**Test Report issued under the responsibility of:**

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

| | |
|---|---|
| **Report Reference No.....:** | **T221-0003/17** |
| **Date of issue.....:** | **2017-02-14** |
| **Total number of pages.....:** | **226 pages** |
| **CB Testing Laboratory.....:** | **SIQ Testing and Certification GmbH** |
| **Address .....:** | **Angerstarße 11, D-86807 Buchloe, Germany** |
| **Applicant's name.....:** | **GlobTek, Inc.** |
| **Address .....:** | **186 Veterans Drive, Northvale, NJ 07647, USA** |
| **Test specification:** | |
| **Standard.....:** | IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012<br>(or IEC 60601-1: 2012 reprint) |
| **Test procedure .....:** | CB Scheme |
| **Non-standard test method……..:** | |
| **Test Report Form No.....:** | IEC60601_1K |
| **Test Report Form Originator.....:** | UL(US) |
| **Master TRF.....:** | 2015-11 |

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

**General disclaimer:**

The test results presented in this report relate only to the object tested.
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| | |
|---|---|
| **Test item description** ..... : | Direct Plug-in or Open frame Power Supply |
| **Trade Mark** ..... : | GlobTek, Inc. |
| **Manufacturer** ..... : | GlobTek, Inc. 186 Veterans Drive, Northvale, NJ 07647, USA |
| **Model/Type reference** ..... : | GT (M or -) 41060 (- or CC) WWVV-X.XA-FW Family where:<br>M or – for marked identification and not related to safety<br>41060: Series code<br>(- or CC): "-" = Constant Voltage Model, CC = Constant Current Model<br>WW: is the rated output wattage designation, with a maximum value of "25"<br>VV: is the standard rated output voltage designation, with a maximum value of "30"<br>- X.X: Denotes the optional deviation, subtracted or added from standard output voltage in 0,1 volt increments or blank to indicate the no voltage different.<br>A is optional for marked identification and not related to safety.<br>- FW: is optional and means open frame power supply<br>Models providing MOPP protection are additionally marked with 2MOPP near model name. |
| **Ratings** ..... : | I/P: 100-240 V~; 50-60 Hz; 0,6 A; Class II<br>O/P: 5-30 V dc; Max. 3,0 A; Max. 25 W<br>See table below. |

**Direct plug-in Power supply:**

| Model name | Output voltage | Max. output current | Max. output power |
|---|---|---|---|
| GTM41060(- or CC)-1505A | 5,0 V dc | 3,0 A | 15 W |
| GTM41060(- or CC)-1706-X.XA | 5,1-6 V dc | 3,0 A | 18 W |
| GTM41060(- or CC)-1807-X.XA | 6,1-7 V dc | 2,95 A | 18 W |
| GTM41060(- or CC)-1809-X.XA | 7,1-9 V dc | 2,54 A | 18 W |
| GTM41060(- or CC)-2512-X.XA | 9,1-12 V dc | 2,75 A | 25 W |
| GTM41060(- or CC)-2515-X.XA | 12,1-15 V dc | 2,07 A | 25 W |
| GTM41060(- or CC)-2518-X.XA | 15,1-18 V dc | 1,66 A | 25 W |
| GTM41060(- or CC)-2520-X.XA | 18,1-20 V dc | 1,38 A | 25 W |
| GTM41060(- or CC)-2524-X.XA | 20,1-24 V dc | 1,24 A | 25 W |
| GTM41060(- or CC)-2530-X.XA | 24,1-30 V dc | 1,04 A | 25 W |

**Open-frame Power supply:**

| Model name | Output voltage | Max. output current | Max. output power |
|---|---|---|---|
| GTM41060(- or CC)-1505A-FW | 5,0 V dc | 3,0 A | 15 W |
| GTM41060(- or CC)-1706-X.XA-FW | 5,1-6 V dc | 3,0 A | 18 W |
| GTM41060(- or CC)-1807-X.XA-FW | 6,1-7 V dc | 2,95 A | 18 W |
| GTM41060(- or CC)-1809-X.XA-FW | 7,1-9 V dc | 2,54 A | 18 W |
| GTM41060(- or CC)-2512-X.XA-FW | 9,1-12 V dc | 2,75 A | 25 W |
| GTM41060(- or CC)-2515-X.XA-FW | 12,1-15 V dc | 2,07 A | 25 W |
| GTM41060(- or CC)-2518-X.XA-FW | 15,1-18 V dc | 1,66 A | 25 W |
| GTM41060(- or CC)-2520-X.XA-FW | 18,1-20 V dc | 1,38 A | 25 W |
| GTM41060(- or CC)-2524-X.XA-FW | 20,1-24 V dc | 1,24 A | 25 W |
| GTM41060(- or CC)-2530-X.XA-FW | 24,1-30 V dc | 1,04 A | 25 W |

| | | |
|---|---|---|
| **Testing procedure and testing location:** | | |
| ☒ **CB Testing Laboratory:** | SIQ Testing and Certification GmbH | |
| **Testing location/ address.....:** | Angerstarße 11, D-86807 Buchloe, Germany | |
| ☐ **Associated CB Testing Laboratory:** | | |
| **Testing location/ address.....:** | | |
| **Tested by (name, function, signature).....:** | Alexander Mayr | |
| **Approved by (name, function, signature)...:** | Boštjan Glavič | |
| | | |
| ☐ **Testing procedure: CTF Stage 1:** | | |
| **Testing location/ address.....:** | | |
| **Tested by (name, function, signature).....:** | | |
| **Approved by (name, function, signature)...:** | | |
| | | |
| ☐ **Testing procedure: CTF Stage 2:** | | |
| **Testing location/ address.....:** | | |
| **Tested by (name, function, signature).....:** | | |
| **Witnessed by (name, function, signature) .:** | | |
| **Approved by (name, function, signature)...:** | | |
| | | |
| ☐ **Testing procedure: CTF Stage 3:** | | |
| ☐ **Testing procedure: CTF Stage 4:** | | |
| **Testing location/ address.....:** | | |
| **Tested by (name, function, signature).....:** | | |
| **Witnessed by (name, function, signature) .:** | | |
| **Approved by (name, function, signature)...:** | | |
| **Supervised by (name, function, signature) :** | | |

| List of Attachments (including a total number of pages in each attachment): |
|---|
| 1. **Test Report (165 pages)**<br>2. **National Differences to IEC 60601-1: 2005 + AM1: 2012 – Enclosure No. 1 (10 pages)**<br>3. **Photo documentation – Enclosure No. 2 (16 pages)**<br>4. **Schematics, layouts and transformer drawings – Enclosure No. 3 (35 pages)** |

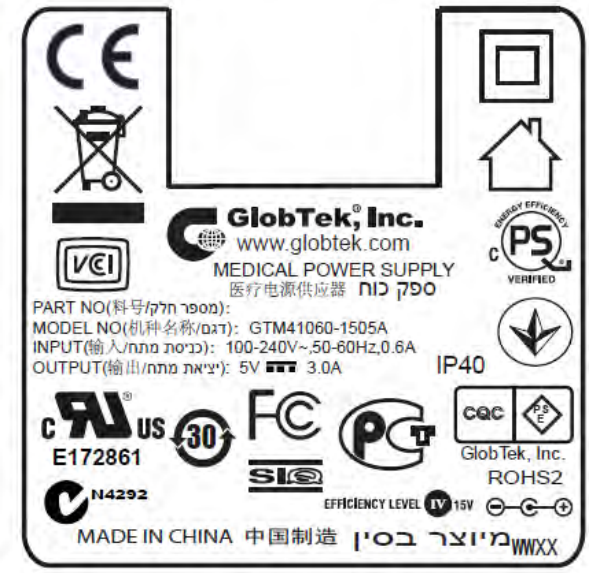
| Summary of testing | |
|---|---|
| **Tests performed (name of test and test clause):** | **Testing location:** |
| **4.11 Power Input**<br>**5.7 Humidity treatment**<br>**7.1.2 Legibility of marking**<br>**7.1.3 Durability of marking**<br>**8.4.2 c) Working Voltage / Power Measurement**<br>**8.4.3 ME equipment intended to be connected to a power source by a plug**<br>**8.5.4 Working voltage Measurement**<br>**8.7.4.6 Touch Current**<br>**8.8.3 Dielectric Strength test of solid insulation materials with safety functions**<br>**8.9.4 Measurement of creepage distances and air clearances**<br>**11.1 Excessive temperatures in ME EQUIPMENT**<br>**13.2 Single Fault conditions**<br>**15.3.2 Push test**<br>**15.3.3 Impact test**<br>**15.3.4 Drop test**<br>**15.3.6 Mould-stress relief test**<br>**15.5.1.2 Transformer short circuit**<br>**15.5.1.3 Transformer overload**<br>**Evaluation of voltage limiting components in SELV circuits** | **Initial report up to report Rev. No. 3.0**<br>**SIQ Ljubljana, Tržaška c. 2, SI-1000, Ljubljana, Slovenia**<br><br>**Report Rev. No. 4.0**<br>**SIQ Testing and Certification GmbH, Angerstaße 11, D-86807 Buchloe, Germany** |

| Summary of compliance with National Differences |
|---|
| List of countries addressed:<br>Austria**, Canada*, France*, Slovenia*, Sweden**, Switzerland*, Turkey*, United Kingdom**, USA* as listed in online CB-Bulletin.<br>* National differences according to IEC 60601-1: 2005 declared.<br>** EU group differences<br>☒ The product fulfils the requirements of EN 60601-1:2006 + A1:2013 + A11:2011+ A12:2014 |

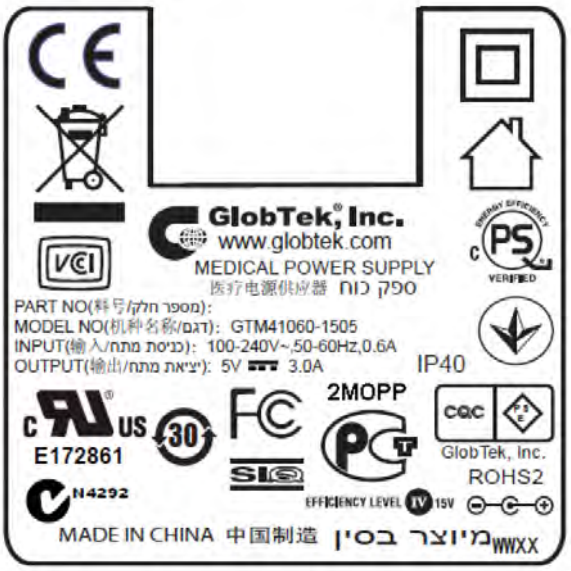
**Copy of marking plate**

**The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.**

a) Marking plate for models provided MOOP protection (example only):

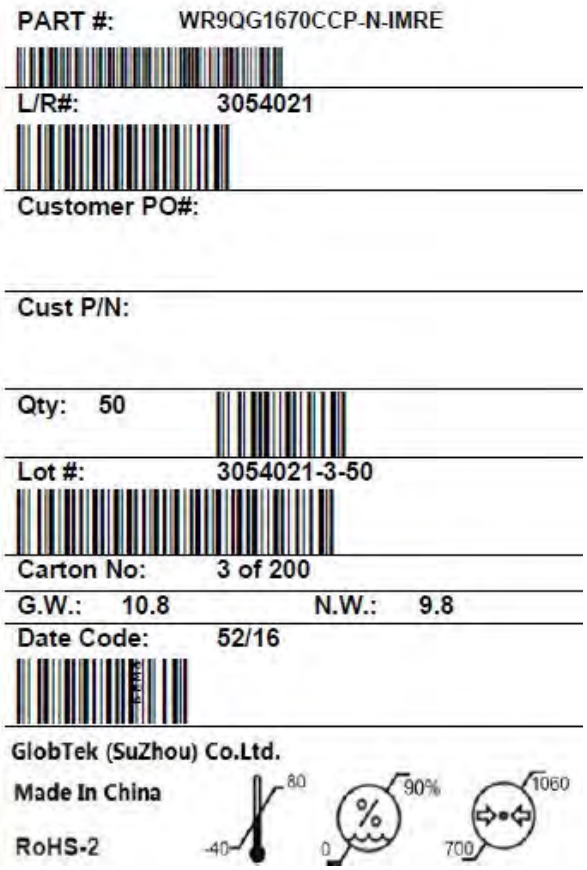



b) Marking plate for models provided MOPP protection (example only):




Serial number label:

Packaging label



| GENERAL INFORMATION | |
|---|---|
| **Test item particulars (see also Clause 6):** | |
| Classification of installation and use ..... : | Portable (direct plug-in power supply) and power supply for building in (open frame power supply) |
| Device type (component/sub-assembly/ equipment/ system): | Component level power supply (Direct plug-in power supply and open frame power supply for building in) |
| Intended use (Including type of patient, application location) : | Power supply is intended to provide power to medical devices with isolation grade MOOP (Means of Operator Protection) or MOPP (Means of Patient Protection) for models additionally marked with 2MOPP. |
| Mode of operation ..... : | Continuous |
| Supply connection ..... | Direct plug-in power supply: mains plug part of the power supply<br>Open frame power supply: for connection to the mains by means of internal mains wirings (end product consideration) |
| 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)..... : | 2013-12-18<br>2016-12-28 Rev.No.: 4.0 |
| Dates tests performed ..... : | From 2014-01-02 to 2014-02-24<br>From 2017-01-09 to 2017-02-13 Rev.No.: 4.0 |
| **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 ..... : MOOP | - means of Patient protection .... : MOPP |

**General remarks:**

**Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "J" of TRF for IEC for 60601-1 3rd edition with Amendment 1.**

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

**Throughout this report a ☒ comma / ☐ point is used as the decimal separator.**

**Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012**

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

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

| | |
|---|---|
| **Name and address of factory (ies) .....:** | **1) GlobTek, Inc.**<br>**186 Veterans Drive, Northvale, NJ 07647, USA**<br>**2) GlobTek (Suzhou) Co., Ltd.**<br>**Building 4, No. 76, Jinling East Road, Suzhou Industrial Park, Jiangsu CN-215021, China** |

**General product information:**

EUT is a protection class II direct plug-in power supply unit or open frame power supply unit intended for supplying end medical product by its output voltage or current. In respect to supply connection the unit is marked with the Model/Type reference number as direct plug-in or open frame.

2 x MOOP (2 x Means of Operator Protection) isolation is provided between primary and secondary side of the power supply. Secondary output circuit is separated from mains by reinforced insulation and rated SELV non hazardous energy levels.

For models additionally marked with 2MOPP near model name: 2 x MOPP (2 x Means of Patient Protection) isolation is provided between primary and secondary side of the power supply. Secondary output circuit is separated from mains by reinforced insulation and rated SELV non hazardous energy levels.

**Model Differences:**

**Differences within the GTM41060 family are limited to minor component changes to determine specific output voltage and current parameters. However change is related to the two different classifications of the use due design. Both models with last two letters of model name (-FW) are for built in use (open frame) and therefore are to be installed within the end product enclosure. End product evaluation is necessary for open frame power supplies.**

**Explanation of the test program:**

1. **The risk management requirements of the standard according to ISO 14971 were addressed.**

2. **Medical power supply does not provide any clinical function and has therefore no essential performance.**

3. **The MEE is not intended to be used in an oxygen rich environment and not to be used in conjunction with flammable anaesthetics.**

4. **The unit provides internally two fuses in line and neutral**

5. **The unit is a direct plug-in equipment.**

6. **Power supply was evaluated for Means of Operator Protection (MOOP):**

   **- 2 x MOOP between primary and secondary circuit**

   **- 2 x MOOP between primary and external plastic enclosure surface (applicable for direct plug-in power supply)**

   **Power supply was evaluated for Means of Patient Protection (MOPP) (for models additionally marked with 2MOPP near model name):**

   **- 2 x MOPP between primary and secondary circuit**

   **- 2 x MOPP between primary and external plastic enclosure surface (applicable for direct plug-in power supply).**

7. **Secondary output circuit is separated from mains by reinforced insulation and rated SELV. The output does not provide hazard energy level.**

8. **Power supply is provided only with technical specification.**

9. **Power supply is rated as class II (provided in fully plastic enclosure) construction. Open-frame power supply complies with Class II construction (end product consideration).**

10. **The transformer T1 provides reinforced insulation. This transformer is built up to fulfil the requirement of insulation class B (130°C). See also list of safety critical components.**

11. **The equipment has been evaluated for use in a Pollution Degree 2 and overvoltage category II environment and a maximum altitude of 3000 m.**

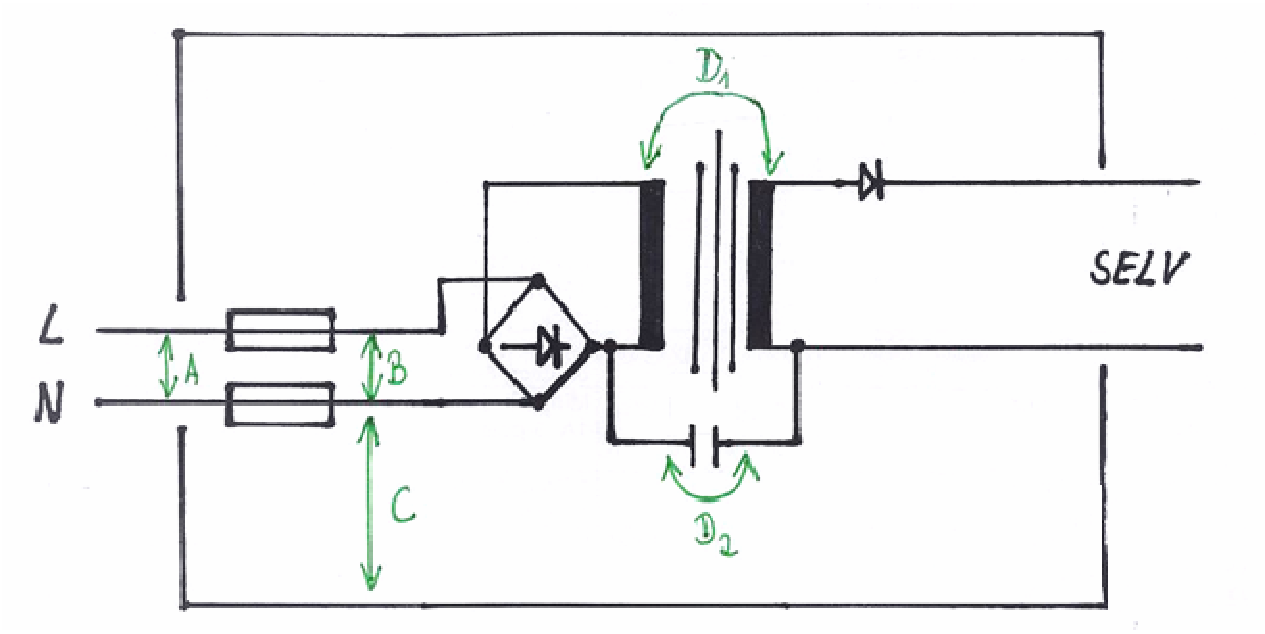
12. **Power supply is provided with plastic enclosure made by non-flammable material UL94 V-1. See also list of safety critical components. Open-frame power supply is provided without external enclosure. Electrical / Fire enclosure shall be considered during end medical product approval.**

13. **The product was evaluated for a maximum ambient of 40°C. The temperature test was performed 100 mm above bench without forced air cooling**

14. **Cleaning/disinfection tests shall be considered within end product investigation.**

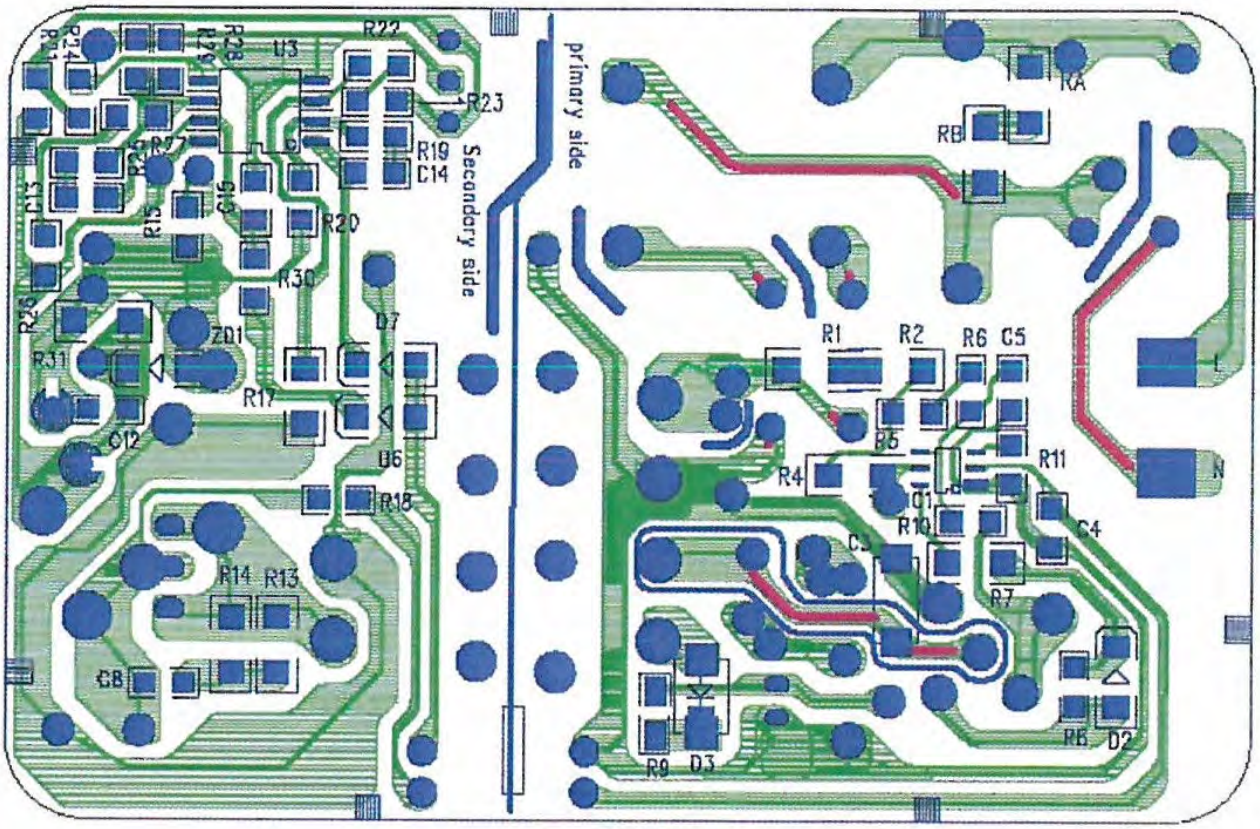
| History Sheet | | | |
|---|---|---|---|
| **Date** | **Report Number** | **Change** | **Revision No.** |
| 2009-11-19 | T223-0286/09 | Initial Test Report issued. | — |
| 2013-03-12 | T223-0102/13 | Revision of the report. Corrected typing errors.<br>No changes that influence on safety. | 1.0 |
| 2013-09-13 | T223-0332/13 | Modified nomenclature.<br>After review, no additional tests were considered necessary. | 2.0 |
| 2014-03-14 | T223-0072/14 | Manufacturer added alternative models to comply with MOPP requirements (change of layouts, change of transformer construction (increase width of margin tapes), 2 x Y1 capacitors in series provided between primary and secondary circuit). No other changes on the product.<br>Additional evaluation of Risk Management File complying with ISO 14971 was performed. Risk Management File provided by the manufacturer.<br>After review, the following tests were considered necessary:<br>- Working voltage measurements<br>- Evaluation of creepage/clearance distances<br>- Leakage current measurements<br>- Dielectric strength test<br>Update of list of critical components. | 3.0 |
| See first page. | See first page. | Standard was upgraded to IEC 60601 1:2005 (Third Edition) + A1:2012<br>No modification of the products.<br>The following tests were performed:<br>- RMF review.<br>- 8.7 Leakage current measurements<br>- 8.10 List of critical components updated<br>All additional tests marked with Rev. No. in order to fulfil traceability requirements. | 4.0 |

