------|--------------------------------|-----------|
| Component (measured between) | | max. voltage (V) (normal operation) | | Voltage Limiting Components | |
| | | V peak | V d.c. | | |
| Choke L100 |) (FL2 to F2) | 20,2 | 11,7 Vrms | L100 (pin F2 t | o pin S2) |
| GT(M)91110P24012-FA(W)-S or -HIOXX or -HOXXX or -HIXXX | | | | | |
| Transforme | er T1 (FL1 to FL2) | 68,0 | 38,4 Vrms | | |
| Diode D100 (Cathode to FL2) | | 26,1 | 24,7 Vrms | D100 | |
| Choke L100 |) (FL2 to S1) | | 11,3 | L100 (pin F1 t | o pin S1) |
| Choke L100 |) (FL2 to F2) | 19,50 | 11,4 Vrms | L100 (pin F2 t | o pin S2) |
| Fault test performed on voltage limiting components Voltage measured (V) in SELV circle (V peak or V d.c.) | | | rcuits | | |
| Diode (D100 short) | | <60 V dc | | | |
| Choke (L100 pin F1 to pin S1 short) | | <60 V dc | | | |
| supplemen | tary information: | | | | |

TABLE: Limited current circuit

The unit was connected to 264Vac, 50Hz. A 2000 Ohms non-inductive resistor and a switch were connected between the user accessible part of a limited current circuit and either pole of the limited current circuit or earth. A storage oscilloscope was connected across the points under consideration. The switch was closed and voltages on resistor were measured.

Ρ

| Limit values | 70 mApeak |
|---------------------------------|---|
| Circuit(s) tested | Bridging components CY8 |
| Measured working voltage: | Measured working voltage: 364,0Vpk, 183,5Vrms |
| Measured frequency | CY8: 100kHz |
| Measured current through 2000 □ | CY8 was opened and the 2000 Ohm resistor in series to CY8 was connected to output minus and output plus. The output was connected to the PE of simulated TN mains. |
| | 40,00Vpk, 4,989 Vrms |
| | 20,0 mApeak, 2,49 mArms |
| Measured capacitance | Capacitance across CY8= 4,7 nF |

Comments:

--

According to an UL PAG the touch current with D1 was measured between the capacitor to PE.

The measured value was: 0,3 mA

The dielectric test was performed on the unit (see table dielectric testing) before the above measurements were done.

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|--|---|-------------|-------------|-------------|---|---------|
| | | IEC 60601-1 | | | | |
| Clause | Requirement + Test | | Resu | lt - Remar | K | Verdict |
| | | | | | |] |
| | TABLE: Distance through insulation measurements | | | Р | | |
| Distance through insulation (DTI) at/of: U peak (V) U rms (V) Test voltage (Vdc) U rms | | | | DTI (mm) | | |
| Tubing on Capacitor C1 544 325 4243 0,4 | | 0,4 | 0,6 | | | |
| Supplementary information: | | | | | | |



Enclosure No. 1

National Differences to IEC 60601-1: 2005 + AM1: 2012

(10 pages including this cover page)

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

| National | standard ANSI/AAMI ES60601-1: 2005 | | |
|----------|---|--|-----|
| 4.8 | Components of ME EQUIPMENT | | Р |
| | When no relevant US ANSI standard existed, the requirements of this standard applied | Considered. | Ρ |
| 4.10.2. | SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS | | Р |
| | 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 | Considered. | Ρ |
| 8.2 | Requirements related to power sources | | Р |
| | Addition to agree with NEC: The requirement, "ALL FIXED ME EQUIPMENT and PERMANENTLY INSTALLED ME EQUIPMENT | EUT is not permanently installed equipment or fixed ME equipment. | Ρ |
| | are CLASS I ME EQUIPMENT" | EUT is intended for building- in. | |
| 8.7.3 | Allowable values: | | Р |
| | 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: | | Р |
| | d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION | | Ρ |
| 8.11. | MAINS PARTS, components and layout | | N/A |
| | Addition to agree with NEC: | | N/A |
| | 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" | EUT is not permanently connected equipment. | N/A |
| | 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 | No cords between equipment parts. EUT is Medical Switch Mode PSU intended for building- | N/A |

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| IEC 60601-1 | | | | |
|-------------|--|---|---------|--|
| Clause | Requirement + Test | Result - Remark | Verdict | |
| | Cable used as external interconnection between units was: | | N/A | |
| | 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 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 | EUT is intended for building- in. EUT is not end medical product; therefore this requirement is not relevant, | N/A | |
| 8.11.3.2. | Addition to agree with NEC: | | N/A | |
| | 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. | | N/A | |