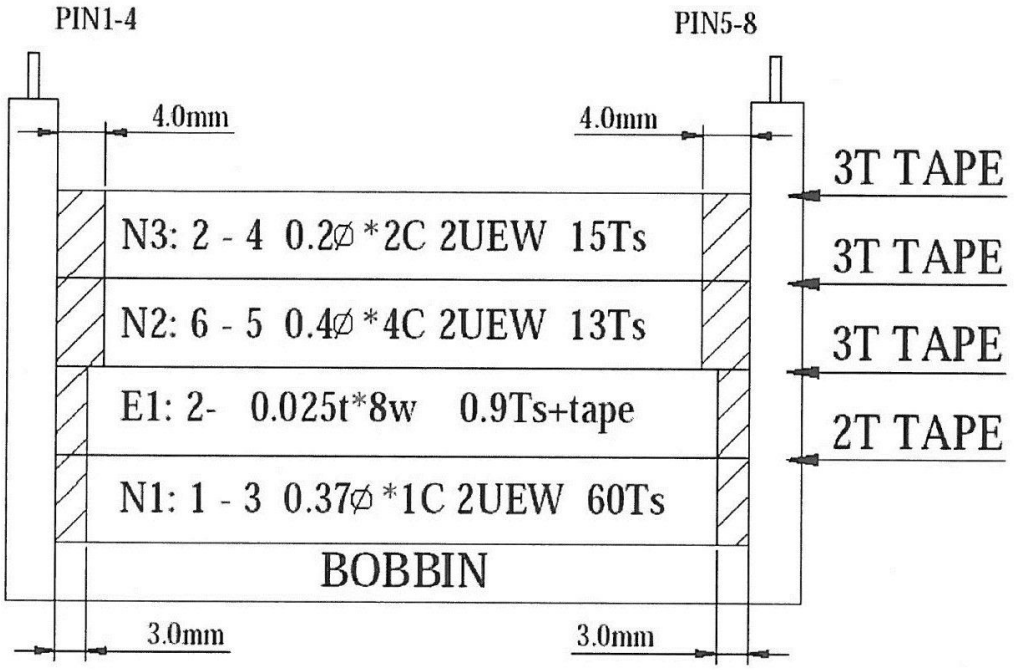
**INSULATION DIAGRAM**



| TABLE: INSULATION DIAGRAM | | P |
|---|---|---|
| Pollution degree .....: | PD2 | — |
| Overvoltage category .....: | OVC II | — |
| Altitude .....: | Up to 3000 meters | — |
| Additional details on parts considered as applied parts .....: | ☒ None ☐ Areas _____ (See Clause 4.6 for details) | — |

| Area | Number and type of Means of Protection: MOOP, MOPP | CTI | Working voltage | | Required creepage (mm) | Required clearance (mm) | Measured creepage (mm) | Measured clearance (mm) | Remarks |
|---|---|---|---|---|---|---|---|---|---|
| | | | $V_{rms}$ | $V_{pk}$ | | | | | |
| Power supply unit evaluated for Means of Operator Protection (MOOP)<br>(Single Y1 capacitor provided between primary and secondary circuit) | | | | | | | | | |
| A | 1 x MOOP | IIIb | 240 | 340 | 2,5 | 2,3<br>(2,0* 1,14) | 3,0 | 3,0 | Before primary fuses. |
| B | -- | IIIb | 240 | 340 | Verified via short-circuiting.<br>See abnormal testing. | | | | |
| C1 | 2 x MOOP | IIIb | 240 | 340 | 5,0 | 4,6<br>(4,0 * 1,14) | 8,7 | 5,7 | Measured between primary components and accessible enclosure |
| D1a | 2 x MOOP | IIIb | 264 | 508 | 5,4 | 5,1<br>(4,4 * 1,14) | 7,0 | 7,0 | Measured on the transformer. |
| D1b | 2 x MOOP | IIIb | 264 | 508 | 5,4 | 5,1<br>(4,4 * 1,14) | 7,8 | 7,8 | Measured on PCB |
| Supplementary Information:<br>Both enclosure parts are fixed together by means of ultrasonic welding.<br>Minimum distance between primary component (Fuse F1) to inner enclosure: 1,2 mm | | | | | | | | | |




**Power supply unit evaluated for Means of Patient Protection (MOPP)**

**(Models additionally marked with 2MOPP near model name)**

**(2 x Y1 capacitors in series provided between primary and secondary circuit)**

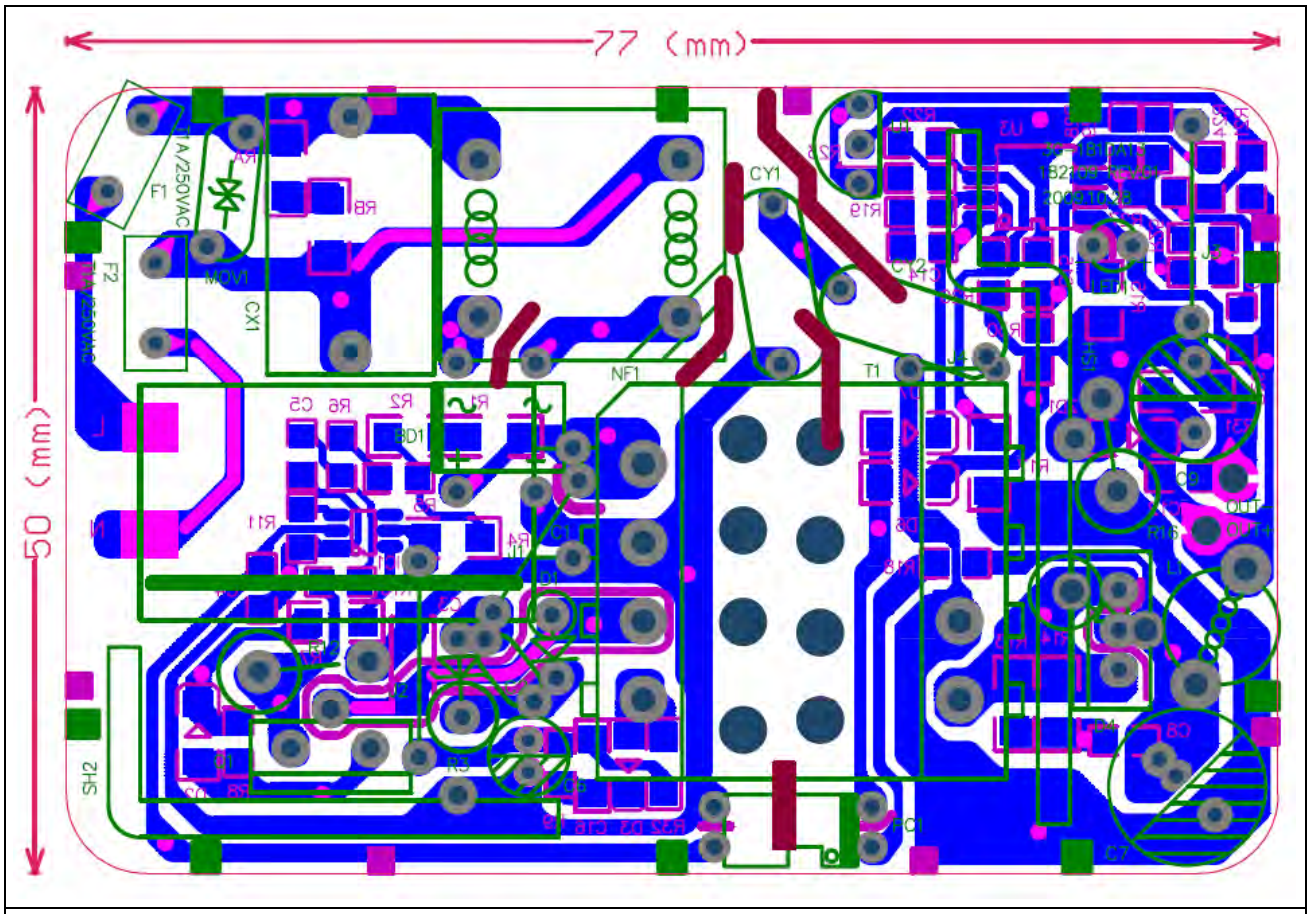
| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **A** | **1 x MOOP** | **IIIb** | **240** | **340** | **2,5** | **2,3 (2,0 * 1,14)** | **3,0** | **3,0** | **Before primary fuses.** |
| **B** | **--** | **IIIb** | **240** | **340** | **Verified via short-circuiting. See abnormal testing.** | | | | |
| **C1** | **2 x MOPP** | **IIIb** | **240** | **340** | **8,0** | **5,0** | **8,7** | **5,7** | **Measured between primary components and accessible enclosure** |
| **D1a** | **2 x MOPP** | **IIIb** | **264** | **508** | **8,4** | **7,0** | **10,0** | **10,0** | **Measured on the transformer.** |
| **D1b** | **2 x MOPP** | **IIIb** | **264** | **508** | **8,4** | **7,0** | **9,0** | **9,0** | **Measured on PCB below transformer** |
| **D1c** | **2 x MOPP** | **IIIb** | **240** | **340** | **8,0** | **5,0** | **9,4** | **5,3** | **Measured on PCB below transformer (Pin 2 to pin 6)** |
| **D** | **2 x MOPP** | **IIIb** | **240** | **358** | **8,0** | **5,0** | **8,5** | **5,0** | **Between CY1 primary side to CY2 secondary side** |
| **D2a** | **1 x MOPP** | **IIIb** | **240** | **358** | **4,0** | **2,5** | **5,5** | **2,5** | **Between CY1 secondary side to secondary** |
| **D2b** | **1 x MOPP** | **IIIb** | **240** | **358** | **4,0** | **2,5** | **4,3** | **3,8** | **Between CY1 secondary side to primary** |
| **D2c** | **1 x MOPP** | **IIIb** | **240** | **358** | **4,0** | **2,5** | **4,2** | **3,8** | **Between CY2 primary side to primary** |
| **D2d** | **1 x MOPP** | **IIIb** | **240** | **358** | **4,0** | **2,5** | **5,5** | **2,5** | **Between CY2 primary side to secondary** |

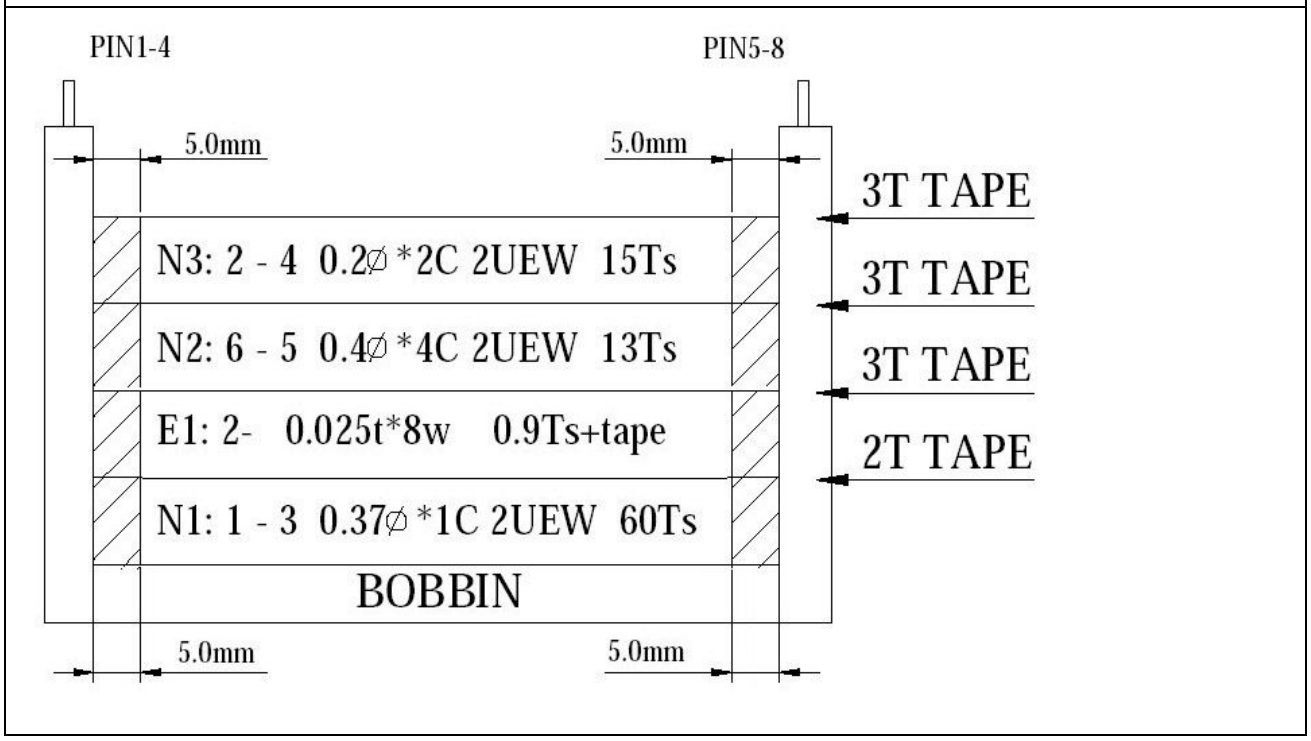
**Supplementary information:**

**Transformer core is considered as floating. Margin tape 5,0 mm provided on both sides of primary and secondary wires. 3 layers of insulation tape provided between primary and secondary windings.**

**Both enclosure parts are fixed together by means of ultrasonic welding.**

**Minimum distance between primary component (Fuse F1) to inner enclosure: 1,2 mm**


77 (mm)
50 (mm)
F1
F2
CX1
CY1
NF1
T1
SH2


PIN1-4
PIN5-8
5.0mm
5.0mm
3T TAPE
N3: 2 - 4 0.2∅*2C 2UEW 15Ts
3T TAPE
N2: 6 - 5 0.4∅*4C 2UEW 13Ts
3T TAPE
E1: 2- 0.025t*8w 0.9Ts+tape
2T TAPE
N1: 1 - 3 0.37∅*1C 2UEW 60Ts
BOBBIN
5.0mm
5.0mm

**INSULATION DIAGRAM CONVENTIONS and GUIDANCE:**

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

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

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

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

| | | | |
|---|---|---|---|
| **4** | **GENERAL REQUIREMENTS** | | **P** |
| **4.1** | **Requirements of this standard applied in NORMAL USE and reasonably foreseeable misuse** | -- | **P** |
| **4.2** | **RISK MANAGEMENT PROCESS FOR ME EQUIPMENT OR ME SYSTEMS** | | **P** |
| **4.2.2** | **General requirement for RISK MANAGEMENT - PROCESS complies with ISO14971 (2007)..... :** | See Appended RM Results Table 4.2.2. | **P** |
| **4.2.3** | **Evaluating RISK** | | **P** |
| **4.2.3.1** | **a) Compliance with the standard reduces residual risk to an acceptable level** | -- | **P** |
| | **b) Manufacturer has defined risk acceptability criteria in the RISK MANAGEMENT PLAN..... :** | RISK MANAGEMENT PLAN Document: GT-RMPLAN2013-008 | **P** |
| | **c) When no specific technical requirements provided manufacturer has determined HAZARDS or HAZARDOUS SITUATIONS exists.** | -- | **P** |
| | **- HAZARDS or HAZARDOUS SITUATIONS have been evaluated using the RISK MANAGEMENT PROCESS.** | -- | **P** |
| **4.2.3.2** | **MANUFACTURER has addressed HAZARDS or HAZARDOUS SITUATIONS not specifically addressed in the IEC 60601-1 series.** | -- | **P** |
| **4.3** | **Performance of clinical functions necessary to achieve INTENDED USE or that could affect the safety of the ME EQUIPMENT or ME SYSTEM were identified during RISK ANALYSIS.** | Power supply unit is not end medical product. | **N/A** |
| | **- Performance limits were identified in both NORMAL CONDITION and SINGLE FAULT CONDITION.** | -- | **N/A** |
| | **- Loss or degradation of performance beyond the limits specified by the MANUFACTURER were evaluated** | -- | **N/A** |
| | **- Functions with unacceptable risks are identified as ESSENTIAL PERFORMANCE..... :** | Power supply unit is not end medical product. | **N/A** |
| | **- RISK CONTROL measures implemented** | -- | **N/A** |
| | **- Methods used to verify the effectiveness of RISK CONTROL measures implemented** | -- | **N/A** |
| **4.4** | **EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE ..... :** | The expected service life is specified by the manufacturer: 10 years. | **P** |
| **4.5** | **Alternative RISK CONTROL methods utilized:** | No equivalent safety used. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **RESIDUAL RISK resulting from the alternative RISK CONTROL measures or tests is acceptable and comparable to RESIDUAL RISK resulting from application of this standard.....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No equivalent safety used. No RM considered necessary | **N/A** |
| | **Alternative means based scientific data or clinical opinion or comparative studies .....:** | -- | **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 .....:** | See Appended Insulation Diagram Table and RM Results Table 4.6<br>No such parts. | **N/A** |
| | **MANUFACTURER assesses the risk of accessible parts coming into contact with the patient ....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No such parts. No RM considered necessary | **N/A** |
| | **Assessment identified the APPLIED PART TYPE requirements .....:** | -- | **N/A** |
| **4.7** | **ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2 .....:** | 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. | **P** |
| | **MANUFACTURER RISK ANALYSIS was used to determine failures to be tested.....:**<br>**(ISO 14971 Cl. 4.2-4.4)** | RISK ANALYSIS reference: EL5<br>(ISO 14971 Cl. 4.2-4.4) | **P** |
| | **Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically .....:** | See appended Table 13.2 for simulated physical test. | **P** |
| **4.8** | **All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified....:** | All components are suitable and used within their rating. See appended table 8.10. | **P** |
| | **Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS** | -- | **P** |
| | **RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | All components are suitable and used within their ratings. No RM considered necessary. | **N/A** |
| | **MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION...:** | All components are suitable and used within their ratings. | **N/A** |
| | **Components determined to be acceptable where used as a MEANS OF PROTECTION .....:** | All components are suitable and used within their ratings. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following** | -- | **P** |
| | **a) Applicable safety requirements of a relevant IEC or ISO standard** | Approved critical components used. | **P** |
| | **b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard** | Considered. | **P** |
| **4.9** | **A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided and selected appropriately..... :** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No such components provided. No RM considered necessary. | **N/A** |
| | **Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC:** | -- | **N/A** |
| **4.10** | **Power supply** | | **P** |
| **4.10.1** | **ME EQUIPMENT is suitable for connection to indicated power source** (select applicable)**..... :** | Supply mains | **P** |
| **4.10.2** | **Maximum rated voltage for ME EQUIPMENT intended to be connected to SUPPLY MAINS:** | -- | **P** |
| | **- 250 V for HAND-HELD ME EQUIPMENT (V)..... :** | Not hand-held MEE. | **N/A** |
| | **– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V)..... :** | 100-240 Vac | **P** |
| | **– 500 V for all other ME EQUIPMENT and ME SYSTEMS** | -- | **N/A** |
| **4.11** | **Power input** | | **P** |
| | **Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%..... :** | See appended Table 4.11 | **P** |