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|--------|--------------------|-----------------|------------------------|--------------|
| | | IEC 60601-1 | | |
| Clause | Requirement + Test | Re | sult - Remark | Verdict |

| CANAD Nationa | A NATIONAL DIFFERENCES to IEC 60601-1 Third edi A standard CAN/CSA-C22.2 No. 60601-1:08 | tion | |
|------------------|--|-------------|---|
| 1.1 | Scope | | Р |
| | This standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be installed in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1; CAN/CSA-C22.2 No. 0; and CAN/CSA-Z32. | Considered. | Р |
| | NOTE 1A: In the IEC 60601 standards series adopted for use in Canada, the Canadian- particular standards may modify, replace, or delete requirements contained in this standard as appropriate for the particular ME EQUIPMENT and ME SYSTEMS under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements. | | |
| 1.3 | Collateral standards | | Р |
| | Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard. | Considered. | P |
| | NOTE 1: When evaluating compliance with CAN/CSA-C22.2 No. 60601-1, it is permissible to assess independently compliance with the adopted Canadian collateral standards | | |
| 1.4 | Particular standards | | Р |
| | A requirement of a Canadian-particular safety standard takes precedence over this standard. | Considered. | Р |
| 2 | Normative references The following referenced documents are indispensable for the application of this document. For dated references, the applicable | Considered. | Р |
| | 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. | | |
| | CSA (Canadian Standards Association) | Considered. | Р |
| | B51-03: Boiler, pressure vessel, and pressure piping code | | |
| | C22.1-06: Canadian Electrical Code, Part I | | |
| | CAN/CSA-C22.2 No. 0-M91 (R2006): General requirements — Canadian Electrical Code, Part | | |

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| | IEC 60601-1 | | | | |
|--------|--|-----------------|---------|--|--|
| Clause | Requirement + Test | Result - Remark | Verdict | | |
| | 11 | | | | |
| | C22.2 No. 21-95 (R2004): Cord sets and power supply cords | | | | |
| | C22.2 No. 42-99 (R2004): General use receptacles, attachment plugs, and similar wiring devices | | | | |
| | C22.2 No. 49-06: Flexible cords and cables | | | | |
| | CAN/CSA-E61558-2-1:03: Safety of power transformers, power supply units and similar — Part 2: Particular requirements for separating transformers for general use | | | | |
| | CAN/CSA-Z32-04: Electrical safety and essential electrical systems in health care facilities | | | | |
| | Z305 series of Standards: | Considered. | Р | | |
| | CAN/CSA-Z305.1-92 (R2001): Non-flammable medical gas piping systems | | | | |
| | CAN/CSA-Z305.6-92 (R2007): Medical oxygen concentrator central supply system for use with non-flammable medical gas piping systems | | | | |
| | CAN/CSA-Z305.8-03. Medical supply units | | | | |
| | CAN/CSA-Z305.12-98 (R2004): Guide for the safe storage, handling and use of portable oxygen systems in home, domiciliary and healthcare settings | | | | |
| | CAN/CSA-Z5359-04: Low pressure hose assemblies for use with medical gases | | | | |
| | CAN/CSA-Z9170-1-00 (R2005): Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum | | | | |
| | CAN/CSA-Z9170-2-00 (R2005): Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems | | | | |
| | CAN/CSA-Z9170-2-00 (R2005): Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems | | | | |
| | CAN/CSA-Z15002-02 (R2007): Flow-metering devices for connection to terminal units of medical gas pipeline systems | | | | |
| | ASME International (American Society of Mechanical Engineers) | | | | |
| | PTC 25-2001: Pressure Relief Devices | | | | |
| | CGA (Compressed Gas Association): | | | | |
| | V-1-2005: Standard for Compressed Gas | | | | |

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| IEC 60601-1 | | | |
|-------------------|--|--|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Cylinder Valve Outlet and Inlet Connections V-5-2005: Diameter Index Safety System (Non | | |
| | interchangeable Low Pressure Connections for Medical Gas Applications) | | |
| | ISO (International Organization for Standardization) | | N/A |
| | 32:1977: Gas cylinders for medical use — Marking for identification of content | | |
| | 407:2004: Small medical gas cylinders — Pin- index yoke-type valve connections | | |
| 3.41 | HIGH VOLTAGE | | N/A |
| | any voltage above 750 V, 1 050 V peak, as defined in the Canadian Electrical Code (CEC), Part I | No such high voltage within the equipment. | N/A |
| 4.8 | Components of ME EQUIPMENT | | Р |
| | a) the applicable safety requirements of a relevant CSA, IEC, or ISO standard; | Considered. | Р |
| | 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. | | |
| | b) where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied | Considered. | Ρ |
| | 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. | | |
| 4.10.2 | SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS | | Р |
| | and shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1: | | Р |
| 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 Canadian Electrical Code (CEC), Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49. | No protective earth conductors provided. | N/A |
| 8.7.3 | Allowable values | Considered. | Р |
| | Allowable values shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1. | Touch current did not exceed 100 μA in NC and 300 μA in SFC. | |
| 8.11.3.2 | POWER SUPPLY CORDS Types | | N/A |

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| IEC 60601-1 | | | |
|-------------|--|--|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be | Power supply cord not part of the investigation. | N/A |
| | i) if molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21; | | |
| | j) hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or | | |
| | k) 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 | EUT is intended for building- in. | N/A |
| | 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; | | |
| | j) can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and | | |
| | k) 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 | | |
| | c) A detachable POWER SUPPLY CORD shall | EUT is intended for building- | N/A |
| | i) comply with the applicable requirements of CSA C22.2 No. 21; and | in. | |
| | j) not be smaller than No. 18 AWG, and the mechanical serviceability shall be not less than | | |
| | 1) Type SJ or equivalent for mobile or exposed | | |
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IEC 60601-1

| | IEC 60601-1 | | |
|--------|---|--------------------------------------|---------|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | to abuse ME EQUIPMENT; and 2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature). 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 Canadian Electrical Code, Part I, as applicable. Connecting cords between equipment parts shall meet the requirements of the Canadian Electrical Code, Part I, as applicable. | EUT is intended for building- in. | N/A |
| 8.11.5 | Mains fuses and OVER-CURRENT RELEASES Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1. | See list of critical components. | Ρ |
| 9.7.5 | Pressure vessels Pressure vessels shall comply with the requirements of CSA B51, as applicable. | No pressure vessels provided. | N/A |
| 9.7.7 | Pressure-relief device A pressure-relief device shall also comply as applicable to the requirements of ASME PTC 25 or equivalent Canadian requirements. | No pressure-relief devices provided. | N/A |
| 15.4.1 | Construction of connectors 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 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. | No gas cylinders provided. | N/A |
| | 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. | | |
| 15.4.8 | Internal wiring of ME EQUIPMENT Internal wiring of ME EQUIPMENT shall be in | | Р |