| | | | |
|---|---|---|---|
| **5** | **GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT** | | **P** |
| **5.1** | **Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods..... :** | -- | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION.**<br>**(ISO 14971 Cl. 4.2-4.4)** | Type test performed according to all applicable clauses of standard IEC 60601-1:2005 + A1:2012. No RM considered necessary. | **N/A** |
| **5.3** | **Tests conducted within the environmental conditions specified in technical description** | -- | **P** |
| | **Temperature (ºC), Relative Humidity (%) .....:** | Temperature: 0 - 40°C<br>Relative humidity: 0 to 90% RH<br>Specified within technical specifications. | **—** |
| | **Atmospheric Pressure (kPa) .....:** | 70 to 106 | **—** |
| **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) .....:** | 90–264 Vac | **P** |
| | **b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz) .....:** | 50-60Hz | **P** |
| | **c) ME EQUIPMENT with more than one RATED voltage, both a.c./ d.c. or both external power and INTERNAL ELECTRICAL POWER SOURCE tested in conditions (see 5.4) related to the least favourable voltage, nature of supply, and type of current .....:** | Rated supply voltage: 100-240 V ac | **N/A** |
| | **d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered.....:** | AC supply voltage only. | **N/A** |
| | **e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions .....:** | No accessories provided. | **N/A** |
| | **f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use** | Mains operated equipment. | **N/A** |
| **5.7** | **ME EQUIPMENT or parts thereof affected by climatic conditions were set up completely, or partially, with covers detached and subjected to a humidity preconditioning prior to tests of Clauses 8.7.4 and 8.8.3 ..... :** | Complete MEE was subjected to humidity preconditioning treatment. | **P** |
| | **ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber and ambient within 2 °C of T in range of +20°C to +32°C for indicated time** | T = 26°C<br>Time – 48H<br>Humidity: 94,5% | **—** |
| **5.9** | **Determination of APPLIED PARTS and ACCESSIBLE PARTS** | | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **5.9.1** | **APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ..... :** | No APPLIED PARTS provided. | **N/A** |
| **5.9.2** | **ACCESSIBLE PARTS** | | **P** |
| **5.9.2.1** | **Accessibility determined using standard test finger of Fig. 6** | See Appended Table 5.9.2 | **P** |
| **5.9.2.2** | **Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s** | See Appended Table 5.9.2<br>Direct plug-in version provided with plastic enclosure without openings.<br>End product consideration for open frame version. | **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, required use of a TOOL ..... :** | No actuating mechanism. | **N/A** |

| | | | |
|---|---|---|---|
| **6** | **CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS** | | **P** |
| **6.2** | **CLASS I ME EQUIPMENT, externally powered** | Not Class I equipment.<br>No protective earth provided. | **N/A** |
| | **CLASS II ME EQUIPMENT, externally powered** | Class II: Direct plug-in version<br>Class II construction: Open frame version | **P** |
| | **INTERNALLY POWERED ME EQUIPMENT** | EUT is not internally powered equipment.<br>Mains operated 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** | Not 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 as per IEC 60529..... :** | IP40<br>(relevant for direct plug-in power supply). | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **6.4** | **ME EQUIPMENT or its parts intended to be sterilized classified according to method(s) of sterilization in instructions for use .....:** | No parts intended to be sterilized. | **N/A** |
| **6.5** | **ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2** | Unit is not intended to be used in an oxygen rich environment. | **N/A** |
| **6.6** | **CONTINUOUS or Non-CONTINUOUS OPERATION.....:** | Unit is intended for continuous operation. | **P** |
| **7** | **ME EQUIPMENT IDENTIFICATION, MARKING, AND DOCUMENTS** | | **P** |
| **7.1.2** | **Legibility of Markings Test for Markings specified in Clause 7.2-7.6.....:** | See Appended Table 7.1.2 | **P** |
| **7.1.3** | **Required markings can be removed only with a TOOL or by appreciable force, are durable and remain CLEARLY LEGIBLE during EXPECTED SERVICE LIFE of ME EQUIPMENT in NORMAL USE** | See appended Tables 7.1.3 | **P** |
| **7.2** | **Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts** | | **P** |
| **7.2.1** | **At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ..... :** | All required markings provided on the marking plate. | **P** |
| | **Remaining markings fully recorded in ACCOMPANYING DOCUMENTS ..... :** | All necessary information are provided on the marking plate. | **N/A** |
| | **Markings applied to individual packaging when impractical to apply to ME EQUIPMENT** | -- | **N/A** |
| | **Single use item marked ..... :** | MEE is not intended for single use. | **N/A** |
| **7.2.2** | **ME EQUIPMENT marked with:** | -- | **P** |
| | **– the name or trademark and contact information of the MANUFACTURER** | -- | **P** |
| | **– a MODEL OR TYPE REFERENCE** | See attached copy of Marking Plate | **P** |
| | **– a serial number or lot or batch identifier; and** | -- | **P** |
| | **– the date of manufacture or use by date** | -- | **P** |
| | **Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or** | No detachable components provided. | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.4)** | No detachable components provided. No RM considered necessary. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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 ..... :** | No PEMS. | **N/A** |
| **7.2.3** | **Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS** | Not required for power supply. | **N/A** |
| | **Safety sign 10 on Table D.2) 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..... :** | No accessories 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 and ME SYSTEM intended to receive power from other equipment, provided with one of the following** | MEE is not intended to receive power from other equipment. Mains operated equipment. | **N/A** |
| | **- the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or** | -- | **N/A** |
| | **– Table D.2, safety sign No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or** | -- | **N/A** |
| | **– Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use.** | -- | **N/A** |
| **7.2.6** | **Connection to the Supply Mains** | | **P** |
| | **Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point** | Marking plate provided on the outer side of the plastic enclosure. | **P** |
| | **For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT** | 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 V~ | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V) .....:** | -- | **P** |
| | **– Nature of supply and type of current.....:** | The following symbol provided near supply voltage range: ''~'' on the marking plate. | **P** |
| | **Symbols 1-5, Table D.1 (used for same parameters.....:** | Symbol No. 1 provided near supply voltage range on the marking plate. | **P** |
| | **– RATED supply frequency or RATED frequency range in hertz .....:** | Supply frequency expressed in Hz. | **P** |
| | **– Symbol 9 of Table D.1 used for CLASS II ME EQUIPMENT .....:** | Symbol No. 9 provided on the marking plate. | **P** |
| **7.2.7** | **RATED input in amps or volt-amps, (A, VA) ..... :** | Rated input expressed in Amperes. | **P** |
| | **RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) ..... :** | Rated input expressed in Amperes. | **P** |
| | **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).....:** | Not relevant for power supply. | **N/A** |
| | **Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) .....:** | -- | **N/A** |
| | **Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA).....:** | -- | **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** | | **P** |
| **7.2.8.2** | **Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment** | Rating of the output provided on the marking plate. | **P** |
| | **Rated Voltage (V), Rated Current (A) .....:** | Rated output voltage and current provided on the marking plate. | **—** |
| | **Rated Power (W), Output Frequency (Hz) .....:** | DC output. | **—** |
| **7.2.9** | **ME EQUIPMENT or its parts marked with the IP environmental Code per IEC 60529 according to classification in 6.3 (Table D.3, Code 2), marking optional for ME EQUIPMENT or parts rated IPX0. ..:** | IP40<br>No protection against ingress of water provided (relevant for direct plug-in power supply). | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **7.2.10** | **Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols ..... :** | No APPLIED PARTS in power supply. | **N/A** |
| | **TYPE B APPLIED PARTS with symbol 19 of Table D.1** | -- | **N/A** |
| | **TYPE BF APPLIED PARTS with symbol 20 of Table D.1 ..... :** | -- | **N/A** |
| | **TYPE CF APPLIED PARTS with symbol 21 of Table D.1 ..... :** | -- | **N/A** |
| | **DEFIBRILLATION-PROOF APPLIED PARTS marked with symbols 25-27 of Table D.1..... :** | -- | **N/A** |
| | **Proper symbol marked adjacent to or on connector for APPLIED PART..... :** | -- | **N/A** |
| | **Safety sign 2 of Table D.2 placed near relevant outlet ..... :** | -- | **N/A** |
| | **An explanation indicating protection of ME EQUIPMENT against effects of discharge of a cardiac defibrillator depends on use of proper cables included in instructions for use ..... :** | -- | **N/A** |
| **7.2.11** | **ME EQUIPMENT suitable for CONTINUOUS OPERATION** | Equipment is intended for continuous operation; therefore no marking is required. | **N/A** |
| | **DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time ..... :** | -- | **N/A** |
| **7.2.12** | **Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder** | No fuse-holder provided. | **N/A** |
| | **Fuse type ..... :** | -- | **—** |
| | **Voltage (V) and Current (A) rating ..... :** | -- | **—** |
| | **Operating speed (s) and Breaking capacity .... :** | -- | **—** |
| **7.2.13** | **Physiological effects – safety sign and warning statements ..... :** | Equipment does not produce physiological effects. | **N/A** |
| | **Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.3)** | MEE does not produce physiological effects. No RM considered necessary. | **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** | No such voltage provided within power supply unit. | **N/A** |
| **7.2.15** | **Requirements for cooling provisions marked .. :** | No cooling provided. | **N/A** |
| **7.2.17** | **Packaging marked with special handling instructions for transport and/or storage ..... :** | No special handling requirements. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Permissible environmental conditions marked on outside of packaging .....:** | Package is marked with environmental conditions. | **P** |
| | **Packaging marked with a suitable safety sign indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK .....:** | No risk of premature unpacking. | **N/A** |
| | **RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK. .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.3-6.4)** | No RM considered necessary. | **N/A** |
| | **Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization** | -- | **N/A** |
| **7.2.18** | **RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and .....:** | No pressure used. | **N/A** |
| | **- the RATED flow rate also marked** | -- | **N/A** |
| **7.2.19** | **Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL .....:** | No functional earth provided. | **N/A** |
| **7.2.20** | **Removable protective means marked to indicate the necessity for replacement when the function is no longer needed .....:** | -- | **N/A** |
| **7.2.21** | **MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms ....:** | -- | **N/A** |
| **7.3** | **Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts** | | **P** |
| **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, or safety sign No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts.....:** | No HIGH VOLTAGE parts within the equipment. | **N/A** |
| **7.3.3** | **Type of battery and mode of insertion 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 would result in an unacceptable RISK.....:** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to an unacceptable RISK if replaced incorrectly ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.3)** | Neither batteries nor battery compartments incorporated. No RM considered necessary. | **N/A** |
| | **ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARD..... :** | No batteries provided. | **N/A** |
| **7.3.4** | **Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified ..... :** | No such fuses provided.<br>Internal fuses marked as follows:<br>F1: T1A/250VAC<br>F2: T1A/250VAC<br>Those fuses not intended to be replaced by the operator. | **P** |
| | **Voltage (V) and Current (A) rating ..... :** | -- | **—** |
| | **Operating speed(s), size & breaking capacity. :** | -- | **—** |
| **7.3.5** | **PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1** | No protective earth terminal provided. | **N/A** |
| | **Markings on or adjacent to PROTECTIVE EARTH TERMINALS not applied to parts requiring removal to make the connection, and remained visible after connection made** | -- | **N/A** |
| **7.3.6** | **Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINALS** | No functional earthing is provided. | **N/A** |
| **7.3.7** | **Terminals for supply conductors marked adjacent to terminals ..... :** | EUT is direct plug-in or open frame power supply unit intended for supplying medical product by its output voltage.<br>No terminals for supply conductors provided. | **N/A** |
| | **Terminals for supply connections are not marked, the RISK MANAGEMENT FILE includes an assessment of the RISKS resulting from misconnections ..... :**<br>**(ISO 14971 Cl. 4.3)** | No terminals for supply conductors provided. No RM considered necessary. | **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** | -- | **N/A** |
| | **Marking for connection to a 3-phase supply, complies with IEC 60445** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made** | -- | **N/A** |
| **7.3.8** | **"For supply connections, use wiring materials suitable for at least X °C" 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** | | **P** |
| **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 or** | No mains switch provided. | **N/A** |
| | **– indicated by an adjacent indicator light, or** | Green indicator light provided to indicate ''Power ON''. | **P** |
| | **– 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, and** | No push buttons provided. | **N/A** |
| | **– status indicated by adjacent indicator light** | -- | **N/A** |
| | **– 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 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** | No control devices provided. | **N/A** |
| | **RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK.....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2, 6.3)** | No controls and instruments provided. No RM considered necessary. | **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 .....:** | -- | **N/A** |
| | **– or an indication of direction in which magnitude of the function changes** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009** | -- | **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..... :** | -- | **N/A** |
| **7.5** | **Safety signs** | | **N/A** |
| | **Safety sign with established meaning used** | No such safety sign provided. | **N/A** |
| | **RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.3)** | No such markings provided.<br>No RM considered necessary. | **N/A** |
| | **Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT** | -- | **N/A** |
| | **Specified colours in ISO 3864-1 used for safety signs ..... :** | -- | **N/A** |
| | **Safety notices include appropriate precautions or instructions on how to reduce RISK(S)** | -- | **N/A** |
| | **Safety signs including any supplementary text or symbols described in instructions for use** | -- | **N/A** |
| | **- and in a language acceptable to the intended OPERATOR** | -- | **N/A** |
| **7.6** | **Symbols** | | **P** |
| **7.6.1** | **Meanings of symbols used for marking described in instructions for use ..... :** | Explanation provided within specifications. | **P** |
| **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** | | **N/A** |
| **7.7.1** | **PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation** | Class II MEE. | **N/A** |
| **7.7.2** | **Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations** | -- | **N/A** |
| **7.7.3** | **Green and yellow insulation identify only following conductors:** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– 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"** | -- | **N/A** |
| **7.7.5** | **Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1** | -- | **N/A** |
| **7.8** | **Indicator lights and controls** | | **P** |
| **7.8.1** | **Red indicator lights used only for Warning** | No red indicator light provided. | **N/A** |
| | **Yellow indicator lights used only for Caution** | No yellow indicator light provided. | **N/A** |
| | **Green indicator lights used only for Ready for use** | Green indicator light indicate ''Power ON'' | **P** |
| | **Other colours: 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** | | **P** |
| **7.9.1** | **ME EQUIPMENT accompanied by documents containing instructions for use, and a technical description** | Power supply unit is not end medical product.<br>Shall be evaluated during end medical product approval.<br>Only technical specifications provided by the manufacturer. | **N/A** |
| | **ACCOMPANYING DOCUMENTS identify ME EQUIPMENT by the following, as applicable:** | -- | **N/A** |
| | **– Name or trade-name of MANUFACTURER and contact information for the RESPONSIBLE ORGANIZATION can be referred to.....:** | Manufacturer name and address and contact information provided within Instruction for use. | **N/A** |
| | **– MODEL or TYPE REFERENCE .....:** | Model name provided within technical specifications provided by the manufacturer. | **N/A** |
| | **When ACCOMPANYING DOCUMENTS provided electronically, USABILITY ENGINEERING PROCESS includes instructions as to what is required in hard copy or as markings on ME EQUIPMENT** | Technical specifications provided in hard copy. | **N/A** |
| | **ACCOMPANYING DOCUMENTS specify special skills, training, and knowledge required of OPERATOR or RESPONSIBLE ORGANIZATION and environmental restrictions on locations of use** | Power supply unit is not end medical product.<br>End product consideration. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **ACCOMPANYING DOCUMENTS written at a level consistent with education, training, and other needs of individuals for whom they are intended** | Only technical specifications provided by the manufacturer (English version). | **N/A** |
| **7.9.2** | **Instructions for use include the required information** | | **P** |
| **7.9.2.1** | **– use of ME EQUIPMENT as intended by the MANUFACTURER:** | -- | **P** |
| | **– frequently used functions,** | -- | **N/A** |
| | **– known contraindication(s) to use of ME EQUIPMENT** | Power supply unit is part of the investigation. | **N/A** |
| | **- parts of the ME EQUIPMENT that are not serviced or maintained while in use with the patient** | No such parts. | **N/A** |
| | **– name or trademark and address of the MANUFACTURER** | Provided within specifications. | **P** |
| | **– MODEL OR TYPE REFERENCE** | Provided within specifications. | **P** |
| | **Instruction for use included the following when the PATIENT is an intended OPERATOR:** | End product consideration. Power supply unit is not end medical product. | **N/A** |
| | **– the PATIENT is an intended OPERATOR** | -- | **N/A** |
| | **– warning against servicing and maintenance while the ME EQUIPMENT is in use** | -- | **N/A** |
| | **- functions the PATIENT can safely use and, where applicable, which functions the PATIENT cannot safely use; and** | -- | **N/A** |
| | **–maintenance the PATIENT can perform** | -- | **N/A** |
| | **Classifications as in Clause 6, all markings per Clause 7.2, and explanation of safety signs and symbols marked on ME EQUIPMENT** | Provided within specifications. | **P** |
| | **Instructions for use are in a language acceptable to the intended operator** | English version provided and evaluated. | **P** |
| **7.9.2.2** | **Instructions for use include all warning and safety notices** | -- | **N/A** |
| | **Warning statement for CLASS I ME EQUIPMENT included** | Not Class I equipment, no protective earth provided. | **N/A** |
| | **Warnings regarding significant RISKS of reciprocal interference posed by ME EQUIPMENT during specific investigations or treatments** | Power supply unit is not end medical product. | **N/A** |
| | **Information on potential electromagnetic or other interference and advice on how to avoid or minimize such interference** | Power supply unit is not end medical product. | **N/A** |
| | **Warning statement for ME EQUIPMENT supplied with an integral MULTIPLE SOCKET-OUTLET provided** | Not supplied from an integral multiple socket-outlet. | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **The RESPONSIBLE ORGANIZATION is referred to this standard for the requirements applicable to ME SYSTEMS** | -- | **N/A** |
| **7.9.2.3** | **Statement on ME EQUIPMENT for connection to a separate power supply provided in instructions** | Mains operated equipment. | **N/A** |
| **7.9.2.4** | **Warning statement for mains- operated ME EQUIPMENT with additional power source not automatically maintained in a fully usable condition indicating the necessity for periodic checking or replacement of power source** | No additional power source incorporated. | **N/A** |
| | **RISK MANAGEMENT FILE assesses the RISK resulting from leakage of batteries ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.3)** | Neither batteries nor battery compartments incorporated. Loss of power does not result in an unacceptable risk. No RM considered necessary. | **N/A** |
| | **Where the RISK is unacceptable, the IFU includes a warning to remove the battery if the ME EQUIPMENT is not likely to be used for some time..... :** | No batteries provided. | **N/A** |
| | **Specifications of replaceable INTERNAL ELECTRICAL POWER SOURCE when provided ..... :** | No internal replaceable power source provided. | **N/A** |
| | **Warning indicating ME EQUIPMENT must be connected to an appropriate power source when loss of power source would result in an unacceptable RISK ..... :** | Power supply unit is not end medical product; shall be considered during end medical product approval. | **N/A** |
| **7.9.2.5** | **Instructions for use include a description of ME EQUIPMENT, its functions, significant physical and performance characteristics together with the expected positions of OPERATOR, PATIENT, or other persons near ME EQUIPMENT in NORMAL USE** | Not relevant for power supply unit. | **N/A** |
| | **Information provided on materials and ingredients PATIENT or OPERATOR is exposed to** | -- | **N/A** |
| | **Restrictions specified on other equipment or NETWORK/DATA COUPLINGS, other than those forming part of an ME SYSTEM, to which a SIGNAL INPUT/OUTPUT PART may be connected** | -- | **N/A** |
| | **APPLIED PARTS specified** | No applied parts provided. | **N/A** |
| **7.9.2.6** | **Information provided indicating where the installation instructions may be found or information on qualified personnel who can perform the installation** | -- | **N/A** |
| **7.9.2.7** | **Instructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device** | Mains plug is considered as disconnecting device (relevant for direct plug-in version).<br>End product consideration for open frame version. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **7.9.2.8** | **Necessary information provided for OPERATOR to bring ME EQUIPMENT into operation** | Not relevant for power supply unit.<br>End medical product consideration. | **N/A** |
| **7.9.2.9** | **Information provided to operate ME EQUIPMENT** | Not relevant for power supply unit.<br>End medical product consideration. | **N/A** |
| | **Meanings of figures, symbols, warning statements, abbreviations and indicator lights described in instructions for use** | -- | **N/A** |
| **7.9.2.10** | **A list of all system messages, error messages, and fault messages provided with an explanation of messages including important causes and possible action(s) to be taken to resolve the problem indicated by the message** | -- | **N/A** |
| **7.9.2.11** | **Information provided for the OPERATOR to safely terminate operation of ME EQUIPMENT** | Green indicator light provided on top side of the enclosure to indicate power ''ON''. | **N/A** |
| **7.9.2.12** | **Information provided on cleaning, disinfection, and sterilization methods, and applicable parameters that can be tolerated by ME EQUIPMENT parts or ACCESSORIES specified** | Power supply unit is not end medical product.<br>End product consideration. | **N/A** |
| | **Components, ACCESSORIES or ME EQUIPMENT marked for single use, except when required by MANUFACTURER to be cleaned, disinfected, or sterilized prior to use** | No sterile parts. | **N/A** |
| **7.9.2.13** | **Instructions provided on preventive inspection, calibration, maintenance and its frequency** | Power supply unit is not end medical product.<br>End product consideration. | **N/A** |
| | **Information provided for safe performance of routine maintenance necessary to ensure continued safe use of ME EQUIPMENT** | -- | **N/A** |
| | **Parts requiring preventive inspection and maintenance to be performed by SERVICE PERSONNEL identified including periods of application** | -- | **N/A** |
| | **Instructions provided to ensure adequate maintenance of ME EQUIPMENT containing rechargeable batteries to be maintained by anyone other than SERVICE PERSONNEL** | -- | **N/A** |
| **7.9.2.14** | **A list of ACCESSORIES, detachable parts, and materials for use with ME EQUIPMENT provided** | No such parts specified within technical specifications. | **N/A** |
| | **Other equipment providing power to ME SYSTEM sufficiently described** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **7.9.2.15** | **Disposal of waste products, residues, etc., and of ME EQUIPMENT and ACCESSORIES at the end of their EXPECTED SERVICE LIFE are identified in the instruction for use .....:** | Provided within technical specifications. | **P** |
| **7.9.2.16** | **Instructions for use include information specified in 7.9.3 or identify where it can be found (e.g. in a service manual)** | Not relevant for power supply unit.<br>End product consideration. | **N/A** |
| **7.9.2.17** | **Instruction for use for ME EQUIPMENT emitting radiation for medical purposes, indicate the nature, type, intensity and distribution of this radiation** | Equipment does not emit radiation for medical purposes. | **N/A** |
| **7.9.2.18** | **The instructions for use for ME EQUIPMENT or ACCESSORIES supplied sterile indicate that they have been sterilized and the method of sterilization** | No parts supplied sterile. | **N/A** |
| | **The instructions for use indicate the necessary instructions in the event of damage to the sterile packaging, and where appropriate, details of the appropriate methods of re-sterilization** | -- | **N/A** |
| **7.9.2.19** | **The instructions for use contain a unique version identifier .....:** | Version QA /11/15/2016 | **P** |
| **7.9.3** | **Technical description** | | **P** |
| **7.9.3.1** | **All essential data provided for safe operation, transport, storage, and measures or conditions necessary for installing ME EQUIPMENT, and preparing it for use** | Provided within technical specifications provided by the manufacturer. | **P** |
| | **Technical description separable from instructions for use contains required information, as follows** | | **N/A** |
| | **– all applicable classifications in Clause 6, warning and safety notices, and explanation of safety signs marked on ME EQUIPMENT** | -- | **N/A** |
| | **– a brief description of the ME EQUIPMENT, how the ME EQUIPMENT functions and its significant physical and performance characteristics; and** | -- | **N/A** |
| | **a unique version identifier .....:** | -- | **N/A** |
| | **MANUFACTURER'S optional requirements for minimum qualifications of SERVICE PERSONNEL documented in technical description** | -- | **N/A** |
| **7.9.3.2** | **The technical description contains the following required information** | | **P** |
| | **–type and full rating of fuses used in SUPPLY MAINS external to PERMANENTLY INSTALLED ME EQUIPMENT .....:** | Not permanently installed. | **N/A** |
| | **– a statement for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD if POWER SUPPLY CORD is replaceable by SERVICE PERSONNEL, and** | MEE does not provide a non-detachable power supply cord. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– instructions for correct replacement of interchangeable or detachable parts specified by MANUFACTURER as replaceable by SERVICE PERSONNEL, and** | No such parts. | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment to determine if replacement of components results in any unacceptable RISKS .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No replaceable components specified by the manufacturer. No RM considered necessary. | **N/A** |
| | **– warnings identifying nature of HAZARD when replacement of a component could result in an unacceptable RISK, and when replaceable by SERVICE PERSONNEL all information necessary to safely replace the component** | The following provided within technical specifications: Globtek Inc. will not be liable for the safety and performance of these power supplies if unauthorized access and repair occurs. End user should consult applicable UL, CSA or EN standards for proper installation instructions. | **P** |
| **7.9.3.3** | **Technical description indicates, MANUFACTURER will provide circuit diagrams, component part lists, descriptions, calibration instructions to assist to SERVICE PERSONNEL in parts repair** | -- | **N/A** |
| **7.9.3.4** | **Means used to comply with requirements of 8.11.1 clearly identified in technical description** | Mains plug is considered as disconnection device.<br>End product consideration for open frame version. | **P** |

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|---|---|---|---|
| **8** | **PROTECTION AGAINST ELECTRICAL HAZARDS FROM ME EQUIPMENT** | | **P** |
| **8.1** | **Limits specified in Clause 8.4 not exceeded for ACCESSIBLE PARTS and APPLIED PARTS in NORMAL or SINGLE FAULT CONDITIONS** | -- | **P** |
| | **RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION .....:**<br>**(ISO 14971 Cl. 4.3)** | RMF Reference to specific RISKS: EL6<br>(ISO 14971 Cl. 4.3) | **P** |
| **8.2** | **Requirements related to power sources** | | **P** |
| **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** | Mains operated equipment. | **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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.2.2** | **Connection to an external d.c. power source** | | **N/A** |
| | **No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source** | Mains operated equipment. | **N/A** |
| | **ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE** | -- | **N/A** |
| | **Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset** | -- | **N/A** |
| **8.3** | **Classification of APPLIED PARTS** | | **N/A** |
| | **a) APPLIED PART specified in ACCOMPANYING DOCUMENTS as suitable for DIRECT CARDIAC APPLICATION is TYPE CF** | No APPLIED PARTS provided | **N/A** |
| | **b) An APPLIED PART provided with a PATIENT CONNECTION intended to deliver electrical energy or an electrophysiological signal to or from PATIENT is TYPE BF or CF APPLIED PART** | -- | **N/A** |
| | **c) An APPLIED PART not covered by a) or b) is a TYPE B, BF, or CF** | -- | **N/A** |
| **8.4** | **Limitation of voltage, current or energy** | | **P** |
| **8.4.2** | **ACCESSIBLE PARTS and APPLIED PARTS** | | **P** |
| | **a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT :** | No APPLIED PARTS provided. | **N/A** |
| | **b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT..... :** | See appended Table 8.7<br>Touch leakage current measured on output and plastic enclosure (metal foil used). | **P** |
| | **c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed** | -- | **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.) ..... :** | -- | **P** |
| | **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) ..... :** | No such output connectors provided. | **N/A** |
| | **d) Voltage and energy limits specified in c) above also applied to the following:** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– internal parts touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and** | No parts accessible by test pin (plastic enclosure without openings provided).<br>End product consideration for open frame power supply unit. | **N/A** |
| | **– internal parts touchable by a metal test rod with a diameter of 4 mm and a length 100 mm, inserted through any opening on top of ENCLOSURE or through any opening provided for adjustment of pre-set controls by RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL** | No parts accessible by test pin (plastic enclosure without openings provided).<br>End product consideration for open frame power supply unit. | **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 | **P** |
| | **When voltage exceeded 60 V, calculated or measured stored charge didn't exceed 45 µC ..:** | The measured voltage did not exceed 60 V. | **N/A** |
| **8.4.4** | **Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC...:** | No removable parts. | **N/A** |
| | **A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1, and manual discharging device specified in technical description ..... :** | -- | **N/A** |
| **8.5** | **Separation of parts** | | **P** |
| **8.5.1** | **MEANS OF PROTECTION (MOP)** | | **P** |
| **8.5.1.1** | **Two MEANS of PROTECTION provided for ME EQUIPMENT to prevent APPLIED and other ACCESSIBLE PARTS from exceeding limits in 8.4** | -- | **P** |
| | **Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION** | No such protection provided. | **N/A** |
| | **Components and wiring forming a MEANS OF PROTECTION comply with 8.10** | -- | **P** |
| **8.5.1.2** | **MEANS OF PATIENT PROTECTION (MOPP)** | Power supply unit evaluated for Means of Patient protection (MOPP) (for models additionally marked with 2MOPP near model name). | **P** |
| | **Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test ..... :** | -- | **P** |
| | **CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12** | -- | **P** |
| | **PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6** | No protective earth provided. | **N/A** |
| | **Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION ..... :** | See appended Tables 8.8.3 and 8.10<br>2 Y1 capacitors (CY1, CY2) in series provided between primary and secondary circuit. | **P** |
| | **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. ..... :** | -- | **N/A** |
| | **Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance** | CY1=CY2=1,0 nF<br>Both rated: 250 Vac | **P** |

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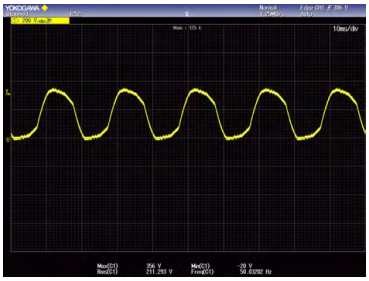
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF).....:** | **GTM41060-1505:**<br>  <br>**GTM41060-2512:**<br> <br>**GTM41060-2524:**<br> | **—** |
| **8.5.1.3** | **MEANS OF OPERATOR PROTECTION (MOOP)** | Power supply unit evaluated for Means of Operator protection (MOOP). | **P** |
| | **Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:** | -- | **P** |
| | **– dielectric strength test .....:** | -- | **P** |
| | **– requirements of IEC 60950-1 for INSULATION CO-ORDINATION** | -- | **N/A** |
| | **CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:** | -- | **P** |
| | **– limits of Tables 13 to 16 (inclusive); or** | -- | **P** |
| | **– 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** | No protective earth provided. | **N/A** |
| | **– or with requirements and tests of IEC 60950-1 for protective earthing .....:** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **A Y2 (IEC 60384-14) capacitor is considered one MEANS OF OPERATOR PROTECTION ..... :** | -- | **N/A** |
| | **A Y1 (IEC 60384-14 ) capacitor is considered two MEANS OF OPERATOR PROTECTION ..... :** | Single Y1 capacitor provided between primary and secondary circuit. | **P** |
| | **Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance** | Single capacitor provided. | **P** |
| | **Voltage $_{Total\ Working}$ (V) and C $_{Nominal}$ (µF) ..... :** | -- | **—** |
| | **Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION** | -- | **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 .... :** | -- | **N/A** |
| **8.5.2** | **Separation of PATIENT CONNECTIONS** | | **N/A** |
| **8.5.2.1** | **PATIENT CONNECTIONS of F-TYPE APPLIED PART separated from all other parts by equivalent to one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to the MAX. MAINS VOLTAGE ..... :** | No patient connections provided.<br>No applied parts provided. | **N/A** |
| | **Separation requirement not applied between multiple functions of a single F-TYPE APPLIED PART** | -- | **N/A** |
| | **PATIENT CONNECTIONS treated as one APPLIED PART in the absence of electrical separation between PATIENT CONNECTIONS of same or another function** | -- | **N/A** |
| | **MANUFACTURER has defined if multiple functions are to be considered as all within one APPLIED PART or as multiple APPLIED PARTS .....:** | -- | **N/A** |
| | **Classification as TYPE BF, CF, or DEFIBRILLATION-PROOF applied to one entire APPLIED PART** | -- | **N/A** |
| | **LEAKAGE CURRENT tests conducted per 8.7.4 .... :** | -- | **N/A** |
| | **Dielectric strength test conducted per 8.8.3.... :** | -- | **N/A** |
| | **CREEPAGE and CLEARANCES measured ..... :** | -- | **N/A** |
| | **A protective device connected between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE to protect against excessive voltages did not operate below 500 V r.m.s** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.5.2.2** | **PATIENT CONNECTIONS of a TYPE B APPLIED PART not PROTECTIVELY EARTHED are separated by one MEANS OF PATIENT PROTECTION from metal ACCESSIBLE PARTS not PROTECTIVELY EARTHED.....:** | No TYPE B APPLIED PART provided. | **N/A** |
| | **– except when metal ACCESSIBLE PART is physically close to APPLIED PART and can be regarded as a part of APPLIED PART; and** | -- | **N/A** |
| | **– RISK that metal ACCESSIBLE PART will make contact with a source of voltage or LEAKAGE CURRENT above permitted limits is acceptably low** | -- | **N/A** |
| | **LEAKAGE CURRENT tests conducted per 8.7.4.....:** | -- | **N/A** |
| | **Dielectric strength test conducted per 8.8.3 ....:** | -- | **N/A** |
| | **Relevant CREEPAGE and CLEARANCES measured** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of the RISK of metal ACCESSIBLE PARTS contacting a source of voltage or LEAKAGE CURRENT above the limits ..... : (ISO 14971 Cl. 4.2-4.4, 5)** | No TYPE B APPLIED PART provided. No RM considered necessary. | **N/A** |
| **8.5.2.3** | **A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable remote from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE** | | **N/A** |
| | **- cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT.....:** | No applied parts provided, no patient leads provided. | **N/A** |
| | **– conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter** | Non-metal connector used for connection of applied part. | **N/A** |
| | **– CLEARANCE between connector pins and a flat surface is at least 0.5 mm** | -- | **N/A** |
| | **– conductive part pluggable into a mains socket protected from making contact with parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1** | -- | **N/A** |
| | **– required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N,** | -- | **N/A** |
| | **Test finger test (10 N) .....:** | -- | **N/A** |
| | **Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5)** | No RM considered necessary. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.5.4** | **WORKING VOLTAGE** | -- | **P** |
| | **– Input supply voltage to ME EQUIPMENT was RATED voltage or voltage within RATED range resulting in highest measured value (V) ..... :** | See Insulation Diagram and Insulation Table. | **P** |
| | **– WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V)..... :** | -- | **N/A** |
| | **– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V)..... :** | -- | **N/A** |
| | **– Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth** | -- | **N/A** |
| | **– WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)..... :** | See Insulation Diagram and Insulation Table. | **P** |
| | **– WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages** | -- | **N/A** |
| | **– WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V) ..... :** | No motors provided. | **N/A** |
| **8.5.5** | **DEFIBRILLATION-PROOF APPLIED PARTS** | No applied parts provided. | **N/A** |
| **8.5.5.1** | **Classification "DEFIBRILLATION-PROOF APPLIED PART" applied to one APPLIED PART in its entirety** | -- | **N/A** |
| | **Isolation of PATIENT CONNECTIONS of a DEFIBRILLATION-PROOF APPLIED PART from other parts of ME EQUIPMENT accomplished as follows:** | -- | **N/A** |
| | **a) No hazardous electrical energies appear during a discharge of cardiac defibrillator ..... :** | -- | **N/A** |
| | **b) ME EQUIPMENT complied with relevant requirements of this standard, providing BASIC SAFETY and ESSENTIAL PERFORMANCE following exposure to defibrillation voltage, and recovery time stated in ACCOMPANYING DOCUMENTS..... :** | -- | **N/A** |
| **8.5.5.2** | **Means provided to limit energy delivered to a 100 Ω load ..... :** | -- | **N/A** |
| **8.6** | **Protective and functional earthing and potential equalization of ME EQUIPMENT** | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.6.1** | **Requirements of 8.6.2 to 8.6.8 applied** | No protective earthing, no functional earthing and no potential equalization provided. | **N/A** |
| | **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 .....:** | -- | **N/A** |
| | **Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL** | -- | **N/A** |
| | **Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside.....:** | -- | **N/A** |
| | **Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL** | -- | **N/A** |
| | **PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing** | -- | **N/A** |
| **8.6.3** | **PROTECTIVE EARTH CONNECTION not used for a moving part,** | -- | **N/A** |
| | **except when MANUFACTURER demonstrated in RISK MANAGEMENT FILE connection will remain reliable during EXPECTED SERVICE LIFE .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No moving parts provided. No RM considered necessary. | **N/A** |
| **8.6.4** | **a) PROTECTIVE EARTH CONNECTIONS carried fault currents reliably and without excessive voltage drop ..... :** | -- | **N/A** |
| | **b) Allowable TOUCH CURRENT and PATIENT LEAKAGE CURRENT in SINGLE FAULT CONDITION were not exceeded, when impedance of PROTECTIVE EARTH CONNECTIONS exceeded values in 8.6.4 a) and Table 8.6.4, due to limited current capability of relevant circuits .....:** | -- | **N/A** |
| **8.6.5** | **Surface coatings** | | **N/A** |
| | **Poorly conducting surface coatings on conductive elements removed at the point of contact** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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 CONDUCTOR** | | **N/A** |
| | **– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE** | -- | **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** |
| **8.6.8** | **FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION** | No functional earth terminal provided. | **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** | Class II MEE with two conductors only. | **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 CURRENTS** | | **P** |
| **8.7.1** | **a) Electrical isolation providing protection against electric shock limits currents to values in 8.7.3..... :** | See appended Tables 8.7 | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **b) Specified values of EARTH LEAKAGE, TOUCH, PATIENT LEAKAGE, and PATIENT AUXILIARY CURRENTS applied in combination of conditions in appended Table 8.7.....:** | See appended Tables 8.7 | **P** |
| **8.7.2** | **Allowable values specified in 8.7.3 applied under SINGLE FAULT CONDITIONS of 8.1 b), except** | -- | **P** |
| | **– where insulation used in conjunction with a PROTECTIVE EARTH CONNECTION, insulation short circuited only under conditions in 8.6.4 b)** | -- | **N/A** |
| | **– the only SINGLE FAULT CONDITION for EARTH LEAKAGE CURRENT was interruption of one supply conductor at a time** | -- | **N/A** |
| | **– LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENT not measured in SINGLE FAULT CONDITION of short circuiting of one constituent part of DOUBLE INSULATION** | -- | **P** |
| | **SINGLE FAULT CONDITIONS not applied at same time as special test conditions of MAXIMUM MAINS VOLTAGE on APPLIED PARTS and non-PROTECTIVELY EARTHED parts of ENCLOSURE** | -- | **N/A** |
| **8.7.3** | **Allowable Values** | | **P** |
| | **a) Allowable values in 8.7.3 b), c), and d) measured based on, and are relative to currents in Fig 12 a), or by a device measuring frequency contents of currents as in Fig 12 b.:** | See appended Table 8.7 | **P** |
| | **b) Allowable values of PATIENT LEAKAGE and AUXILIARY CURRENTS are according to Tables 3 & 4, and values of a.c. are relative to currents having a frequency not less than 0.1Hz.....:** | See appended Table 8.7 | **P** |
| | **c) TOUCH CURRENT did not exceed 100 µA in NORMAL CONDITION and 500 µA in SINGLE FAULT CONDITION ($I_{TNC}$, $I_{TSFC}$) .....:** | See appended Table 8.7 | **P** |
| | **d) EARTH LEAKAGE CURRENT did not exceed 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION ($I_{ENC}$, $I_{ESFC}$).....:** | See appended Table 8.7<br>No protective earth; therefore earth leakage current not relevant. | **N/A** |
| | **Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 .....:** | No protective earth. | **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 0,18 mA.<br>(Revision No. 4) | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION ..... :** | No functional earth conductor provided. | **N/A** |
| **8.7.4** | **LEAKAGE and PATIENT AUXILIARY CURRENTS measurements ..... :** | See appended Table 8.7 | **P** |
| **8.8** | **Insulation** | | **P** |
| **8.8.1** | **Insulation relied on as MEANS OF PROTECTION, including REINFORCED INSULATION subjected to testing** | -- | **P** |
| | **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** | | **P** |
| | **Solid insulation forming SUPPLEMENTARY or REINFORCED INSULATION for a PEAK WORKING VOLTAGE greater than 71 V provided with:** | See below. | **P** |
| | **a) 0.4 mm, min, distance through insulation, or** | Optocoupler between primary and secondary. | **P** |
| | **b) does not form part of an ENCLOSURE and not subject to handling or abrasion during NORMAL USE, and comprised of:** | -- | **P** |
| | **– at least two layers of material, each passed the appropriate dielectric strength test..... :** | -- | **N/A** |
| | **– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test..... :** | 3 layers of insulation tape provided between primary and secondary windings within transformer.<br>Additional margin tape provided on all ends of transformer windings.<br>See appended Table 8.10. | **P** |
| | **Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION** | -- | **N/A** |
| | **Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION** | 2 layers tested for reinforced insulation. | **P** |
| | **BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when** | -- | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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** |
| | **Finished component complied with routine dielectric strength tests of 8.8.3 .....:** | -- | **N/A** |
| | **Tests of Annex L not repeated since material data sheets confirm compliance .....:** | -- | **N/A** |
| **8.8.3** | **Dielectric Strength** | | **P** |
| | **Solid insulating materials with a safety function withstood dielectric strength test voltages .....:** | See appended Table 8.8.3 | **P** |
| **8.8.4** | **Insulation other than wire insulation** | | **P** |
| **8.8.4.1** | **Resistance to heat retained by all insulation and insulating partition walls during EXPECTED SERVICE LIFE of ME EQUIPMENT** | -- | **P** |
| | **ME EQUIPMENT and design documentation examined.....:** | Approved components provided with adequate safety insulation.<br>See appended table 8.10. | **P** |
| | **RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | Approved components provided with adequate safety insulation. See appended Table 8.10. No RM considered necessary. | **P** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :** | Approved materials used. See appended table 8.10. No additional test was considered required. | **P** |
| | **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... :** | -- | **N/A** |
| | **b) Parts of insulating material supporting uninsulated parts of MAINS PART subjected to ball-pressure test in a), except at 125 °C ± 2 ° C or ambient indicated in technical description ±2°C plus temperature rise determined during test of 11.1 of relevant part, if higher (°C)..... :** | Ball pressure test performed on transformer bobbin. | **P** |
| | **Test not performed on parts of ceramic material, insulating parts of commutators, brush-caps, and similar, and on coil formers not used as REINFORCED INSULATION** | -- | **N/A** |
| **8.8.4.2** | **Resistance to environmental stress** | | **P** |
| | **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** | -- | **P** |
| | **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** | | **P** |
| **8.9.1.1** | **CREEPAGE DISTANCES and AIR CLEARANCES are equal to or greater than values in Tables 12 to 16 (inclusive)..... :** | -- | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **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 , min CREEPAGE and CLEARANCES not applied.....:** | Sufficient creepage and clearance distances provided between parts of opposite polarity before mains fuses. Short circuit performed after primary fuses. No hazardous situation. See appended table 13.2. | **P** |
| **8.9.3** | **Spaces filled by insulating compound** | | **P** |
| **8.9.3.1** | **Only solid insulation requirements applied where distances between conductive parts filled with insulating compound** | Thermal cycling performed on optocouplers separately.<br>See appended Table 8.10. | **P** |
| | **Thermal cycling, humidity preconditioning, and dielectric strength tests** | -- | **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 (cl. 8.8.3 at 1,6 x test voltage).....:** | -- | **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 followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage .....:** | -- | **N/A** |
| | **– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage** | -- | **N/A** |
| **8.9.4** | **Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree ……** | Pollution degree: 2 | **P** |
| | **Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.10** | **Components and wiring** | | **P** |
| **8.10.1** | **Components of ME EQUIPMENT likely to result in an unacceptable RISK by their movements mounted securely ..... :** | All parts are secured. | **P** |
| | **RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components ..... :**<br>**(ISO 14791 Cl. 4.2-4.4, 5, 6.2-6.5)** | RMF Reference to specific RISKS: EL3<br>(ISO 14971 Cl. 4.2-4.4, 5) | **P** |
| **8.10.2** | **Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment..... :** | See Appended RM Results Table 8.10.2 | **P** |
| | **Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS** | -- | **N/A** |
| **8.10.3** | **Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken ..... :** | No such flexible cord provided. | **N/A** |
| **8.10.4** | **Cord-connected HAND-HELD parts and cord-connected foot-operated control devices** | | **N/A** |
| **8.10.4.1** | **Control devices of ME EQUIPMENT and their connection cords contain only conductors and components operating at 42.4 V peak a.c., max, or 60 V d.c. in circuits isolated from MAINS PART by two MEANS OF PROTECTION** | No cord-connected hand-held parts and cord-connected foot-operated control device provided. | **N/A** |
| **8.10.4.2** | **Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3** | -- | **N/A** |
| | **Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3** | -- | **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 ..... :** | See Appended RM Results Table 8.10.5<br>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** | No access cover provided. | **N/A** |
| **8.10.6** | **Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead** | -- | **N/A** |
| **8.10.7** | **a) Insulating sleeve adequately secured..... :** | Sleeves are heat-shrinkable. | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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 of ME EQUIPMENT subject to temperatures exceeding 70 °C .....:** | -- | **N/A** |
| **8.11** | **MAINS PARTS, components and layout** | | **P** |
| **8.11.1** | **a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles .....:** | EUT is direct plug-in or open frame power supply unit intended for supplying medical product by its output voltage.<br>Direct plug-in power supply unit: Mains plug is considered as disconnecting device.<br>Open frame power supply: End product consideration. | **P** |
| | **PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)** | Not permanently installed 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** | MEE is not permanently installed equipment. | **N/A** |
| | **- the isolation device specified in the ACCOMPANYING DOCUMENTS** | Final determination in the end product. | **N/A** |
| | **b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description .....:** | Direct plug-in power supply unit: Mains plug is considered as disconnecting device.<br>Open frame power supply: End product consideration. | **N/A** |
| | **c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV .....:** | No mains switch provided. | **N/A** |
| | **d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead** | No power supply cord provided. | **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 used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH .....:** | Direct plug-in power supply unit: Mains plug is considered as disconnecting device.<br>Open frame power supply: End product consideration. | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **g) A fuse or a semiconductor device not used as an isolating means** | -- | **P** |
| | **h) ME EQUIPMENT not provided with a device causing disconnection of ME EQUIPMENT from SUPPLY MAINS by producing a short circuit resulting in operation of an overcurrent protection device** | -- | **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** | -- | **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 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. | **N/A** |
| **8.11.3.2** | **POWER SUPPLY CORDS are no less robust than ordinary tough rubber sheathed flexible cord (IEC 60245-1:2003, Annex A, designation 53) or ordinary polyvinyl chloride sheathed flexible cord (IEC 60227-1:1993, Annex A, design 53)... :** | -- | **N/A** |
| | **Only polyvinyl chloride insulated POWER SUPPLY CORD with appropriate temperature rating used for ME EQUIPMENT having external metal parts with a temperature > 75 °C touchable by the cord in NORMAL USE ..... :** | -- | **N/A** |
| **8.11.3.3** | **NOMINAL cross-sectional area of conductors of POWER SUPPLY CORDS of ME EQUIPMENT is not less than in Table 17 ..... :** | -- | **N/A** |
| **8.11.3.4** | **APPLIANCE COUPLERS complying with IEC 60320-1 are considered to comply with 8.11.3.5 and 8.11.3.6..... :** | -- | **N/A** |
| **8.11.3.5** | **Cord anchorage** | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage** | No power supply cord provided. | **N/A** |
| | **b) Cord anchorage of POWER SUPPLY CORD is an 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** | -- | **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** | -- | **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** | -- | **N/A** |
| | **f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR** | -- | **N/A** |
| | **Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18.....:** | -- | **N/A** |
| | **Cord subjected to a torque in Table 18 for one minute 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 protected against excessive bending at inlet opening of equipment** | -- | **N/A** |
| | **Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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) ..... :** | -- | **N/A** |
| | **Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance** | -- | **N/A** |
| | **Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D..... :** | -- | **N/A** |
| **8.11.4** | **MAINS TERMINAL DEVICES** | | **N/A** |
| **8.11.4.1** | **PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection** | -- | **N/A** |
| | **Terminals alone are not used to keep conductors in position** | -- | **N/A** |
| | **Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors** | -- | **N/A** |
| | **Screws and nuts clamping external conductors do not serve to secure any other component** | -- | **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** |
| | **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 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** | -- | **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** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Correct connection and positioning of conductors before ACCESS COVER verified by an installation test** | -- | **N/A** |
| **8.11.5** | **Mains fuses and OVER-CURRENT RELEASES** | | **P** |
| | **A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection..:** | Two primary fuses provided (in line and neutral). | **P** |
| | **- in at least one supply lead for other single-phase CLASS II ME EQUIPMENT .....:** | See appended table 8.10. | **P** |
| | **– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT** | Not permanently installed equipment. | **N/A** |
| | **– fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART** | -- | **N/A** |
| | **Protective devices have adequate breaking capacity to interrupt the max. fault current.....:** | See appended Table 8.10 | **P** |
| | **A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR** | No protective earth provided. | **N/A** |
| | **Justification for omission of fuses or OVER-CURRENT RELEASES documented .....:** | Fuses or OVER-CURRENT RELEASES were not omitted. | **N/A** |
| **8.11.6** | **Internal wiring of the MAINS PART** | | **P** |
| | **a) Cross-sectional area of internal wiring in a MAINS PART between MAINS TERMINAL DEVICE or APPLIANCE INLET and protective devices suitable .....:** | No internal wiring provided between mains terminal device and protective device. | **N/A** |
| | **b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient.....:** | PCB tracks provided. | **P** |