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|--------|--|----------------------------|--------------|
| | IEC 60601-1 | | |
| Clause | Requirement + Test | Result - Remark | Verdict |
| | accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1. | | |
| 16.1 | MULTIPLE SOCKET OUTLET | No multiple socket outlets | N/A |
| | The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements. | provided. | |
| | - 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. | | |

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

| Nationa | I standard SN EN 60601-1:06 | | |
|---------|---|--|-----|
| 1 | Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7, | No mercury used during normal use of the | N/A |
| | Mercury - Annex 1.7 of SR 814.81 applies for mercury. | equipment. | |
| | Switches containing mercury such as thermostats, relays and level controllers are not allowed. | | N/A |
| | Ordinance on chemical hazardous risk reduction SR 814.81, Annex 2.15: Batteries | | N/A |
| | Annex 2.15 of SR 814.81 applies for batteries containing cadmium and mercury. | No batteries incorporated. | N/A |
| | 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). | | N/A |
| | 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: | Power supply cord not part of the investigation. | N/A |
| | - 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 | | |
| 4 | 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, | Power supply cord not part of the investigation | N/A |
| | SEV 1011 and one of the following dimension sheets: | | |
| | - 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. | | N/A |
| | See TRF template regulatory requirements Switzerland on IECEE Website R.R. TRF templates. | | N/A |



Enclosure No. 2

Photo documentation

(7 pages including this cover page)





















Enclosure No. 3

Schematics, layouts and transformer drawings

(43 pages including this cover page)



SIQ



 Part No.: 530–0096
 PCB MASK COLOR: RED

 Material: FR-4; 1.6mm
 Tolerance: +/- 0.1(mm)

 Copper: 2oz.
 Rev: G

 Text Color: White
 Last Updated 12/17/10

 PCB VENDOR: ADD UL APPROVED MANUFACTURER LOGO,
 PCB MATERIAL & FLAMABILITY

GlobTek Inc. GTM91110P240XX Main PCB, Rev G Top Side





SI®



Part No.: 530–0097 Material: FR-4, 1.6mm Copper: 2oz. Text Color: White PCB VENDOR: ADD UL APPROVED MANUFACTURER LOGO, PCB MATERIAL & FLAMABILITY

> GlobTek Inc. GTM91110P240XX PCB Control Board











SIS









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4. MATERIAL LIST

| 10 | ITEM | MATERIAL | SUPPLIER | UL No |
|----|--------------------|--|---|--------------------------------|
| 1 | BOBBIN | FR PHENOL BPQ 32/32-1112CP OR EQUIVALENT | TDK OR EQUIVALENT | E59481(S) |
| 2 | CORE | FERRITE CORE PC44PQ32/30Z-12 OR EQUIVALENT | TDK OR EQUIVALENT | |
| 3 | WIRE | POLYURETHANE ENAMELLED COPPER WIRE 130C | WAN WON INDUSTRIAL CORP. PACIFIC ELECTONIC WIRE & CABLE CO LTD | E104091(S) E 84081 (S) |
| 4 | TRIPPLE | TRIPPLE INSULATION WIRE TEX-E | FURUKAMA ELECTRIC CO. LTD OR EQUIVALENT | E206440 |
| 5 | INSULATION TAPE | POLYESTER CT-280 POLYESTER CT-1350 POLYESTER CT-317F | JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO., LTD MINNESO TAMING & MFG 3M CENTER BONDTEC PACIFIC CO LTD | E165111 E7385(N) E175968 |
| 6 | TUBE | TEFLON 150V 200C | FLUO TECH INDUCTRIES CO.,LTD | E175982(S) |
| 7 | SHIELD | COPPER FOIL | DIANGIANG MATERIAL CO.,LTD PACIFIC ELECTONIC WIRE & CABLE COOPER WIRE | |
| 8 | VARNISH | WA -238A V-130FC 180C | HITACHI CHEMICAL CO.,LTD PD GEORGE/VIKING | E72979 E73071 |
| 9 | EPOXY | 9001 A/B | GUANGZHOU WELLS CHEMICAL CO LTD | E222812 |