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|---|---|---|---|
| **9** | **PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS** | | **P** |
| **9.2** | **HAZARDS associated with moving parts** | | **N/A** |
| **9.2.1** | **When ME EQUIPMENT with moving parts PROPERLY INSTALLED, used per ACCOMPANYING DOCUMENTS or under foreseeable misuse, RISKS associated with moving parts reduced to an acceptable level..... :** | No moving parts provided. | **N/A** |
| | **RISK from contact with moving parts reduced to an acceptable level using protective measures, (access, function, shape of parts, energy, speed of motion, and benefits to PATIENT considered)** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **RESIDUAL RISK associated with moving parts considered acceptable when exposure was needed for ME EQUIPMENT to perform its intended function, and** | -- | **N/A** |
| | **RISK CONTROLS implemented ..... :** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of RISKS associated with moving parts ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No moving parts provided. No RM considered necessary. | **N/A** |
| | **All RISKS associated with moving parts have been reduced to an acceptable level** | | **N/A** |
| **9.2.2** | **TRAPPING ZONE** | | **N/A** |
| **9.2.2.1** | **ME EQUIPMENT with a TRAPPING ZONE complied with one or more of the following as feasible:** | No trapping zones. | **N/A** |
| | **– Gaps in Clause 9.2.2.2, or** | -- | **N/A** |
| | **– Safe distances in Clause 9.2.2.3, or** | -- | **N/A** |
| | **– GUARDS and other RISK CONTROL measures in 9.2.2.4, or** | -- | **N/A** |
| | **– Continuous activation in Clause 9.2.2.5** | -- | **N/A** |
| | **Control of relevant motion complied with 9.2.2.6 when implementation of above protective measures were inconsistent with INTENDED USE of ME EQUIPMENT or ME SYSTEM** | -- | **N/A** |
| **9.2.2.2** | **A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when gaps of TRAPPING ZONE complied with dimensions per Table 20 .....:** | -- | **N/A** |
| **9.2.2.3** | **A TRAPPING ZONE considered not to present a MECHANICAL HAZARD when distances separating OPERATOR, PATIENT, and others from TRAPPING ZONES exceeded values in ISO 13857:2008 ..... :** | -- | **N/A** |
| **9.2.2.4** | **GUARDS and other RISK CONTROL measures** | | **N/A** |
| **9.2.2.4.1** | **A TRAPPING ZONE do not to present a MECHANICAL HAZARD when GUARDS or other RISK CONTROL measures are of robust construction, not easy to bypass or render non-operational, and did not introduce additional unacceptable RISK .....:** | No guards used. | **N/A** |
| **9.2.2.4.2** | **FIXED GUARDS held in place by systems that can only be dismantled with a TOOL** | -- | **N/A** |
| **9.2.2.4.3** | **Movable GUARDS that can be opened without a TOOL remained attached when GUARD was open** | No movable guards used. | **N/A** |
| | **– they are associated with an interlock preventing relevant moving parts from starting to move while TRAPPING ZONE is accessible, and stops movement when the GUARD is opened,** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– absence or failure of one of their components prevents starting, and stops moving parts** | -- | **N/A** |
| | **Movable GUARDS complied with any applicable tests** | -- | **N/A** |
| **9.2.2.4.4** | **Other RISK CONTROL designed and incorporated into to the control system stops movement and** | No protective measures used. | **N/A** |
| | **– SINGLE FAULT CONDITIONS have a second RISK CONTROL, or** | -- | **N/A** |
| | **ME EQUIPMENT is SINGLE FAULT SAFE** | -- | **N/A** |
| **9.2.2.5** | **Continuous activation** | | **N/A** |
| | **Continuous activation used as a RISK CONTROL, complies with the following** | -- | **N/A** |
| | **a) movement was in OPERATOR'S field of view** | -- | **N/A** |
| | **b) movement of ME EQUIPMENT or its parts was possible only by continuous activation of control by OPERATOR** | -- | **N/A** |
| | **c) a second RISK CONTROL provided for SINGLE FAULT CONDITION of continuous activation system, or** | -- | **N/A** |
| | **- the continuous activation system is SINGLE FAULT SAFE** | -- | **N/A** |
| **9.2.2.6** | **Speed of movement(s) positioning parts of ME EQUIPMENT or PATIENT limited to allow OPERATOR control of the movement** | -- | **N/A** |
| | **Over travel of such movement occurring after operation of a control to stop movement, did not result in an unacceptable RISK** | -- | **N/A** |
| **9.2.3** | **Other MECHANICAL HAZARDS associated with moving parts** | | **N/A** |
| **9.2.3.1** | **Controls positioned, recessed, or protected by other means so that they cannot be accidentally actuated** | No moving parts provided. | **N/A** |
| | **- unless for the intended PATIENT, the USABILITY ENGINEERING PROCESS concludes otherwise (e.g. PATIENT with special needs), or** | -- | **N/A** |
| | **- activation does not result in an unacceptable RISK** | -- | **N/A** |
| **9.2.3.2** | **Over travel past range limits of the ME EQUIPMENT prevented ..... :** | -- | **N/A** |
| | **Over travel means provided with mechanical strength to withstand loading in NORMAL CONDITION & reasonably foreseeable misuse ... :** | -- | **N/A** |
| **9.2.4** | **Emergency stopping devices** | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Where necessary to have one or more emergency stopping device(s), emergency stopping device complied with all the following, except for actuating switch capable of interrupting all power .....:** | No emergency stopping device provided. | **N/A** |
| | **a) Emergency stopping device reduced RISK to an acceptable level** | -- | **N/A** |
| | **RISK MANAGEMENT FILE indicates the use of an emergency stopping device reduces the RISK to an acceptable level .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.6)** | No emergency stopping device provided. No RM considered necessary. | **N/A** |
| | **b) Proximity and response of OPERATOR to actuate emergency stopping device could be relied upon to prevent HARM** | -- | **N/A** |
| | **c) Emergency stopping device actuator was readily accessible to OPERATOR** | -- | **N/A** |
| | **d) Emergency stopping device(s) are not part of normal operation of ME EQUIPMENT** | -- | **N/A** |
| | **e) Emergency switching operation or stopping means neither introduced further HAZARD nor interfered with operation necessary to remove original MECHANICAL HAZARD** | -- | **N/A** |
| | **f) Emergency stopping device was able to break full load of relevant circuit, including possible stalled motor currents and the like** | -- | **N/A** |
| | **g) Means for stopping of movements operate as a result of one single action** | -- | **N/A** |
| | **h) Emergency stopping device provided with an actuator in red and easily distinguishable and identifiable from other controls** | -- | **N/A** |
| | **i) An actuator interrupting/opening mechanical movements marked on or immediately adjacent to face of actuator with symbol 18 of Table D.1 or "STOP"** | -- | **N/A** |
| | **j) Emergency stopping device, once actuated, maintained ME EQUIPMENT in disabled condition until a deliberate action, different from that used to actuate it, was performed** | -- | **N/A** |
| | **k) Emergency stopping device is suitable for its application** | -- | **N/A** |
| **9.2.5** | **Means provided to permit quick and safe release of PATIENT in event of breakdown of ME EQUIPMENT or failure of power supply, activation of a RISK CONTROL measure, or emergency stopping ..... :** | Equipment does not require fixation of patient. | **N/A** |
| | **– and uncontrolled or unintended movement of ME EQUIPMENT that could result in an unacceptable RISK prevented** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– Situations where PATIENT is subjected to unacceptable RISKS due to proximity of moving parts, removal of normal exit routes, or other HAZARDS prevented** | -- | **N/A** |
| | **– Measures provided to reduce RISK to an acceptable level when after removal of counterbalanced parts, other parts of ME EQUIPMENT can move in a hazardous way** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of RISKS to the PATIENT related to breakdown of the ME EQUIPMENT ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No moving parts provided. No fixation of patient. No RM considered necessary. | **N/A** |
| **9.3** | **Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered..... :** | No rough surfaces, no sharp corners and no sharp edges. | **P** |
| **9.4** | **Instability HAZARDS** | | **N/A** |
| **9.4.1** | **ME EQUIPMENT and its parts, other than FIXED, for placement on a surface did not overbalance (tip over) or move unexpectedly in NORMAL USE** | Instability tests not applicable. | **N/A** |
| **9.4.2** | **Instability – overbalance** | | **N/A** |
| **9.4.2.1** | **ME EQUIPMENT or its parts did not overbalance when prepared per ACCOMPANYING DOCUMENTS, or when tested ..... :** | -- | **N/A** |
| **9.4.2.2** | **Instability excluding transport** | | **N/A** |
| | **ME EQUIPMENT or its did not overbalance when placed in different positions of NORMAL USE,... :** | -- | **N/A** |
| | **A warning provided when overbalance occurred during 10° inclined plane test** | -- | **N/A** |
| **9.4.2.3** | **Instability from horizontal and vertical forces** | | **N/A** |
| | **a) ME EQUIPMENT or its parts with a mass of 25kg or more, intended to be used on the floor, didn't overbalance due to pushing, leaning against it** | -- | **N/A** |
| | **Surfaces of ME EQUIPMENT or its parts where a RISK of overbalancing exists from pushing, etc., permanently marked with a warning of the RISK** | -- | **N/A** |
| | **ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3 a)** | -- | **N/A** |
| | **b) ME EQUIPMENT, for use on the floor or on a table, did not overbalance due to sitting or stepping** | -- | **N/A** |
| | **ME EQUIPMENT or its parts, for use on the floor or on a table, where RISK of overbalancing exists, permanently marked with the RISK warning.... :** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **ME EQUIPMENT did not overbalance when tested according to Cl. 9.4.2.3b) .....:** | -- | **N/A** |
| **9.4.2.4** | **Castors and wheels** | | **N/A** |
| **9.4.2.4.1** | **Means used for transportation of MOBILE ME EQUIPMENT did not result in an unacceptable RISK when MOBILE ME EQUIPMENT moved or parked in NORMAL USE** | No castors and wheels provided. | **N/A** |
| **9.4.2.4.2** | **Force required to move MOBILE ME EQUIPMENT did not exceed 200 N .....:** | -- | **N/A** |
| **9.4.2.4.3** | **MOBILE ME EQUIPMENT exceeding 45 kg able to pass over threshold .....:** | -- | **N/A** |
| **9.4.3** | **Instability from unwanted lateral movement (including sliding)** | | **N/A** |
| **9.4.3.1** | **a) Brakes of power-driven MOBILE ME EQUIPMENT normally activated and could only be released by continuous actuation of a control** | -- | **N/A** |
| | **b) MOBILE ME EQUIPMENT provided with locking means to prevent unwanted movements** | -- | **N/A** |
| | **c) No unwanted lateral movement resulted when MOBILE ME EQUIPMENT placed in its transport position when test per 9.4.3.1** | -- | **N/A** |
| **9.4.3.2** | **Instability excluding transport** | | **N/A** |
| | **a) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with 5° tilt test .....:** | -- | **N/A** |
| | **b) MOBILE ME EQUIPMENT provided with wheel locks or braking system compliant with lateral stability test** | -- | **N/A** |
| **9.4.4** | **Grips and other handling devices** | | **N/A** |
| | **a) ME EQUIPMENT with a mass of over 20 kg requiring lifting in NORMAL USE or transport provided with suitable handling means, or ACCOMPANYING DOCUMENTS specify safe lifting method** | No grips and other handling devices provided. | **N/A** |
| | **Handles, suitably placed to enable ME EQUIPMENT or its part to be carried by two or more persons and by examination of EQUIPMENT, its part, or ACCOMPANYING DOCUMENTS** | -- | **N/A** |
| | **b) PORTABLE ME EQUIPMENT with a mass > 20 kg provided with one or more carrying-handles suitably placed to enable carrying by two or more persons as confirmed by actual carrying** | -- | **N/A** |
| | **c) Carrying handles and grips and their means of attachment withstood loading test .....:** | -- | **N/A** |
| **9.5** | **Expelled parts HAZARD** | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **9.5.1** | **Suitability of means of protecting against expelled parts determined by assessment and examination of RISK MANAGEMENT FILE ..... :**<br>**(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)** | No risk of expelled parts. No RM considered necessary. | **N/A** |
| | **All identified RISKS associated with expelled parts mitigated to an acceptable level** | -- | **N/A** |
| **9.5.2** | **Cathode Ray tube(s) complied with IEC 60065:2001, Clause 18, or IEC 61965..... :** | No cathode ray tubes. | **N/A** |
| **9.6** | **Acoustic energy (including infra- and ultrasound) and vibration** | | **N/A** |
| **9.6.1** | **Human exposure to acoustic energy and vibration from ME EQUIPMENT doesn't result in unacceptable RISK and** | Equipment does not produce significant acoustic energy or vibration. | **N/A** |
| | **If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, and PATIENT sensitivity..... :** | -- | **N/A** |
| | **If necessary, confirmed in RISK MANAGEMENT FILE including audibility of auditory alarm signals, PATIENT sensitivity, and**<br>**(ISO 14971 Cl. 4.2-44, 5, 6.2-6.5)** | Equipment does not produce significant acoustic energy or vibration. No RM considered necessary. | **N/A** |
| | **All identified RISKS mitigated to an acceptable level** | -- | **N/A** |
| **9.6.2** | **Acoustic energy** | | **N/A** |
| **9.6.2.1** | **PATIENT, OPERATOR, and other persons are not exposed to acoustic energy from ME EQUIPMENT in NORMAL USE** | -- | **N/A** |
| | **– 80 dBA for a cumulative exposure of 24 h over a 24 h period (dBA) ..... :** | -- | **—** |
| | **- 83 dBA (when halving the cumulative exposure time) (dBA) ..... :** | -- | **—** |
| | **– 140 dBC (peak) sound pressure level for impulsive or impact acoustic energy (dB) ..... :** | -- | **—** |
| **9.6.2.2** | **RISK MANAGEMENT FILE examined ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | Equipment does not produce infrasound and ultrasound. No RM considered necessary. | **N/A** |
| **9.6.3** | **Hand-transmitted vibration** | | **N/A** |
| | **Means provided to protect PATIENT and OPERATOR when hand-transmitted frequency-weighted r.m.s. acceleration generated in NORMAL USE exceeds specified values** | -- | **N/A** |
| | **– 2.5 m/s$^2$ for a cumulative time of 8 h during a 24 h period (m/s$^2$)..... :** | -- | **N/A** |
| | **– Accelerations for different times, inversely proportional to square root of time (m/s$^2$) ..... :** | -- | **N/A** |
| **9.7** | **Pressure vessels and parts subject to pneumatic and hydraulic pressure** | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **9.7.2** | **Pneumatic and hydraulic parts of ME EQUIPMENT or ACCESSORIES met requirements based on examination of RISK MANAGEMENT FILE.....:**<br>**(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)** | No pneumatic and hydraulic parts. No RM considered necessary. | **N/A** |
| | **– No unacceptable RISK resulted from loss of pressure or loss of vacuum** | -- | **N/A** |
| | **– No unacceptable RISK resulted from a fluid jet caused by leakage or a component failure** | -- | **N/A** |
| | **– Elements of ME EQUIPMENT or an ACCESSORY, especially pipes and hoses leading to an unacceptable RISK protected against harmful external effects** | -- | **N/A** |
| | **– Reservoirs and similar vessels leading to an unacceptable RISK are automatically depressurized when ME EQUIPMENT is isolated from its power supply** | -- | **N/A** |
| | **Means provided for isolation, or local depressurizing reservoirs and similar vessels, and pressure indication when above not possible** | -- | **N/A** |
| | **– All elements remaining under pressure after isolation of ME EQUIPMENT or an ACCESSORY from its power supply resulting in an unacceptable RISK provided with clearly identified exhaust devices, and a warning to depressurize these elements before setting or maintenance activity** | -- | **N/A** |
| **9.7.3** | **Maximum pressure a part of ME EQUIPMENT can be subjected to in NORMAL and SINGLE FAULT CONDITIONS considered to be highest of following:** | -- | **N/A** |
| | **a) RATED maximum supply pressure from an external source** | -- | **N/A** |
| | **b) Pressure setting of a pressure-relief device provided as part of assembly** | -- | **N/A** |
| | **c) Max pressure that can develop by a source of pressure that is part of assembly, unless pressure limited by a pressure-relief device** | -- | **N/A** |
| **9.7.4** | **Max pressure in NORMAL and SINGLE FAULT CONDITIONS did not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE for EQUIPMENT part, except as allowed in 9.7.7, confirmed by inspection of THE MANUFACTURER'S data for the component, ME EQUIPMENT, and by functional tests.....:** | -- | **N/A** |
| **9.7.5** | **A pressure vessel withstood a HYDRAULIC TEST PRESSURE when pressure was more than 50 kPa, and product of pressure and volume was more than 200 kPal .....:** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **9.7.6** | **Pressure-control device regulating pressure in ME EQUIPMENT with pressure-relief device completed 100,000 cycles of operation under RATED load and prevented pressure from exceeding 90 % of setting of pressure-relief device in different conditions of NORMAL USE . :** | -- | **N/A** |
| **9.7.7** | **Pressure-relief device(s) used where MAXIMUM PERMISSIBLE WORKING PRESSURE could otherwise be exceeded met the following, as confirmed by MANUFACTURER'S data, ME EQUIPMENT, RISK MANAGEMENT FILE, and functional tests..... :** | -- | **N/A** |
| | **a) Connected as close as possible to pressure vessel or parts of system it is to protect** | -- | **N/A** |
| | **b) Installed to be readily accessible for inspection, maintenance, and repair** | -- | **N/A** |
| | **c) Could be adjusted or rendered inoperative without a TOOL** | -- | **N/A** |
| | **d) With discharge opening located and directed as to not to release material towards any person** | -- | **N/A** |
| | **e) With discharge opening located and directed as to not to deposit material on parts that could result in an unacceptable RISK** | -- | **N/A** |
| | **f) Adequate discharge capacity provided to ensure that pressure will not exceed MAXIMUM PERMISSIBLE WORKING PRESSURE of system it is connected to by more than 10 % when failure occurs in control of supply pressure** | -- | **N/A** |
| | **g) No shut-off valve provided between a pressure-relief device and parts it is to protect** | -- | **N/A** |
| | **h) Min number of cycles of operation 100 000, except for one-time use devices (bursting disks)** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of the risks associated with the discharge opening of the pressure relief device..... :**<br>**(ISO 14971 Cl. 4.3, 4.4, 5, 6.2-6.5)** | No pressure-relief devices provided. No RM considered necessary. | **N/A** |
| **9.8** | **HAZARDS associated with support systems** | | **N/A** |
| **9.8.1** | **ME EQUIPMENT parts designed to support loads or provide actuating forces when a mechanical fault could constitute an unacceptable RISK .. :** | Equipment does not have any support system. | **N/A** |
| | **– Construction of support, suspension, or actuation system complied with Table 21 and TOTAL LOAD** | -- | **N/A** |
| | **– Means of attachment of ACCESSORIES prevent possibility of incorrect attachment that could result in an unacceptable RISK** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– RISK ANALYSIS of support systems included MECHANICAL HAZARDS from static, dynamic, vibration, foundation and other movements, impact and pressure loading, temperature, environmental, manufacture and service conditions ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No support system provided.<br>No RM considered necessary. | **N/A** |
| | **– RISK ANALYSIS included effects of failures such as excessive deflection, plastic deformation, ductile/brittle fracture, fatigue fracture, instability (buckling), stress-assisted corrosion cracking, wear, material creep and deterioration, and residual stresses from manufacturing PROCESSES** | -- | **N/A** |
| | **– Instructions on attachment of structures to a floor, wall, ceiling, included in ACCOMPANYING DOCUMENTS making adequate allowances for quality of materials used to make the connection and list the required materials** | -- | **N/A** |
| | **Additional instructions provided on checking adequacy of surface of structure parts will be attached to** | -- | **N/A** |
| **9.8.2** | **Support systems maintain structural integrity during EXPECTED SERVICE LIFE, and TENSILE SAFETY FACTORS are not less than in Table 21, except when an alternative method used to demonstrate structural integrity throughout EXPECTED SERVICE LIFE, or for a foot rest** | -- | **N/A** |
| | **Compliance with 9.8.1 and 9.8.2 confirmed by examination of ME EQUIPMENT, RISK MANAGEMENT FILE, specifications and material processing .. :** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of the structural integrity of support system .. :**<br>**(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)** | No support system provided.<br>No RM considered necessary. | **N/A** |
| | **All identified RISKS are mitigated to an acceptable level** | -- | **N/A** |
| | **When test were conducted, testing consisted of application of a test load to support assembly equal to TOTAL LOAD times required TENSILE SAFETY FACTOR while support assembly under test was in equilibrium after 1 min, or not resulted in an unacceptable RISK..... :** | -- | **N/A** |
| | **Where the equipment is not at equilibrium after 1 min, the RISK MANAGEMENT FILE includes an assessment of the test results ..... :**<br>**(ISO 14971 Cl. 4.3-4.4, 5, 6.2-6.5)** | No support system provided.<br>No RM considered necessary. | **N/A** |
| **9.8.3** | **Strength of PATIENT or OPERATOR support or suspension systems** | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **9.8.3.1** | **ME EQUIPMENT parts supporting or immobilizing PATIENTS presents no unacceptable RISK of physical injuries and accidental loosening of secured joints ..... :** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes assessment of the RISKS associated with physical injuries and accidental loosening of fixings ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No support system provided. No RM considered necessary. | **N/A** |
| | **SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS or OPERATORS is sum of mass of PATIENTS or mass of OPERATORS plus mass of ACCESSORIES supported by ME EQUIPMENT or its parts** | -- | **N/A** |
| | **Supporting and suspending parts for adult human PATIENTS or OPERATORS designed for a PATIENT or OPERATOR with a min mass of 135 kg and ACCESSORIES with a min mass of 15 kg, unless stated by MANUFACTURER** | -- | **N/A** |
| | **Maximum mass of PATIENT included in SAFE WORKING LOAD of ME EQUIPMENT or its parts supporting or suspending PATIENTS adapted when MANUFACTURER specified applications** | -- | **N/A** |
| | **Max allowable PATIENT mass < 135 kg marked on ME EQUIPMENT and stated in ACCOMPANYING DOCUMENTS** | -- | **N/A** |
| | **Max allowable PATIENT mass over 135 kg stated in ACCOMPANYING DOCUMENTS** | -- | **N/A** |
| | **Examination of markings, ACCOMPANYING DOCUMENTS, and RISK MANAGEMENT FILE confirmed compliance ..... :** | -- | **N/A** |
| **9.8.3.2** | **a) Entire mass of PATIENT or OPERATOR distributed over an area of 0.1 $m^2$ on a foot rest temporarily supporting a standing PATIENT or OPERATOR ..... :** | -- | **N/A** |
| | **Compliance confirmed by examination of ME EQUIPMENT specifications of materials and their processing, and tests..... :** | -- | **N/A** |
| | **b) Deflection of a support surface from PATIENT or OPERATOR loading on an area of support/ suspension where a PATIENT or OPERATOR can sit did not result in an unacceptable RISK** | -- | **N/A** |
| | **Compliance confirmed by examination of ME EQUIPMENT, specifications of materials and their processing, and by a test ..... :** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| **9.8.3.3** | **Dynamic forces that can be exerted on equipment parts supporting or suspending a PATIENT or OPERATOR in NORMAL USE maintained BASIC SAFETY and ESSENTIAL PERFORMANCE confirmed test** | -- | **N/A** |
| **9.8.4** | **Systems with MECHANICAL PROTECTIVE DEVICES** | | **N/A** |
| **9.8.4.1** | **a) A MECHANICAL PROTECTIVE DEVICE provided for the support system** | -- | **N/A** |
| | **b) MECHANICAL PROTECTIVE complies with the requirements as follows:** | -- | **N/A** |
| | **– Designed based on TOTAL LOAD** | -- | **N/A** |
| | **– Has TENSILE SAFETY FACTORS for all parts not less than Table 21, row 7** | -- | **N/A** |
| | **– Activated before travel produced an unacceptable RISK** | -- | **N/A** |
| | **– Takes into account Clauses 9.2.5 and 9.8.4.3** | -- | **N/A** |
| | **Compliance confirmed by examination of ME EQUIPMENT over travel calculations and evaluation plus functional tests .....:** | -- | **N/A** |
| **9.8.4.2** | **Activation of MECHANICAL PROTECTIVE DEVICE is made obvious to OPERATOR when ME EQUIPMENT can still be used after failure of suspension or actuation means and activation of a MECHANICAL PROTECTIVE DEVICE** | -- | **N/A** |
| | **MECHANICAL PROTECTIVE DEVICE requires use of a TOOL to be reset or replaced** | -- | **N/A** |
| **9.8.4.3** | **MECHANICAL PROTECTIVE DEVICE intended to function once** | | **N/A** |
| | **–use of ME EQUIPMENT not possible until replacement of MECHANICAL PROTECTIVE DEVICE :** | -- | **N/A** |
| | **– ACCOMPANYING DOCUMENTS provided with required information on replacement by service personal** | -- | **N/A** |
| | **– ME EQUIPMENT permanently marked with safety sign 2 of Table D.** | -- | **N/A** |
| | **– Marking is adjacent to MECHANICAL PROTECTIVE DEVICE** | -- | **N/A** |
| | **– Compliance confirmed by examination and following test.....:** | -- | **N/A** |
| | **A chain, cable, band, spring, belt, jack screw nut, pneumatic or hydraulic hose, structural part or the like, employed to support a load, defeated by a convenient means causing maximum normal load to fall from most adverse position permitted by construction of ME EQUIPMENT** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Load included SAFE WORKING LOAD in 9.8.3.1 when system was capable of supporting a PATIENT or OPERATOR** | -- | **N/A** |
| | **No evidence of damage to MECHANICAL PROTECTIVE DEVICE affecting its ability to perform its intended function** | -- | **N/A** |
| **9.8.5** | **Systems without MECHANICAL PROTECTIVE DEVICES** | | **N/A** |
| | **Support Systems does not require MECHANICAL PROTECTIVE DEVICES..... :** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of RISKS associated with wear on the support system ..... :**<br>**(ISO 14971 Cl. 4.3,4.4,5,6.2-6.5)** | No support system provided. No RM considered necessary. | **N/A** |

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| **10** | **PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS** | | **N/A** |
| **10.1** | **X-Radiation** | | **N/A** |
| **10.1.1** | **The air kerma did not exceed 5 µGy/hat 5 cm from surface of ME EQUIPMENT.....:** | Equipment does not produce X-radiations. | **N/A** |
| | **Annual exposure reduced taking into account the irradiated body part, national regulations, and/or international recommendations for ME EQUIPMENT that has permanent proximity to a PATIENT as part of the INTENDED USE** | -- | **N/A** |
| **10.1.2** | **RISK from unintended X-radiation from ME EQUIPMENT producing X-radiation for diagnostic and therapeutic purposes addressed application of applicable particular and collateral standards, or.....:** | -- | **N/A** |
| | **RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE.....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | MEE does not produce diagnostic or therapeutic X-radiation. No RM considered necessary. | **N/AA** |
| **10.2** | **RISK associated with alpha, beta, gamma, neutron, and other particle radiation, addressed in RISK MANAGEMENT PROCESS as shown in RISK MANAGEMENT FILE.....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | MEE does not produce alpha, beta, gamma, neutron and other radiation. No RM considered necessary. | **N/A** |
| **10.3** | **The power density of unintended microwave radiation at frequencies between 1 GHz and 100 GHz does not exceed 10 W/m2** | MEE does not produce microwave radiation. | **N/A** |
| | **Microwave radiation is propagated intentionally** | -- | **N/A** |
| **10.4** | **Relevant requirements of IEC 60825-1:2007 applied to lasers, laser light barriers or similar with a wavelength range of 180nm to 1 mm.** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| **10.5** | **RISK associated with visible electromagnetic radiation other than emitted by lasers and LEDS, when applicable, addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | MEE does not produce other visible electromagnetic radiation. No RM considered necessary. | **N/A** |
| **10.6** | **RISK associated with infrared radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | Equipment does not produce infrared radiation. No RM considered necessary. | **N/A** |
| **10.7** | **RISK associated with ultraviolet radiation other than emitted by lasers and LEDS addressed in RISK MANAGEMENT PROCESS as indicated in RISK MANAGEMENT FILE..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | Equipment does not produce ultraviolet radiation. No RM considered necessary. | **N/A** |

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| **11** | **PROTECTION AGAINST EXCESSIVE TEMPERATURES AND OTHER HAZARDS** | | **P** |
| **11.1** | **Excessive temperatures in ME EQUIPMENT** | | **P** |
| **11.1.1** | **Temperatures on ME EQUIPMENT parts did not exceed values in Tables 22 and ..... :** | See appended Table 11.1.1 and appended RM Results Table 11.1.1 | **P** |
| | **Surfaces of test corner did not exceed 90 °C** | -- | **P** |
| | **THERMAL CUT-OUTS did not operate in NORMAL CONDITION** | No thermal cut-outs provided. | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | RMF Reference to specific RISK: H2<br>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4) | **P** |
| **11.1.2** | **Temperature of APPLIED PARTS** | | **N/A** |
| **11.1.2.1** | **APPLIED PARTS (hot or cold intended to supply heat to a PATIENT comply..... :** | No APPLIED PARTS provided. | **N/A** |
| | **Clinical effects determined and documented in the RISK MANAGEMENT FILE (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No APPLIED PARTS provided. No RM considered necessary. | **N/A** |
| | **Temperature (hot or cold) of APPLIED PARTS intended to supply heat to a PATIENT disclosed in the instructions for use** | -- | **N/A** |
| **11.1.2.2** | **APPLIED PARTS not intended to supply heat to a PATIENT complies with the limits of Table 24 in NORMAL CONDITION and SINGLE FAULT CONDITION :** | See appended Table 11.1.2.2 and appended RM Results Table 11.1.2.2<br>No applied parts provided. | **N/A** |
| | **APPLIED PARTS surface temperature exceeds 41°C disclosed in the instruction manual:** | -- | **N/A** |
| | **Maximum Temperature ..... :** | -- | **—** |

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| | **Conditions for safe contact, e.g. duration or condition of the PATIENT .....:** | -- | **—** |
| | **Clinical effects with respect to characteristics taken or surface pressure documented in the RISK MANAGEMENT FILE**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No applied parts provided. No RM considered necessary. | **N/A** |
| | **APPLIED PARTS surface temperature of equal to or less than 41°C** | -- | **N/A** |
| | **Analysis documented in the RISK MANAGEMENT FILE show that APPLIED PART temperatures are not affected by operation of the ME EQUIPMENT including SINGLE FAULT CONDITIONS. Measurement of APPLIED PART temperature according to 11.1.3 is not conducted.....:** | -- | **N/A** |
| | **Surfaces of APPLIED PARTS that are cooled below ambient temperatures evaluated in the RISK MANAGEMENT PROCESS.....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No applied parts provided. No RM considered necessary. | **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.....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | Temperature measurement was performed. No heating effect of nearby surfaces. No RM considered necessary. | **P** |
| | **Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No heating effect of nearby surfaces. No RM considered necessary. | **N/A** |
| | **Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | RMF Reference to specific RISKS: H2<br>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4) | **P** |
| | **e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE .....:** | Temperature measurement was performed. | **N/A** |
| **11.1.4** | **GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL** | -- | **N/A** |
| **11.2** | **Fire prevention** | | **P** |
| **11.2.1** | **ENCLOSURE has strength and rigidity necessary to prevent a fire and met mechanical strength tests for ENCLOSURES in 15.3** | See clause 15.3. | **P** |
| **11.2.2** | **Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS** | | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| **11.2.2.1** | **RISK of fire in an OXYGEN RICH ENVIRONMENT reduced by means limiting spread of..... :** | Equipment is not for use in an oxygen rich environment. | **N/A** |
| | **a) No sources of ignition discovered in an OXYGEN RICH ENVIRONMENT under any of the following conditions** | -- | **N/A** |
| | **1) when temperature of material raised to its ignition temperature** | -- | **N/A** |
| | **2) when temperatures affected solder or solder joints causing loosening, short circuiting, or other failures causing sparking or increasing material temperature to its ignition temperature** | -- | **N/A** |
| | **3) when parts affecting safety cracked or changed outer shape exposing temperatures higher than 300°C or sparks due to overheating** | -- | **N/A** |
| | **4) when temperatures of parts or components exceeded 300°C, atmosphere was 100 % oxygen, contact material solder, and fuel cotton** | -- | **N/A** |
| | **5) when sparks provided adequate energy for ignition by exceeding limits of Figs 35 to 37 (inclusive), atmosphere was 100 % oxygen, contact material solder, and fuel cotton** | -- | **N/A** |
| | **Deviations from worst case limits in 4) and 5) above based on lower oxygen concentrations or less flammable fuels justified and documented in RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | MEE is not intended to be used in an oxygen rich environment. No RM considered necessary. | **N/A** |
| | **Alternative test in this clause did not identify existence of ignition sources at highest voltage or current, respectively ..... :** | -- | **N/A** |
| | **A safe upper limit determined by dividing upper limit of voltage or current, respectively, with safety margin factor of three..... :** | -- | **N/A** |
| | **b) RESIDUAL RISK of fire in an OXYGEN RICH ENVIRONMENT as determined by application of RISK MANAGEMENT PROCESS is based on following configurations, or in combination ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | MEE is not intended to be used in an oxygen rich environment. No RM considered necessary. | **N/AA** |
| | **1) Electrical components in an OXYGEN RICH ENVIRONMENT provided with power supplies having limited energy levels lower than those considered sufficient for ignition in 11.2.2.1 a) as determined by examination, measurement or calculation of power, energy, and temperatures in NORMAL and SINGLE FAULT CONDITIONS identified in 11.2.3 ..... :** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **2) Max oxygen concentration measured until it did not exceed 25 % in ventilated compartments with parts that can be a source of ignition only in SINGLE FAULT CONDITION and can be penetrated by oxygen due to an undetected leak (%) .....:** | -- | **N/A** |
| | **3) A compartment with parts or components that can be a source of ignition only under SINGLE FAULT CONDITION separated from another compartment containing an OXYGEN RICH ENVIRONMENT by sealing all joints and holes for cables, shafts, or other purposes** | -- | **N/A** |
| | **Effect of possible leaks and failures under SINGLE FAULT CONDITION that could cause ignition evaluated using a RISK ASSESSMENT to determine maintenance intervals by examination of documentation and RISK MANAGEMENT FILE .....:** | -- | **N/A** |
| | **4) Fire initiated in ENCLOSURE of electrical components in a compartment with OXYGEN RICH ENVIRONMENT that can become a source of ignition only under SINGLE FAULT CONDITIONS self-extinguished rapidly and no hazardous amount of toxic gases reached PATIENT as determined by analysis of gases .....:** | -- | **N/A** |
| **11.2.2.2** | **RISK of ignition did not occur and oxygen concentration did not exceed 25% in immediate surroundings due to location of external exhaust outlets of an OXYGEN RICH ENVIRONMENT** | -- | **N/A** |
| **11.2.2.3** | **Electrical connections within a compartment containing an OXYGEN RICH ENVIRONMENT under NORMAL USE did not produce sparks** | -- | **N/A** |
| | **– Screw-attachments protected against loosening during use by varnishing, use of spring washers, or adequate torques** | -- | **N/A** |
| | **– Soldered, crimped, and pin-and-socket connections of cables exiting ENCLOSURE include additional mechanical securing means** | -- | **N/A** |
| **11.2.3** | **SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered** | | **N/A** |
| | **– Failure of a ventilation system constructed in accordance with 11.2.2.1 b) 2) .....:** | Equipment is not for use in an oxygen rich environment. | **N/A** |
| | **– Failure of a barrier constructed in accordance with 11.2.2.1 b) 3) .....:** | -- | **N/A** |
| | **– Failure of a component creating a source of ignition (as defined in 11.2.2.1 a).....:** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– Failure of solid insulation or creepage and clearances providing equivalent of at least one MEANS OF PATIENT PROTECTION but less than two MEANS OF PATIENT PROTECTION that could create a source of ignition defined in 11.2.2.1 a) ..... :** | -- | **N/A** |
| | **– Failure of a pneumatic component resulting in leakage of oxygen-enriched gas..... :** | -- | **N/A** |
| **11.3** | **Constructional requirements for fire ENCLOSURES of ME EQUIPMENT** | | **P** |
| | **ME EQUIPMENT met this clause for alternate means of compliance with selected HAZARDOUS SITUATIONS and fault conditions in 13.1.2..... :** | Equipment complies with the constructional requirements for fire enclosures.<br>Not applicable for open-frame version (no external enclosure provided). | **N/A** |
| | **Constructional requirements were met, or** | Equipment fulfils the constructional requirements of the standard. | **P** |
| | **- constructional requirements specifically analysed in RISK MANAGEMENT FILE ..... :**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | Equipment complies with the constructional requirements for fire enclosure. No RM considered necessary. | **N/A** |
| | **Justification, when requirement not met ..... :** | -- | **N/A** |
| | **a) Flammability classification of insulated wire within fire ENCLOSURE is FV-1, or better, based on IEC 60695 series as determined by examination of data on materials ..... :** | See appended Table 8.10 | **P** |
| | **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..... :** | All internal materials are rated V-2 or better or are mounted on a PCB rated V-0.<br>See appended Table 8.10. | **P** |
| | **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:** | -- | **P** |
| | **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** | Plastic enclosure provided without openings. | **P** |
| | **2) No openings on the sides within the area included within the inclined line C in Fig 39** | Plastic enclosure provided without openings. | **P** |
| | **3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials ..... :** | Plastic enclosure rated minimum V-1.<br>See appended Table 8.10. | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **11.4** | **ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics** | | **N/A** |
| | **ME EQUIPMENT, ME SYSTEMS and parts described in ACCOMPANYING DOCUMENTS for use with flammable with Annex G** | Equipment is not intended to use in conjunction with flammable agents. | **N/A** |
| **11.5** | **ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents** | | **N/A** |
| | **MANUFACTURER'S RISK MANAGEMENT PROCESS addresses possibility of fire and associated mitigations as confirmed by examination of RISK MANAGEMENT FILE .....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | MEE is not intended to be used in conjunction with flammable agents. No RM considered necessary. | **N/A** |
| **11.6** | **Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT** | | **N/A** |
| **11.6.1** | **Sufficient degree of protection provided against overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection and sterilization, and compatibility with substances used with ME EQUIPMENT ..... :** | -- | **N/A** |
| **11.6.2** | **Overflow in ME EQUIPMENT** | -- | **N/A** |
| | **ME EQUIPMENT incorporates a reservoir or liquid storage that did not wet any MEANS OF PROTECTION, nor result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE.....:** | Equipment does not contain a reservoir or liquid storage chamber. | **N/A** |
| | **Maximum fill level is indicated by marking on the ME EQUIPMENT and a warning or safety notice is given, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber is filled to its maximum capacity and the TRANSPORTABLE ME EQUIPMENT is tilted through an angle of 10°, or for MOBILE ME EQUIPMENT exceeding 45 kg, is moved over a threshold as described in 9.4.2.4.3.** | -- | **N/A** |
| | **No warning or safety notice provided regarding the maximum fill level, no HAZARDOUS SITUATION (as specified in 13.1) or unacceptable RISK due to overflow developed when the reservoir or liquid storage chamber was filled to 15 % above the maximum capacity and the TRANSPORTABLE ME EQUIPMENT was tilted through an angle of 10°, or in MOBILE ME EQUIPMENT exceeding 45 kg, was moved over a threshold as described in 9.4.2.4.3.** | -- | **N/A** |
| **11.6.3** | **Spillage on ME EQUIPMENT and ME SYSTEM** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **ME EQUIPMENT and ME SYSTEMS handling liquids constructed that spillage does not wet parts as determined by review of the RISK MANAGEMENT FILE and test ..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | Equipment does not require handling of liquids in normal or foreseeable misuse. No RM considered necessary. | **N/A** |
| | **RISK ANALYSIS identifies the type of liquid, volume, duration and location of the spill ..... :** | -- | **N/A** |
| **11.6.5** | **Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS** | | **N/A** |
| | **ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :** | MEE classified IPX0. No testing required. | **N/A** |
| | **ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION...:** | -- | **N/A** |
| **11.6.6** | **Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS** | | **N/A** |
| | **ME EQUIPMENT/ME SYSTEM and their parts and ACCESSORIES cleaned or disinfected using methods specified in instructions for use..... :** | Needs to be considered during end medical use. | **N/A** |
| | **Effects of multiple cleanings/disinfections during EXPECTED SERVICE LIFE of EQUIPMENT evaluated by MANUFACTURER ..... :** | -- | **N/A** |
| **11.6.7** | **Sterilization of ME EQUIPMENT and ME SYSTEMS** | | **N/A** |
| | **ME EQUIPMENT, ME SYSTEMS and their parts or ACCESSORIES intended to be sterilized assessed and documented and compliant with tests..... :** | No parts intended to be sterilized. | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of the RISKS associated with any deterioration following sterilization..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No parts subjected to sterilization. No RM considered necessary. | **N/A** |
| **11.6.8** | **RISKS associated with compatibility of substances used with ME EQUIPMENT addressed in RISK MANAGEMENT PROCESS..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No special substances used in conjunction with the equipment. No RM considered necessary. | **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** | No such parts. | **N/A** |
| **11.8** | **Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **12** | **ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS** | | **N/A** |
| **12.1** | **RISKS associated with accuracy of controls and instruments stated .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No controls and instruments provided. No RM considered necessary. | **N/A** |
| **12.2** | **RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING .....:** | No usability required for medical power supply. | **N/A** |
| **12.3** | **MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8. .....:** | No alarm system incorporated. | **N/A** |
| **12.4** | **Protection against hazardous output** | | **N/A** |
| **12.4.1** | **RISKS associated with hazardous output arising from intentional exceeding of safety limits addressed in RISK MANAGEMENT PROCESS .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | -- | **N/A** |
| **12.4.2** | **- need for indication associated with hazardous output addressed in RISK MANAGEMENT PROCESS .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | -- | **N/A** |
| **12.4.3** | **RISKS associated with accidental selection of excessive output values for ME EQUIPMENT with a multi-purpose unit addressed in RISK MANAGEMENT PROCESS .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No multi-purpose equipment. No RM considered necessary. | **N/A** |
| **12.4.4** | **RISKS associated with incorrect output addressed in RISK MANAGEMENT PROCESS .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No incorrect output possible. No RM considered necessary. | **N/A** |
| **12.4.5** | **Diagnostic or therapeutic radiation** | | **N/A** |
| **12.4.5.1** | **Adequate provisions to protect OPERATORS, PATIENTS, other persons and sensitive devices in vicinity of unwanted or excessive radiation** | -- | **N/A** |
| | **Radiation safety ensured by compliance with requirements of appropriate standards** | -- | **N/A** |
| **12.4.5.2** | **ME EQUIPMENT and ME SYSTEMS designed to produce X-radiation for diagnostic imaging purposes complied with IEC 60601-1-3 .....:** | MEE does not produce diagnostic or therapeutic radiation. | **N/A** |
| **12.4.5.3** | **RISKS associated with radiotherapy addressed in RISK MANAGEMENT PROCESS as.....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | MEE does not produce diagnostic or therapeutic radiation. No RM considered necessary. | **N/A** |
| **12.4.5.4** | **RISKS associated with ME EQUIPMENT producing diagnostic or therapeutic radiation other than diagnostic X-rays and radiotherapy addressed in RISK MANAGEMENT PROCESS as.....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | MEE does not produce diagnostic or therapeutic radiation. No RM considered necessary. | **N/A** |