GlobTek, Inc. 186 Veterans Dr. Northvale, NJ 07647 Tel 201-784-1000 Fax 201-784.0111 DWG TITLE: POWER TRANSFORMER 240 W 12V

| MODEL NO: | GT(M)91110P | REV. D |
|-----------|-------------|--------------|
| PART NO: | 403-0054(R) | SHEET 3 OF 0 |



| TEST ITEM | TEST CONDITION | RESULT |
|-----------------------|---|--|
| INDUCTANCE | @1KHz 0.25V (4 - 6) | 10.0 mH ± 25% |
| LEAKAGE INDUCTANCE | @1 KHz 0.25V (4 - 5) SHORT PIN 3,1 FL1, FL2 | 20 µH max |
| D.C. RESISTANCE | @25°C (2 - 1) (4 - 5) (FL1, FL2) | 0.005 ohm max 0.130 ohm max 0.0015 ohm max |
| HI-POT | @10 mA 1 MIN | P S 4000 VAC P -C 1500 VAC S - C 1500 VAC |
| | | |

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6. WINDING TABLE

| PIN | COPPER WIRE | TURNS | WINDING | TAPE TURNS | TUBE |
|----------|--|--|--|--|--|
| 4 - X | 0.5 x 2P | 22 | CLOSED | 1 | - |
| 10 | 0.025 x 17 mm | 0.8 | COPPER FOIL | 1 | 25L x 55 mm |
| FL1- FL2 | 0.28 x 24 STRANDS LITZ WIRE x 2P | 4 | CLOSED | 1 | 10L x 50 mm |
| 10 | 0.025 x 17 mm | 0.8 | COPPER FOIL | 1 | 25L x 55 mm |
| X - 5 | 0.5 x 2P | 22 | CLOSED | 1 | - |
| 2 - 1 | 0.37 x 1P | 2 | CLOSED | 3 | 2 |
| | PIN 4 - X 10 FL1- FL2 10 X - 5 2 - 1 | PIN COPPER WIRE 4 - X 0.5 x 2P 10 0.025 x 17 mm FL1- FL2 0.28 x 24 STRANDS LITZ WIRE x 2P 10 0.025 x 17 mm X - 5 0.5 x 2P 2 - 1 0.37 x 1P | PIN COPPER WIRE TURNS 4 - X 0.5 x 2P 22 10 0.025 x 17 mm 0.8 FL1- FL2 0.28 x 24 STRANDS LITZ WIRE x 2P 4 10 0.025 x 17 mm 0.8 X - 5 0.5 x 2P 22 2 - 1 0.37 x 1P 2 | PIN COPPER WIRE TURNS WINDING METHOD 4 - X 0.5 x 2P 22 CLOSED 10 0.025 x 17 mm 0.8 COPPER FOIL FL1- FL2 0.28 x 24 STRANDS LITZ WIRE x 2P 4 CLOSED 10 0.025 x 17 mm 0.8 COPPER FOIL X - 5 0.5 x 2P 22 CLOSED 2 - 1 0.37 x 1P 2 CLOSED | PIN COPPER WIRE TURNS WINDING METHOD TAPE TURNS 4 - X 0.5 x 2P 22 CLOSED 1 10 0.025 x 17 mm 0.8 COPPER FOIL 1 10 0.025 x 17 mm 0.8 COPPER FOIL 1 FL1- FL2 0.28 x 24 STRANDS LITZ WIRE x 2P 4 CLOSED 1 10 0.025 x 17 mm 0.8 COPPER FOIL 1 10 0.025 x 17 mm 0.8 COPPER FOIL 1 10 0.025 x 17 mm 0.8 COPPER FOIL 1 X - 5 0.5 x 2P 22 CLOSED 1 2 - 1 0.37 x 1P 2 CLOSED 3 |

| G Glob | Tek, Inc. | 186 Veterans Dr. Northvale, NJ 07647 Tel. 201-784-1000 Fax 201.784.0111 |
|------------|-------------|--|
| DWG TITLE: | POWER TRAN | SFORMER 240 W 12V |
| | | |
| MODEL NO; | GT(M)91110P | REV. D |















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4. MATERIAL LIST

| NO | ITEM | MATERIAL | SUPPLIER | UL No |
|----|--------------------|--|---|--------------------------------|
| 1 | BOBBIN | FR PHENOL BPQ 32/32-1112CP OR EQUIVALENT | TDK OR EQUIVALENT | E59481(S) |
| 2 | CORE | FERRITE CORE PC44PQ32/30Z-12 OR EQUIVALENT | TDK OR EQUIVALENT | |
| 3 | WIRE | POLYURETHANE ENAMELLED COPPER WIRE 130C | WAN WON INDUSTRIAL CORP. PACIFIC ELECTONIC WIRE & CABLE CO LTD | E104091(S) E 84081 (S) |
| 4 | TRIPPLE | TRIPPLE INSULATION WIRE TEX-E | FURUKAMA ELECTRIC CO. LTD OR EQUIVALENT | E206440 |
| 5 | INSULATION TAPE | POLYESTER CT-260 POLYESTER CT-1350 POLYESTER CT-317F | JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO., LTD MINNESO TAMING & MFG 3M CENTER BONDTEC PACIFIC CO LTD | E165111 E7385(N) E175868 |
| 6 | TUBE | TEFLON 150V 200C | FLUO TECH INDUCTRIES CO.,LTD | E175982(S) |
| 7 | SHIELD | COPPER FOIL | DIANQIANG MATERIAL CO.,LTD PACIFIC ELECTONIC WIRE & CABLE COOPER WIRE | |
| 8 | VARNISH | WA -238A V-130FC 180C | HITACHI CHEMICAL CO.,LTD PD GEORGE/VIKING | E72979 E73071 |
| 9 | EPOXY | 9001 A/B | GUANGZHOU WELLS CHEMICAL CO LTD | E222812 |
| | | | | |