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| **12.4.6** | **RISKS associated with diagnostic or therapeutic acoustic pressure addressed in RISK MANAGEMENT..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | MEE does not produce diagnostic or therapeutic radiation. No RM considered necessary. | **N/A** |
| **13** | **HAZARDOUS SITUATIONS AND FAULT CONDITIONS** | | **P** |
| **13.1** | **Specific HAZARDOUS SITUATIONS** | | **P** |
| **13.1.2** | **Emissions, deformation of ENCLOSURE or exceeding maximum temperature** | | **P** |
| | **– Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur** | No fire, emission of molten metal or ignition of substances was noted during the tests. | **P** |
| | **– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur** | No deformation was noted during the tests. | **P** |
| | **– Temperatures of APPLIED PARTS did not exceed allowable values in Table 24 ..... :** | No applied parts provided. | **N/A** |
| | **– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23..... :** | See appended Tables 13.2 | **P** |
| | **–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded** | Considered. | **P** |
| | **Limits for windings in Tables 26, 27, and 31 not exceeded** | Temperature of transformer windings not exceeded. | **P** |
| | **Table 22 not exceeded in all other cases** | -- | **P** |
| | **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 did not exceed ..... :** | See appended Table 8.7 | **P** |
| | **– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS did not exceed ..... :** | See appended Table 8.7 | **P** |
| **13. 2** | **SINGLE FAULT CONDITIONS** | | **P** |
| **13.2.1** | **During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination** | Considered. | **P** |
| | **ME EQUIPMENT complied with 13.2.2 -13.2.12..... :** | See appended Table 13.2 | **P** |
| | **RISK MANAGEMENT FILE includes and assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....: (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | MEE does not contain liquids. No RM considered necessary. | **N/A** |
| | **RISK MANAGEMENT FILE defines the appropriate test conditions.....:** | MEE does not contain liquids. | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| **13.2.13** | **ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment temperature** | -- | **N/A** |
| | **ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted** | -- | **N/A** |
| | **For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION, the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).** | -- | **N/A** |
| **13.2.13.2** | **ME EQUIPMENT with heating elements** | | **N/A** |
| | **a 1) thermostatically controlled ME EQUIPMENT with heating elements for building-in, r for unattended operation, or with a capacitor not protected by a fuse connected in parallel with THERMOSTAT contacts met tests** | No heating elements provided. | **N/A** |
| | **a 2) ME EQUIPMENT with heating elements RATED for non-CONTINUOUS OPERATION met tests** | -- | **N/A** |
| | **a 3) other ME EQUIPMENT with heating elements met test** | -- | **N/A** |
| | **When more than one test was applicable to same ME EQUIPMENT, tests performed consecutively** | -- | **N/A** |
| | **Heating period stopped when a heating element or an intentionally weak part of a non-SELF-RESETTING THERMAL CUT-OUT ruptured, or current interrupted before THERMAL STABILITY without possibility of automatic restoration** | -- | **N/A** |
| | **Test repeated on a second sample when interruption was due to rupture of a heating element or an intentionally weak part** | -- | **N/A** |
| | **Both samples met 13.1.2, and open circuiting of a heating element or an intentionally weak part in second sample not considered a failure by itself** | -- | **N/A** |
| | **b) ME EQUIPMENT with heating elements without adequate heat discharge, and supply voltage set at 90 or 110 % of RATED supply voltage, least favourable of the two (V).....:** | -- | **N/A** |
| | **Operating period stopped when a non-SELF-RESETTING THERMAL CUT-OUT operated, or current interrupted without possibility of automatic restoration before THERMAL STABILITY** | -- | **N/A** |
| | **ME EQUIPMENT switched off as soon as THERMAL STABILITY established and allowed to cool to room temperature when current not interrupted** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Test duration was equal to RATED operating time for non-CONTINUOUS OPERATION** | -- | **N/A** |
| | **c) Heating parts of ME EQUIPMENT tested with ME EQUIPMENT operated in NORMAL CONDITION at 110 % of RATED supply voltage and as in 11.1, and** | -- | **N/A** |
| | **1) Controls limiting temperature in NORMAL CONDITION disabled, except THERMAL CUT-OUTS** | -- | **N/A** |
| | **2) When more than one control provided, they were disabled in turn** | -- | **N/A** |
| | **3) ME EQUIPMENT operated at RATED DUTY CYCLE until THERMAL STABILITY achieved, regardless of RATED operating time** | -- | **N/A** |
| **13.2.13.3** | **ME EQUIPMENT with motors** | | **N/A** |
| | **a 1) For the motor part of the ME EQUIPMENT, compliance checked by tests of 13.2.8- 13.2.10, 13.2.13.3 b), 13.2.13.3 c), and 13.2.13.4, as applicable** | No motor provided. | **N/A** |
| | **To determine compliance with 13.2.9 and 13.2.10 motors in circuits running at 42.4 V peak a.c./ 60 V d.c. or less are covered with a single layer of cheesecloth which did not ignite during the test** | -- | **N/A** |
| | **a 2) Tests on ME EQUIPMENT containing heating parts conducted at prescribed voltage with motor & heating parts operated simultaneously to produce the least favourable condition** | -- | **N/A** |
| | **a 3) Tests performed consecutively when more tests were applicable to the same ME EQUIPMENT** | -- | **N/A** |
| | **b) Motor met running overload protection test of this clause when:** | -- | **N/A** |
| | **1) it is intended to be remotely or automatically controlled by a single control device with no redundant protection, or** | -- | **N/A** |
| | **2) it is likely to be subjected to CONTINUOUS OPERATION while unattended** | -- | **N/A** |
| | **Motor winding temperature determined during each steady period and maximum value did not exceed Table 27 (Insulation Class, Maximum temperature measured °C) ..... :** | -- | **N/A** |
| | **Motor removed from ME EQUIPMENT and tested separately when load could not be changed in appropriate steps** | -- | **N/A** |
| | **Running overload test for motors operating at 42.4 V peak a.c./60 V d.c. or less performed only when examination and review of design indicated possibility of an overload** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Test not conducted where electronic drive circuits maintained a substantially constant drive current** | -- | **N/A** |
| | **Test not conducted based on other justifications (justification) .....:** | -- | **N/A** |
| | **c) ME EQUIPMENT with 3-phase motors operated with normal load, connected to a 3-phase SUPPLY MAINS with one phase disconnected, and periods of operation per 13.2.10** | -- | **N/A** |
| **13.2.13.4** | **ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION** | | **N/A** |
| | **ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated** | Equipment is designed for continuous operation.<br>No markings provided on the outer side of the equipment. | **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) .....:** | -- | **—** |

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| **14** | **PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)** | | **N/A** |
| **14.1** | **Requirements in 14.2 to 14,12 not applied to PEMS when it provides no functionality necessary for BASIC SAFETY or ESSENTIAL PERFORMANCE, or** | No PEMS. | **N/A** |
| | **- when application of RISK MANAGEMENT showed that failure of PESS does not lead to unacceptable RISK .....:** | -- | **N/A** |
| | **RISK MANAGEMENT FILE contains an assessment of RISKS associated with the failure of the PESS: (ISO 14971 Cl. 4.2-4.4, 5)** | -- | **N/A** |
| | **Requirements of 14.13 not applied to PEMS intended to be incorporated into an IT NETWORK** | -- | **N/A** |
| | **When the requirements of 14.2 to 14.13 apply, the requirements of IEC 62304:2006 clause 4.3, 5, 7, 8 and 9 apply for the development or modification of software of each PESS** | -- | **N/A** |
| | **Software development process for Software Classification applied in accordance with Clause 4.3 of IEC 62304.....:** | -- | **N/A** |
| | **Software development process applied according to Clause 5 of IEC 62304 .....:** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Software development process for Software risk management applied according to Clause 7 of IEC 62304 ..... :** | -- | **N/A** |
| | **Software development process Configuration Management applied according to Clause 8 of IEC 62304..... :** | -- | **N/A** |
| | **Software development process for Software Problem Resolution applied according to Clause 9 of IEC 62304 ..... :** | -- | **N/A** |
| **14.2** | **Documents required by Clause 14 reviewed, approved, issued and revised according to a formal document control process ..... :** | -- | **N/A** |
| **14.3** | **RISK MANAGEMENT plan required by 4.2.2 includes reference to PEMS VALIDATION plan** | -- | **N/A** |
| **14.4** | **A PEMS DEVELOPMENT LIFE-CYCLE including a set of defined milestones has been documented** | -- | **N/A** |
| | **At each milestone, activities to be completed, and VERIFICATION methods to be applied to activities have been defined** | -- | **N/A** |
| | **Each activity including its inputs and outputs defined, and each milestone identifies RISK MANAGEMENT activities that must be completed before that milestone** | -- | **N/A** |
| | **PEMS DEVELOPMENT LIFE-CYCLE tailored for a specific development by making plans detailing activities, milestones, and schedules** | -- | **N/A** |
| | **PEMS DEVELOPMENT LIFE-CYCLE includes documentation requirements** | -- | **N/A** |
| **14.5** | **A documented system for problem resolution within and between all phases and activities of PEMS DEVELOPMENT LIFE-CYCLE has been developed and maintained** | -- | **N/A** |
| **14.6** | **RISK MANAGEMENT PROCESS** | | **N/A** |
| **14.6.1** | **MANUFACTURER considered HAZARDS associated with software and hardware aspects of PEMS including those associated with the incorporating PEMS into an IT-NETWORK, components of third-party origin, legacy subsystems when compiling list of known or foreseeable HAZARDS.....:** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes known or foreseeable HAZARDS associated with software, hardware, incorporation of the PEMS into an IT-NETWORK, components of 3rd party origin and legacy subsystems.....: (ISO 14971 Cl. 4.3)** | No RM considered necessary. | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| **14.6.2** | **Suitably validated tools and PROCEDURES assuring each RISK CONTROL measure reduces identified RISK(S) satisfactorily provided in addition to PEMS requirements in Clause 4.2.2. :** | -- | **N/A** |
| | **RISK MANAGEMENT FILE documents the suitability of tools and procedures to validate each RISK CONTROL measure ..... : (ISO 14971 Cl. 6.1)** | No RM considered necessary. | **N/A** |
| **14.7** | **A documented requirement specification for PEMS and each of its subsystems (e.g. for a PESS) which includes ESSENTIAL PERFORMANCE and RISK CONTROL measures implemented by that system or subsystem..... : (ISO 14971 Cl. 6.3)** | No RM considered necessary. | **N/A** |
| **14.8** | **An architecture satisfying the requirement is specified for PEMS and each of subsystems..... : (ISO 14971 Cl. 6.3)** | No RM considered necessary. | **N/A** |
| **14.9** | **Design is broken up into sub systems and descriptive data on design environment documented..... :** | -- | **N/A** |
| **14.10** | **A VERIFICATION plan containing the specified information used to verify and document functions implementing BASIC SAFETY, ESSENTIAL PERFORMANCE, or RISK CONTROL measures ..... : (ISO 14971 Cl. 6.3)** | No RM considered necessary. | **N/A** |
| | **– milestone(s) when VERIFICATION is to be performed for each function** | -- | **N/A** |
| | **– selection and documentation of VERIFICATION strategies, activities, techniques, and appropriate level of independence of the personnel performing the VERIFICATION** | -- | **N/A** |
| | **– selection and utilization of VERIFICATION tools** | -- | **N/A** |
| | **– coverage criteria for VERIFICATION** | -- | **N/A** |
| | **The VERIFICATION performed according to the VERIFICATION plan and results of the VERIFICATION activities documented** | -- | **N/A** |
| **14.11** | **A PEMS VALIDATION plan containing validation of BASIC SAFETY & ESSENTIAL PERFORMANCE ..... :** | -- | **N/A** |
| | **The PEMS VALIDATION performed according to the PEMS VALIDATION plan with results of PEMS VALIDATION activities and methods used for PEMS VALIDATION documented** | -- | **N/A** |
| | **The person with overall responsibility for PEMS VALIDATION is independent** | -- | **N/A** |

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| | **All professional relationships of members of PEMS VALIDATION team with members of design team documented in RISK MANAGEMENT FILE (ISO 14971 Cl. 6.3)** | No RM considered necessary. | **N/A** |
| **14.12** | **Continued validity of previous design documentation assessed under a documented modification/change PROCEDURE** | -- | **N/A** |
| | **Software Classification for Software changes applied in accordance with Clause 4.3 of IEC 62304..... :** | -- | **N/A** |
| | **Software Process for Software changes applied according to Clause 5 of IEC 62304..... :** | -- | **N/A** |
| | **RISK MANAGEMENT for Software changes applied according to Clause 7 of IEC 62304..... :** | -- | **N/A** |
| | **Configuration management of software changes applied per Clause 8 of IEC 62304 .... :** | -- | **N/A** |
| | **Problem resolution for Software changes applied according to Clause 9 of IEC 62304.... :** | -- | **N/A** |
| **14.13** | **For PEMS incorporated into an IT-NETWORK not VALIDATED by the PEMS MANUFACTURER, instructions made available for implementing the connection include the following..... :** | -- | **N/A** |
| | **a) Purpose of the PEMS connection to an IT-NETWORK** | -- | **N/A** |
| | **b) required characteristics of the IT-NETWORK** | -- | **N/A** |
| | **c) required configuration of the IT-NETWORK** | -- | **N/A** |
| | **d) technical specifications of the network connection, including security specifications** | -- | **N/A** |
| | **e) intended information flow between the PEMS, the IT-NETWORK and other devices on the IT-NETWORK, and the intended routing through the IT-NETWORK** | -- | **N/A** |
| | **f) a list of HAZARDOUS SITUATIONS resulting from failure of the IT-NETWORK to provide the required characteristics (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.3)** | No RM considered necessary. | **N/A** |
| | **ACCOMPANYING DOCUMENTS for the RESPONSIBLE ORGANIZATION include the following:** | | **N/A** |
| | **– statement that connection to IT-NETWORKS including other equipment could result in previously unidentified RISKS TO PATIENTS, OPERATORS or third parties** | -- | **N/A** |
| | **– Notification that the RESPONSIBLE ORGANIZATION should identify, analyse, evaluate and control these RISKS** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– Notification that changes to the IT-NETWORK could introduce new RISKS that require additional analysis** | -- | **N/A** |
| | **- Changes to the IT-NETWORK include:<br>- changes in network configuration<br>- connection of additional items<br>- disconnection of items<br>- update of equipment<br>- upgrade of equipment** | -- | **N/A** |
| **15** | **CONSTRUCTION OF ME EQUIPMENT** | | **P** |
| **15.1** | **RISKS associated with arrangement of controls and indicators of ME EQUIPMENT addressed through the application of a USABILITY ENGINEERING PROCESS .....:** | Only green indicator light provided to indicate power on.<br>No other controls or indicators provided. | **N/A** |
| **15.2** | **Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance** | No such parts provided. | **N/A** |
| | **Inspection, servicing, replacement, and adjustment of parts of ME EQUIPMENT can easily be done without damage to or interference with adjacent parts or wiring** | -- | **N/A** |
| **15.3** | **Mechanical strength** | | **P** |
| **15.3.1** | **Mould stress relief, push, impact, drop, and rough handling tests did not result in loss of BASIC SAFETY or ESSENTIAL PERFORMANCE** | -- | **P** |
| **15.3.2** | **Push test conducted.....:** | See Appended Table 15.3 | **P** |
| | **No damage resulting in an unacceptable RISK sustained** | Equipment does not sustain any damage during testing. | **P** |
| **15.3.3** | **Impact test conducted.....:** | See Appended Table 15.3 | **P** |
| | **No damage resulting in an unacceptable RISK sustained** | Equipment does not sustain any damage during testing. | **P** |
| **15.3.4** | **Drop test** | | **P** |
| **15.3.4.1** | **Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested.....:** | See Appended Table 15.3 | **P** |
| | **No unacceptable RISK resulted** | Equipment does not sustain any damage during testing. | **P** |
| **15.3.4.2** | **Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD withstood stress as demonstrated by test..... :** | See Appended Table 15.3 | **P** |
| | **No damage resulting in an unacceptable RISK sustained** | Equipment does not sustain any damage during testing. | **P** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| **15.3.5** | **MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests..... :** | Equipment is not mobile equipment. | **N/A** |
| | **No damage resulting in an unacceptable RISK sustained** | -- | **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** | -- | **P** |
| | **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..... :** | Duration: 7 hours<br>Test temperature: 94°C | **P** |
| | **No damage resulting in an unacceptable RISK** | Equipment does not sustain any damage during testing. | **P** |
| **15.3.7** | **INTENDED USE, EXPECTED SERVICE LIFE, and conditions for transport and storage were taken into consideration for selection and treatment of materials used in construction of ME EQUIPMENT** | -- | **N/A** |
| | **Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK** | -- | **N/A** |
| **15.4** | **ME EQUIPMENT components and general assembly** | | **N/A** |
| **15.4.1** | **Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists,..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No such connectors provided. No RM considered necessary. | **N/A** |
| | **a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions,..... :** | No patient leads provided. | **N/A** |
| | **b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection ..... :** | No medical gas connections provided. | **N/A** |
| **15.4.2** | **Temperature and overload control devices** | | **P** |
| **15.4.2.1** | **a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION..... : (ISO 14971 Cl. 4.2-4.4, 5)** | No automatic resetting thermal cut-out or over-current release provided. No RM considered necessary. | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT** | Equipment does not use thermal cut-out that is reset by soldering. | **N/A** |
| | **c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided.....: (ISO 14971 Cl. 4.2-4.4)** | No thermostat provided. No RM considered necessary. | **N/A** |
| | **d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE ....: (ISO 14971 Cl. 4.2-4.4)** | No thermal cut-out or over current release provided. No RM considered required. | **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 as verified by following tests** | No thermal cut-out or over current release provided. | **N/A** |
| | **- Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17** | -- | **N/A** |
| | **- ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13.....:** | -- | **P** |
| | **- SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions 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 operated 200 times** | -- | **N/A** |
| | **Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards** | -- | **N/A** |
| | **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 incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating** | No fluid filled container with heating means provided. | **N/A** |
| | **h) ME EQUIPMENT with tubular heating elements provided with protection against overheating.: (ISO 14971 Cl. 4.2-4.4)** | No tubular heating elements provided. No RM considered necessary. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **15.4.2.2** | **Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS** | No thermostats incorporated. | **N/A** |
| **15.4.3** | **Batteries** | | **N/A** |
| **15.4.3.1** | **Battery housings provided with ventilation.... :**<br>**(ISO 14971 Cl. 4.2-4.4)** | Neither batteries nor battery compartments incorporated.<br>No RM considered necessary. | **N/A** |
| | **Battery compartments designed to prevent accidental short circuiting** | -- | **N/A** |
| **15.4.3.2** | **Means provided to prevent incorrect connection of polarity ..... :** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries ..... :**<br>**(ISO 14971 Cl. 4.2-4.4)** | Neither batteries nor battery compartments incorporated.<br>No RM considered necessary. | **N/A** |
| **15.4.3.3** | **Overcharging of battery prevented by virtue of design ..... :** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries..... :**<br>**(ISO 14971 Cl. 4.2-4.4)** | Neither batteries nor battery compartments incorporated.<br>No RM considered necessary. | **N/A** |
| **15.4.3.4** | **Primary lithium batteries comply with IEC 80086-4** | No primary lithium battery used. | **N/A** |
| | **Secondary lithium batteries comply with IEC 62133** | No secondary lithium battery used. | **N/A** |
| **15.4.3.5** | **A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire ..... :** | -- | **N/A** |
| | **Protective device has adequate breaking capacity** | --- | **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** | -- | **N/A** |
| **15.4.4** | **Indicator lights provided to indicate ME EQUIPMENT is ready for ..... :** | Indicator lights provided and complying with clause 7.8.1. | **P** |
| | **An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s,** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational** | No heaters provided. | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters .....: (ISO 14971 Cl. 4.2-4.4)** | No heaters provided. No RM considered necessary. | **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** | -- | **N/A** |
| | **Colours of indicator lights complied with 7.8.1** | Only green indicator light provided to indicate connection to the mains. | **P** |
| | **Charging mode visibly indicated** | No charging mode incorporated. | **N/A** |
| **15.4.5** | **RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS .....:**<br>**(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No pre-set controls provided. No RM considered necessary. | **N/A** |
| **15.4.6** | **Actuating parts of controls of ME EQUIPMENT** | | **N/A** |
| **15.4.6.1** | **a) Actuating parts cannot be pulled off or loosened during NORMAL USE** | -- | **N/A** |
| | **b) Controls secured so that the indication of any scale always corresponds to the position of the control** | -- | **N/A** |
| | **c) Incorrect connection prevented by adequate construction when it could be separated without use of a TOOL** | -- | **N/A** |
| | **When torque values per Table 30 applied knobs did not rotate .....:** | -- | **N/A** |
| | **Tests conducted with no unacceptable RISK ..:** | | **N/A** |
| **15.4.6.2** | **Stops on rotating/ movable parts of controls are of adequate mechanical strength .....:** | -- | **N/A** |
| | **Torque values in Table 30 applied .....:** | -- | **N/A** |
| | **No unexpected change of the controlled parameter when tested.....:** | -- | **N/A** |
| **15.4.7** | **Cord-connected HAND-HELD and foot-operated control devices** | | **N/A** |
| **15.4.7.1** | **a) HAND-HELD control devices of ME EQUIPMENT complied with 15.3.4.1** | See clause 15.3.4.1.<br>No cord-connected hand-held or foot-operated control devices provided. | **N/A** |