| G Glob | Tek, Inc. | 186 Veterans Dr. Northvale, NJ 07647 Tel. 201-784-1000 Fax 201.784.0111 |
|------------|-------------|--|
| DWG TITLE: | POWER TRAN | SFORMER 240 W 18V |
| MODEL NO: | GT(M)91118P | REV. B |
| PART NO: | 403-0053(R) | SHEET 3 OF 6 |



| @1KHz 0.25V | 10.0 mH + 25% |
|---|---|
| (4-0) | 10.0 1111 2 2070 |
| @1 KHz 0.25V (4 - 5) SHORT PIN 3,1 FL1- FL2 | 20 µH max |
| @25°C (2 - 1) (4 - 5) (FL1 - FL2) | 0.005 ohm max 0.130 ohm max 0.004 ohm max |
| @10 mA 1 MIN | P S 4000 VAC P -C 1500 VAC S - C 1500 VAC |
| | |
| | @1 KHz 0.25V (4 - 5) SHORT PIN 3.1 FL1- FL2 @25°C (2 - 1) (4 - 5) (FL1 - FL2) @10 mA 1 MIN |

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6. WINDING TABLE

| WINDING NO | PIN | COPPER WIRE | TURNS | WINDING | TAPE TURNS | TUBE |
|---------------|----------|-------------------------------------|-------|----------------|---------------|-------------|
| N1 | 4 - X | 0.5 x 2P | 22 | CLOSED | 1 | - |
| E1 | 10 | 0.025 x 17 mm | 0.8 | COPPER FOIL | 1 | 25L x 55 mm |
| N2 | FL1- FL2 | 0.28 x 32 STRANDS LITZ WIRE x 1P | 6 | CLOSED | 1 | 8L x 55mm |
| E2 | 10 | 0.025 x 17 mm | 0.8 | COPPER FOIL | 1 | 25L x 55 mm |
| N3 | X - 5 | 0.5 x 2P | 22 | CLOSED | 1 | - |
| N4 | 2 - 1 | 0.37 x 1P | 2 | CLOSED | 3 | 22 |
| | | 1 | | | - | |

| G Glob | Tek, Inc. | 186 Veterans Dr. Northvale, NJ 07647 Tel. 201-784-1000 Fax 201.784.0111 |
|------------|--------------|--|
| DWG TITLE: | POWER TRAN | SFORMER 240 W 18V |
| | GT/M0011108 | REV. |
| MODEL NO: | Ortholoritie | E |















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4. MATERIAL LIST

| 10 | ITEM | MATERIAL | SUPPLIER | UL No |
|----|--------------------|--|---|--------------------------------|
| 1 | BOBBIN | FR PHENOL BPQ 32/32-1112CP OR EQUIVALENT | TDK OR EQUIVALENT | E59481(S) |
| 2 | CORE | FERRITE CORE PC44PQ32/30Z-12 OR EQUIVALENT | TDK OR EQUIVALENT | |
| 3 | WIRE | POLYURETHANE ENAMELLED COPPER WIRE 130C | WAN WON INDUSTRIAL CORP. PACIFIC ELECTONIC WIRE & CABLE CO LTD | E104091(S) E 84081 (S) |
| 4 | TRIPPLE WIRE | TRIPPLE INSULATION WIRE TEX-E | FURUKAMA ELECTRIC CO. LTD OR EQUIVALENT | E206440 |
| 5 | INSULATION TAPE | POLYESTER CT-280 POLYESTER CT-1350 POLYESTER CT-317F | JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO., LTD MINNESO TAMING & MFG 3M CENTER BONDTEC PACIFIC CO LTD | E165111 E7385(N) E175868 |
| 6 | TUBE | TEFLON 150V 200C | FLUO TECH INDUSTRIES CO., LTD | E175982(S) |
| 7 | SHIELD | COPPER FOIL | DIANQIANG MATERIAL CO.,LTD PACIFIC ELECTONIC WIRE & CABLE COOPER WIRE | |
| 8 | VARNISH | WA -238A V-130FC 180C | HITACHI CHEMICAL CO.,LTD PD GEORGE/VIKING | E72979 E73071 |
| 9 | EPOXY | 9001 A/B | GUANGZHOU WELLS CHEMICAL CO LTD | E222812 |
| | | | | |

| • • • • • • • • • • • • | | Tel. 201-784-1000 | Fax 201.784.0111 |
|-------------------------|--------------|-------------------|------------------|
| WG TITLE: | POWER TRAN | SFORMER 240 W 24 | ŧV |
| ODEL NO: | GT(M)91110P3 | 24024-8 | REV. |

| IODEL NO: | GT(M)91110P24024-S | P |
|-----------|--------------------|--------------|
| ART NO: | 403-0052(R) | SHEET 3 OF 6 |



| TEST ITEM | TEST CONDITION | RESULT |
|-----------------------|---|---|
| INDUCTANCE | @1KHz 0.25V (4 - 6) | 10.0 mH ± 25% |
| LEAKAGE INDUCTANCE | @1 KHz 0.25V (4 - 5) SHORT PIN 2, 1, FL1, FL2 | 20 µH max |
| D.C. RESISTANCE | @25°C (2 - 1) (4 - 5) (FL1-FL2) | 0.030 ohm max 0.130 ohm max 0.007 ohm max |
| HI-POT | @10 mA 1 MIN | P S 4000 VAC P -C 1500 VAC S - C 1500 VAC |
| | | |

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6. WINDING TABLE

| WINDING NO | PIN | COPPER WIRE | TURNS | WINDING METHOD | TAPE | TUBE |
|---------------|----------|-------------------------------------|-------|-----------------------|------|--------------------------|
| N1 | 4 - X | 0.5 x 2P | 22 | CLOSED | 1 | 15 mm (2x) |
| E1 | 10 | 0.025 x 17 mm | 0.8 | COPPER FOIL | 1 | 15 mm (1x) |
| N2 | FL1- FL2 | 0.28 x 24 STRANDS LITZ WIRE x 1P | 8 | CLOSED | 1 | 40 mm (1x) 15 mm (1x) |
| E2 | 10 | 0.025 x 17 mm | 0.8 | COPPER FOIL | 1 | 15 mm (1x) |
| N3 | X - 5 | 0.5 x 2P | 22 | CLOSED | 1 | 15 mm (2x) |
| N4 | 2 - 1 | 0.37 x 1P | 2 | CLOSED | 3 | 15 mm (2x) |
| BELLY BAND | 10 | 0.025 x 12 mm | 1 | COPPER FOIL CLOSED | 3 | 15 mm (1x) |

| G Glob | Tek, Inc. | 186 Veterans Dr. No Tel. 201-784-1000 | orthvale, NJ 07647 Fax 201.784.0111 |
|------------|---------------|--|--|
| DWG TITLE: | POWER TRAN | SFORMER 240 W 24 | v |
| MODEL NO: | GT(M)91110P24 | 4024-5 | REV, F |
| PART NO: | 403-0052(R) | 5 | SHEET S OF |






| PROPRIETARY INFORMATION | | | | | REVISION | | _ | |
|---|----------------|-------------------|---|------------------------|---|--|--------------------|-----------|
| ROPRIETARY OF GLOBTEK, INC. ANY R | EPRODUCTION. | DISCLOSURE OR | REV | DESCRIP | TION | DA | TE | APPROVED |
| SE OF THIS DRAWING, IN WHOLE OR IN | PART, IS HEREB | Y | A | INITIAL RELEA | SE, 12921, JB | 01/3 | 1/08 | HM |
| OHIBITED EXCEPT AS SPECIFIED IN W | ICTING BY GLO | BLEK, INC. | B UPO | ATE SPEC. AND SCHEMA | TIC, RFS. 13377, | JB 04/1 | 3/08 | HM |
| | | | C UPD | TE DRAWING RFS. 1350 | 33, 18 | 05/1 | 3/08 | HM |
| | | | D UPO | ATE DRAWING RFS. 1593 | BL , 20 | 04/0 | 3/09 | HM |
| | | | E CHA | VGE N2 TO Ø0.28 PER VI | ENDOR, RFS. 16 | 295, JB 05/1 | 909 | HM |
| DINELCAL DIMEN | ETONE (| INTER | 1 100 | 42 bitl, 0 20, bitle | 510110, 10 C. 107 | 1,00 | | |
| LABEL #2 See note 10 | | |) ABEL #1 | | - E | D FL1 | F | T L2 |
| 12 | 1 | 0000 | т 7 | | B (m/m) C (m/m) D (m/m) E (m/m) F (m/m) G (m/m) H (m/m) | $\begin{array}{r} 33.0 \text{ MAX} \\ 4.0 \pm 0.5 \\ 36.0 \text{ MAX} \\ 0.8 \pm 0.1 \\ 7.5 \pm 0.5 \\ 5.0 \pm 0.5 \\ 30.5 \pm 0.5 \\ 30.5 \pm 0.5 \\ \end{array}$ | | |
| e Note: block for, will not be liable for the by and performance of these power sugplies authorited access and report occurs. End sitesid accessit opticable UL, GAA or | DASH NO. | PART NO R | 19. | DESC TABULATION E | RIPTION BLOCK | | | NOTES |
| abadanda for proper installation instructions abades of Use: Atck product are not earlierized for use as | | | TOLERANCES SECONDER ANEL AL VALUE AL VALUE | | ek, Inc. stek.com | 186 Veterans Dr. N Tel. 201-784-1000 | orthvale Fax 20 | NJ 07647 |
| tion critical components in Bile support. | NIT.BY: FB | DATE: | AN 40.83 40.8 | DWGTITLE P | OWER TRANSP | ORMER 240 W 48 | V AND | 0.55V |
| raft applications without prior written reveal from the CEO of Globick Inc. | RAWN: NF | DATE: 01/31/08 | | MODEL NO: | GT(M)91110P | | Ĩ | REV. F |
| centents of this document are subject to A | PRVD : HM | DATE: | SCALE: NONE | PART NO: | 403-0051(R) | | | SHEET I O |



| | T AS SPECIFIED IN WRITING BY GLOBIE | h _e true | | | | |
|--|---|--|------------------|-------------|--|-------------------|
| | LABEL #1 | | | LABE | L #2 | |
| | 403-0051(R) REV. F XXXX YYYY | 9.0 mm | | Hit | 12 mm | |
| Whe XXX YYY | ere: X = Vendor insulation numb Y = Vendor name | er | | | | |
| Label 1 a | and 2 material: ULappro | oved, Clear/Transparer | nt with Bl | ack text. | | |
| | | | | | | |
| Add suitab Add Mylar Add Mylar Install the S. Add Mylar Adad Mylar Add Mylar Cut pins 3, Add Label Dip transft Derform h add hipot | le amount of black epoxy to secur r tape around the core, 2 layers, 0.0 r tape around the winding, 2 layers shield E3 and terminate to pin. 10. r tape on top of shield E3, 3 layers, r tape around the core, 3 layers, 0.0 ,6,8,9, 11 and 12. Is 1 and 2. ormer is varnish and dry it. ipot test, P-S 4000Vac, P-C 1500V sticker only when transformer pas | e core to core and core to bobbin 125 mm*10 mm. , 0.025 mm*18 mm. , 0.025 mm*18 mm. 025 mm*22 mm. /////////////////////////////////// | | | | |
| | | | | | | |
| | | 1 | G Glob | Tek, Inc. | 186 Veterans Dr. No Tel. 201-784-1000 | ethvale, NJ 07647 |
| | | | www. | globtek.com | SECENER MAD IN 491 | / AND SU |
| | | Di | WWW WG TITLE: | power tran | SFORMER 240 W 48V | / AND 55V REV. |







| | 11 CW | MATERIAL | SUPPLIER | UL NO |
|---|--------------------|--|---|--|
| 1 | BOBBIN | FR PHENOL BPQ 32/32-1112CP OR EQUIVALENT | TDK OR EQUIVALENT | E59481(S) |
| 2 | CORE | FERRITE CORE PC44PQ32/30Z-12 OR EQUIVALENT | TDK OR EQUIVALENT | |
| 3 | WIRE | POLYURETHANE ENAMELLED COPPER WIRE 130C | WAN WON INDUSTRIAL CORP. PACIFIC ELECTONIC WIRE & CABLE CO LTD | E104091(S) E 84081 (S) |
| 4 | TRIPPLE | TRIPPLE INSULATION WIRE TEX-E | FURUKAMA ELECTRIC CO. LTD OR EQUIVALENT | E206440 |
| 5 | INSULATION TAPE | POLYESTER CT-280 POLYESTER CT-1350 POLYESTER CT-317F | JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO., LTD MINNESO TAMING & MFG 3M CENTER BONDTEC PACIFIC CO LTD | E165111 E7385(N) E175868 |
| 6 | TUBE | TEFLON 150V 200C | FLUO TECH INDUSTRIES CO.,LTD | E175982(S) |
| 7 | SHIELD | COPPER FOIL | DIANQIANG MATERIAL CO.,LTD PACIFIC ELECTONIC WIRE & CABLE COOPER WIRE | |
| 8 | VARNISH | WA -238A V-130FC 180C | HITACHI CHEMICAL CO.,LTD PD GEORGE/VIKING | E72979 E73071 |
| 9 | EPOXY | 9001 A/B | GUANGZHOU WELLS CHEMICAL CO LTD | E222812 |
| | | | | |
| | | | GlobTek, Inc. 186 Veter Tel. 201- | ans Dr. Northvale, NJ 0764 784-1000 Fax 201.784.011 |
| | | | DWG TITLE: POWER TRANSFORMER | 240 W 48V AND 55V |
| | | | MODEL NO: GT(M)91110P | REV. F |



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5. ELECTRICAL CHARACTERISTIC

| TEST ITEM | TEST CONDITION | RESULT |
|-----------------------|---|---|
| INDUCTANCE | @1KHz 0.25V (4 - 5) | 10.0 mH ± 25% |
| LEAKAGE INDUCTANCE | @1 KHz 0.25V (4 - 5) SHORT PIN 2 & 1 FL1, FL2 | 20 µH max |
| D.C. RESISTANCE | @25°C (2 - 1) (4 - 5) (FL1 - FL2) | 0.030 ohm max 0.130 ohm max 0.030 ohm max |
| HI-POT | @10 mA 1 MIN | P-S 4000 VAC P-C 1500 VAC S-C 1500 VAC |
| | | |
| | | |
| | | |

DWG TITLE POWER TRANSFORMER 240 W 48V AND 55V

REV.

SHEET 5 OF 7

GT(M)91110P MODEL NO: PART NO:

403-0051(R)



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6. WINDING TABLE

| WINDING NO | PIN | COPPER WIRE | TURNS | WINDING | TAPE TURNS | TUBE |
|---------------|----------|------------------------------------|-------|----------------|---------------|-----------|
| N1 | 4 - X | 0.5 x 2P | 22 | CLOSED | 1 | 15 mm, 2X |
| E1 | 10 | 0.025 x 17 mm | 0.8 | COPPER FOIL | 1 | 15 mm, 1X |
| N2 | FL1- FL2 | 0.28 x 6 STRANDS LITZ WIRE x 2P | 16 | CLOSED | 1 | 20 mm, 4X |
| E2 | 10 | 0.025 x 17 mm | 0.8 | COPPER FOIL | 1 | 15 mm, 1X |
| N3 | X - 5 | 0.5 x 2P | 22 | CLOSED | 1 | 15 mm, 2X |
| N4 | 2 - 1 | 0.37 x 1P | 2 | CLOSED | 3 | 15 mm, 2X |
| E3 | 10 | 0.025 x 12 mm | 1 | COPPER | 3 | 15 mm, 1X |

| G Glob | Tek, Inc. | 186 Veterans Dr. Northvale, NJ 07647 Tel. 201-784-1000 Fax 201.784.0111 |
|------------|-------------|--|
| DWG TITLE: | POWER TRAN | SFORMER 240 W 48V AND 55V |
| MODEL NO: | GT(M)91110P | REV. P |
| PART NO: | 403-0051(R) | SHEET 6 O |







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TRF No. IEC60601_1J_PS

| APPROVED | 0 | 8 9 | | | | | | | | | | NOTES | | Ltd | vary globatica | | Rev. | 1.10 |
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| DATE 2008.04.10 | 2. SCHEWATIC: | 4 • NI NI=N | | | | | | | | | AWING | NDITTINOSID | | k(Suzhou). Co | -0045 Fact +166-21-4916-0422 Wch: | mmon Mode Chake, LF2 | PART NO: 321-0217800005 | 1 SHEET 1 |
| VISION CRIPTION LEASE ROMMAN | Name of the second | | | | | 4 如何所 | A AS THE DRAVIN | | | | NTROL DR/ | | | GlobTe | Tak 446-21-6914 | DWG Title: | MODEL NO. | |
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| arv A | AN ANA | | | NUCCES . | 1. 依线均匀平 | 2. ACABACCEPT | 3. A&AM 管子 2. A&AM 管子 2. A&AM 管子 2. A&AM 管子 2. A&AM M 2. A | | | | SPECIFIC | P.V | | 1100 | | N DATE 2000 NO | DATE 2002 04.10 | |
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| S-R-RUM STICKLE PART, IS HEREB BUTHALIY CALOR | 1. MBCH | | | | | | | | CLASS | 130° C | | | 130° C | | | ĸ | subject to | |
| 4. LENDADOR ON K INC. ANY RI K INC. ANY RI IN MICLEOR | | | | /0.25V | i/0, 25V | | | Ì | UL NO | E201757 | | | E216733 | | 1 | 资本的支持等得 有 | Pilo dicensei arc | Del prior reflor |
| 2.5 F 6 9 K R F (Laters 2 Latts 2 elligitistics) Carestrative secondaria constantive of 910810 Constantive of 910810 R USE OF 1988 Deavements R USE OF 1988 Deavements R USE OF 1988 Deavements | | | INDUCTANCE | 6mH Min, 1KHz | 6nH Min, 1KHz | | | | | ABLE CO., LTD | A Equivalent | | GUAN) LTD. | | | 1000 | Canterio of | day Afteria |
| 1 am 61709 | | CH100 | TURNS | 40T | 40T | | | | PLER | NIRE & C | 3.7E HS72 (| | TECH (DOMG | | 1000 | 176411254 . I&0 402,00025 | for the case of th | much data us |
| By Jepson & at 310 | | н мануулус ч | COLOR | YELLOW | YELLOW | | to AO coord | NICTION DECISION | SUI | IFIC TRONTRIA | N: T22. 1+6, 4+1 | WG YE CO., LTI | AK CHEMISTRY | | | LALEN FRAME (1994) ADDREAM (1994) BARAN SPHOLTARY BARAN (1994) | Met production of reality data setting components in reduce development, multip | Realitions without, prior who 1 the CEIT of Clickwaller |
| | | THAT INH | WIRE SIZE | 0. 75mm X1 | 0.75mm X1 | | An And No. | 1 201 101 10 | RIAL. | W PACI | a TDK. P | FR4 XIA | c gun GUD | | 100 BB | The second secon | Addin and a | SAGEN NO PAR |
| | | PT DES TID | HSINIS | 4 | 9 | ax. | C 50Hz/5 | nananan | NATE | 206 | Perrits | 1, 0ml | Black | 2 | a management | ARTICLE RENT | be listly for the 1 these points? | Applicable U. C. |
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| | | | NO | N | N2 | Rdc 1 | 4. HI-P | rddur | QN. | | 2 | 5 | 4 | 10 | | | 3-3762 | 85 |







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SHEET 2 OF 2

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|---|---|-----------------------------|-----------------|-------------------------------------|--------------|
| 4. SPECIFICATIO | N | | | | |
| ITEM | S | PECIFICATION | | | |
| TURNS | 1S - 1F: 40T | | | | |
| | 2S -2F: 7T, SPREAD EVENLY | ACROSS THE ENTIRE CORE | | | 1 |
| WIRE GAUGE | 1S - 1F: 0.85 X 2P, 2UEW , YELL | .OW; 2S - 2F: AWG #22, 2UEV | V, RED; | | |
| | SHIELD TERMINATION: AWG | 22, WIRE WITH TEFLON TUBE | | | |
| INDUCTANCE | 1S - 1F: 150 µH TO 170µH ME | ASURED 1 KHz 0.25V | | | |
| DC RESISTANCE | 1S - 1F: 20 mOhm MAXIMUM | | | | |
| ORE | CM234125 X1, CHANG SUNG | CORPORATION, NO SUBSTIT | UTION ALLOWED | | |
| IPOT | HIPOT BETWEEN N1 TO SHIEL | LD AND N2 TO SHIELD, 1500 | /ac, 1 MINUTE | | |
| 4.0 | SHIELD AWG 221 25 mp 10 | MYLAR TAPI | | | |
| | | | G 186 Vetera | lobTek, Inc. | 7647 |
| | | | DWG Title: | OUTPUT CHOKE 48 FOR GTM91110P240 | V, 55V 55 |
| | | | MODEL: | PART NO: 403-0056 | REV |