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| | **b) Foot-operated control device supported an actuating force of 1350 N in its position of NORMAL USE with no damage ..... :** | -- | **N/A** |
| **15.4.7.2** | **Control device of HAND-HELD and foot-operated control devices turned in all possible abnormal positions and placed on a flat surface ..... :** | -- | **N/A** |
| | **No unacceptable RISK caused by changing control setting when accidentally placed in an abnormal position** | -- | **N/A** |
| **15.4.7.3** | **a) Foot-operated control device is at least rated IPX1** .....: | -- | **N/A** |
| | **b) ENCLOSURE of foot operated control devices containing electrical circuits is at least IPX6.....:** | -- | **N/A** |
| **15.4.8** | **Aluminium wires less than 16 mm$^2$ in cross-sectional area are not used** | -- | **N/A** |
| **15.4.9** | **a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed** | -- | **N/A** |
| | **b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport** | -- | **N/A** |
| | **A pressure-release device operating during NORMAL USE is provided** | -- | **N/A** |
| | **c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage** | -- | **N/A** |
| | **ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements** | -- | **N/A** |
| **15.5** | **MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and transformers providing separation in accordance with 8.5** | | **P** |
| **15.5.1** | **Overheating** | | **P** |
| **15.5.1.1** | **Transformers of ME EQUIPMENT are protected against overheating..... :** | See appended Tables 15.5.1.2 and 15.5.1.3 | **P** |
| | **During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31** | -- | **P** |
| | **Dielectric strength test conducted after short circuit and overload tests ..... :** | Dielectric strength test performed. See appended table 8.8.3. | **P** |
| **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 | **P** |
| | **Short circuit applied directly across output windings** | Short circuit performed on transformer output windings. | **P** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| **15.5.1.3** | **Multiple overload tests conducted on windings .....:** | Overload performed on output to verify transformer overload. | **P** |
| **15.5.2** | **Transformers operating at a frequency above 1kHz tested according to clause 8.8.3 .....:** | Switch mode transformer tested in accordance with clause 8.8.3. | **P** |
| | **Transformer windings provided with adequate insulation** | Switch mode transformer provided. Therefore this test is not applicable. | **N/A** |
| | **Dielectric strength tests were conducted .....:** | Switch mode transformer provided; therefore this test is not applicable.<br>Dielectric strength according to Clause 8.8.3 performed. | **N/A** |
| **15.5.3** | **Transformers forming MEANS OF PROTECTION as required by 8.5 comply with.....:** | See appended Table 8.10<br>Transformer tested within the equipment. | **P** |
| | **- Means provided to prevent displacement of end turns** | Use of margin tape and tubed outlets. | **P** |
| | **- protective earth screens with a single turn have insulated overlap** | -- | **N/A** |
| | **- Exit of wires form internal windings of toroid transformers protected with double sleeving** | No toroid transformer construction. | **N/A** |
| | **- insulation between primary and secondary windings complies with 8.8.2** | Thin sheet material used. | **P** |
| | **- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4** | -- | **P** |

| | | | |
|---|---|---|---|
| **16** | **ME SYSTEMS** | | **N/A** |
| **16.1** | **After installation or subsequent modification, ME SYSTEM didn't result in an unacceptable RISK** | Not electrical medical system. | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of RISKS associated with installation and modification of an ME SYSTEM ..... : (ISO 14971 Cl. 4.2-4.4, 5)** | No RM considered necessary. | **N/A** |
| | **Only HAZARDS arising from combining various equipment to form a ME SYSTEM considered** | -- | **N/A** |
| | **– ME SYSTEM provides the level of safety within the PATIENT ENVIRONMENT equivalent to ME EQUIPMENT complying with this standard** | -- | **N/A** |
| | **– ME SYSTEM provides the level of safety outside PATIENT ENVIRONMENT equivalent to equipment complying with their respective IEC or ISO safety standards** | -- | **N/A** |
| | **– tests performed in NORMAL CONDITION, except as specified** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– tests performed under operating conditions specified by MANUFACTURER of ME SYSTEM** | -- | **N/A** |
| | **Safety tests previously conducted on individual equipment of ME SYSTEM according to relevant standards not repeated** | -- | **N/A** |
| | **RISK MANAGEMENT methods used by MANUFACTURER of an ME SYSTEM reconfigurable by RESPONSIBLE ORGANIZATION or OPERATOR** | -- | **N/A** |
| | **Non-ME EQUIPMENT used in ME SYSTEM complied with applicable IEC or ISO safety standards** | -- | **N/A** |
| | **Equipment relying only on BASIC INSULATION for protection against electric shock not used in ME SYSTEM** | -- | **N/A** |
| **16.2** | **ACCOMPANYING DOCUMENTS of an ME SYSTEM** | | **N/A** |
| | **Documents containing all data necessary for ME SYSTEM to be used as intended by MANUFACTURER including a contact address accompany ME SYSTEM or modified ME SYSTEM** | -- | **N/A** |
| | **ACCOMPANYING DOCUMENTS regarded as a part of ME SYSTEM** | -- | **N/A** |
| | **a) ACCOMPANYING DOCUMENTS provided for each item of ME EQUIPMENT supplied by MANUFACTURER** | -- | **N/A** |
| | **b) ACCOMPANYING DOCUMENTS provided for each item of non-ME EQUIPMENT supplied by MANUFACTURER** | -- | **N/A** |
| | **c) the required information is provided:** | -- | **N/A** |
| | **– specifications, instructions for use as intended by MANUFACTURER, and a list of all items forming the ME SYSTEM** | -- | **N/A** |
| | **– instructions for installation, assembly, and modification of ME SYSTEM to ensure continued compliance with this standard** | -- | **N/A** |
| | **– instructions for cleaning and, when applicable, disinfecting and sterilizing each item of equipment or equipment part forming part of the ME SYSTEM** | -- | **N/A** |
| | **– additional safety measures to be applied during installation of ME SYSTEM** | -- | **N/A** |
| | **– identification of parts of ME SYSTEM suitable for use within the PATIENT ENVIRONMENT** | -- | **N/A** |
| | **– additional measures to be applied during preventive maintenance** | -- | **N/A** |
| | **– a warning forbidding placement of MULTIPLE SOCKET-OUTLET, when provided and it is a separate item, on the floor** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– a warning indicating an additional MULTIPLE SOCKET-OUTLET or extension cord not to be connected to ME SYSTEM** | -- | **N/A** |
| | **– a warning to connect only items that have been specified as part of ME SYSTEM or specified as being compatible with ME SYSTEM** | -- | **N/A** |
| | **– maximum permissible load for any MULTIPLE SOCKET-OUTLET(S) used with ME SYSTEM** | -- | **N/A** |
| | **– instructions indicating MULTIPLE SOCKET-OUTLETS provided with the ME SYSTEM to be used only for supplying power to equipment intended to form part of ME SYSTEM** | -- | **N/A** |
| | **– an explanation indicating RISKS of connecting non-ME EQUIPMENT supplied as a part of ME SYSTEM directly to wall outlet when non-ME EQUIPMENT is intended to be supplied via a MULTIPLE SOCKET-OUTLET with a separating transformer** | -- | **N/A** |
| | **– an explanation indicating RISKS of connecting any equipment supplied as a part of ME SYSTEM to MULTIPLE SOCKET-OUTLET** | -- | **N/A** |
| | **– permissible environmental conditions of use for ME SYSTEM including conditions for transport and storage** | -- | **N/A** |
| | **– instructions to OPERATOR not to, simultaneously, touch parts referred to in 16.4 and PATIENT** | -- | **N/A** |
| | **d) the following instructions provided for use by RESPONSIBLE ORGANIZATION:** | -- | **N/A** |
| | **– adjustment, cleaning, sterilization, and disinfection PROCEDURES** | -- | **N/A** |
| | **– assembly of ME SYSTEMS and modifications during actual service life shall be evaluated based on the requirements of this standard** | -- | **N/A** |
| **16.3** | **Instructions for use of ME EQUIPMENT intended to receive its power from other equipment in an ME SYSTEM, describe the other equipment to ensure compliance with these requirements** | -- | **N/A** |
| | **Transient currents restricted to allowable levels for the specified IPS or UPS .....:** | -- | **N/A** |
| | **Technical description and installation instructions specify the actual transient currents where an IPS or UPS is not specified** | -- | **N/A** |

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| Clause | Requirement + Test | Result - Remark | Verdict |
| **16.4** | **Parts of non-ME EQUIPMENT in PATIENT ENVIRONMENT subject to contact by OPERATOR during maintenance, calibration, after removal of covers, connectors operated at a voltage ≤ voltage in 8.4.2 c)** | -- | **N/A** |
| **16.5** | **Safety measures incorporating a SEPARATION DEVICE applied when FUNCTIONAL CONNECTION between ME EQUIPMENT and other items of an ME SYSTEM or other systems can cause allowable values of LEAKAGE CURRENT to exceed** | -- | **N/A** |
| | **SEPARATION DEVICE has dielectric strength, CREEPAGE and CLEARANCES required for one MEANS OF OPERATOR PROTECTION** | -- | **N/A** |
| | **WORKING VOLTAGE was highest voltage across SEPARATION DEVICE during a fault condition, but not less than MAXIMUM MAINS VOLTAGE (V)..... :** | -- | **N/A** |
| **16.6** | **LEAKAGE CURRENTS** | | **N/A** |
| **16.6.1** | **TOUCH CURRENT in NORMAL CONDITION did not exceed 100 µA..... :** | -- | **N/A** |
| | **TOUCH CURRENT did not exceed 500 µA in event of interruption of any non-PERMANENTLY INSTALLED PROTECTIVE EARTH CONDUCTOR..... :** | -- | **N/A** |
| **16.6.2** | **Current in PROTECTIVE EARTH CONDUCTOR of MULTIPLE SOCKET-OUTLET didn't exceed 5 mA.... :** | -- | **N/A** |
| **16.6.3** | **PATIENT LEAKAGE CURRENT and total PATIENT LEAKAGE CURRENT of ME SYSTEM in NORMAL CONDITION did not exceed values ..... :** | -- | **N/A** |
| **16.7** | **ME SYSTEM complied with applicable requirements of Clause 9..... :** | -- | **N/A** |
| **16.8** | **Interruption and restoration power to the ME SYSTEM or any part of the ME SYSTEM did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE** | -- | **N/A** |
| **16.9** | **ME SYSTEM connections and wiring** | | **N/A** |
| **16.9.1** | **Incorrect connection of accessible connectors, removable without a TOOL, prevented where unacceptable RISK can result..... :** | -- | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of RISKS associated with plugs for connection of PATIENT leads or cables likely to be located in the PATIENT ENVIRONMENT..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | No RM considered necessary. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– Plugs for connection of PATIENT leads or PATIENT cables could not be connected to other outlets of the same ME SYSTEM likely to be located in PATIENT ENVIRONMENT, except when examination of connectors and interchanging them proved no unacceptable RISK results** | -- | **N/A** |
| | **Medical gas connections on the ME SYSTEM for different gasses operated in NORMAL USE are not interchangeable** | -- | **N/A** |
| **16.9.2** | **MAINS PARTS, components and layout** | | **N/A** |
| **16.9.2.1** | **a) – MULTIPLE SOCKET-OUTLET only allows connection using a TOOL, or** | -- | **N/A** |
| | **– MULTIPLE SOCKET-OUTLET is of a type that cannot accept MAINS PLUGS of any of the kinds specified in IEC/TR 60083, or** | -- | **N/A** |
| | **– MULTIPLE SOCKET-OUTLET is supplied via a separating transformer** | -- | **N/A** |
| | **b) – MULTIPLE SOCKET-OUTLET marked with safety sign 2 of Table D.2 visible in NORMAL USE, and** | -- | **N/A** |
| | **– marked either individually or in combinations, with the maximum allowed continuous output in amperes or volt-amperes, or** | -- | **N/A** |
| | **– marked to indicate the equipment or equipment parts it may safely be attached to** | -- | **N/A** |
| | **– MULTIPLE SOCKET-OUTLET is a separate item or an integral part of ME EQUIPMENT or non-ME EQUIPMENT** | -- | **N/A** |
| | **c) MULTIPLE SOCKET-OUTLET complied with IEC 60884-1 and the following requirements:** | -- | **N/A** |
| | **– CREEPAGE and CLEARANCES complied with 8.9** | -- | **N/A** |
| | **– It is CLASS I, and PROTECTIVE EARTH CONDUCTOR is connected to earthing contacts in socket-outlets** | -- | **N/A** |
| | **– PROTECTIVE EARTH TERMINALS and PROTECTIVE EARTH CONNECTIONS comply with 8.6:** | -- | **N/A** |
| | **– ENCLOSURE complied with 8.4.2 d)** | -- | **N/A** |
| | **– MAINS TERMINAL DEVICES and wiring complied with 8.11.4, when applicable** | -- | **N/A** |
| | **– RATINGS of components are not in conflict with conditions of use .....:** | -- | **N/A** |
| | **– Electrical terminals and connectors of MULTIPLE SOCKET-OUTLETS prevent incorrect connection of accessible connectors removable without a TOOL** | -- | **N/A** |
| | **– POWER SUPPLY CORD complied with 8.11.3** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **d) Additional requirements applied when MULTIPLE SOCKET-OUTLET combined with a separating transformer:** | -- | **N/A** |
| | **– Separating transformer complied with this standard or IEC 61558-2-1, ..... :** | -- | **N/A** |
| | **– Separating transformer is CLASS I** | -- | **N/A** |
| | **– Degree of protection against ingress of water specified as in IEC 60529** | -- | **N/A** |
| | **– Separating transformer assembly marked according to 7.2 and 7.3** | -- | **N/A** |
| | **– MULTIPLE SOCKET-OUTLET permanently connected to separating transformer, or socket-outlet of separating transformer assembly cannot accept MAINS PLUGS as identified in IEC/TR 60083** | -- | **N/A** |
| **16.9.2.2** | **The impedance between the protective earth pin in the MAINS PLUG and any part that is PROTECTIVELY EARTHED did not exceed 200 mΩ** | -- | **N/A** |
| | **Removal of any single item of equipment in ME SYSTEM will not interrupt the protective earthing of any other part without simultaneous disconnection of electrical supply to that part** | -- | **N/A** |
| | **Additional PROTECTIVE EARTH CONDUCTORS can be detachable only by use of a TOOL** | -- | **N/A** |
| **16.9.2.3** | **Conductors connecting different items within an ME SYSTEM protected against mechanical damage** | -- | **N/A** |

| | | | |
|---|---|---|---|
| **17** | **ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS** | | **P** |
| | **RISKS associated confirmed by review..... :** | -- | **P** |
| | **– electromagnetic phenomena at locations where ME EQUIPMENT or ME SYSTEM is to be used as stated in ACCOMPANYING DOCUMENTS ..... :** | Shall be evaluated during end medical use. | **N/A** |
| | **RISK MANAGEMENT FILE includes an assessment of risks associated with the introduction of electromagnetic phenomena into the environment by the EQUIPMENT or SYSTEM..... : (ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.5)** | RMF Reference to specific RISKS: M1<br>(ISO 14971 Cl. 4.2-4.4, 5, 6.2-6.4) | **P** |
| | **– introduction of electromagnetic phenomena into environment by ME EQUIPMENT or ME SYSTEM that might degrade performance of other devices, electrical equipment, and systems** | Shall be evaluated during end medical use. | **N/A** |

| | | |
|---|---|---|
| **ANNEX G** | **PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES** | **N/A** |

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **G.2** | **Locations and basic requirements** | | **N/A** |
| **G.2.1** | **Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR occurs are CATEGORY AP or APG ME EQUIPMENT and complied with G.3, G.4, and G.5** | -- | **N/A** |
| **G.2.2** | **FLAMMABLE AESTHETIC MIXTURE WITH** | -- | **N/A** |
| **G.2.3** | **A FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN or NITROUS OXIDE** | -- | **N/A** |
| **G.2.4** | **ME EQUIPMENT specified for use with FLAMMABLE AESTHETIC MIXTURE WITH AIR complied with G.4 and G.5** | -- | **N/A** |
| **G.2.5** | **ME EQUIPMENT or parts thereof for use with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE comply with G.4 and G.6** | -- | **N/A** |
| | **ME EQUIPMENT in G.2.4 to G.2.5 met appropriate tests of G.3-G.5 conducted after tests of 11.6.6 and 11.6.7** | -- | **N/A** |
| **G.3** | **Marking, ACCOMPANYING DOCUMENTS** | | **N/A** |
| **G.3.1** | **CATEGORY APG ME EQUIPMENT prominently marked "APG" (symbol 23 in Table D.1) .....:** | -- | **N/A** |
| | **Length of green-coloured band is ≥ 4 cm, and size of marking is as large as possible for particular case** | -- | **N/A** |
| | **When above marking not possible, relevant information included in instructions for use ...:** | -- | **N/A** |
| | **Marking complied with tests and criteria of 7.1.2 and 7.1.3** | -- | **N/A** |
| **G.3.2** | **CATEGORY AP ME EQUIPMENT prominently marked, with a green-coloured circle "AP" (symbol 22 in Table D.1) .....:** | -- | **N/A** |
| | **Marking is as large as possible for the particular case** | -- | **N/A** |
| | **When above marking not possible, the relevant information included in instructions for use ...:** | -- | **N/A** |
| | **Marking complied with tests and criteria of 7.1.2 and 7.1.3** | -- | **N/A** |
| **G.3.3** | **The marking placed on major part of ME EQUIPMENT for CATEGORY AP or APG parts** | -- | **N/A** |
| **G.3.4** | **ACCOMPANYING DOCUMENTS contain an indication enabling the RESPONSIBLE ORGANIZATION to distinguish between CATEGORY AP and APG parts** | -- | **N/A** |
| **G.3.5** | **Marking clearly indicates which parts are CATEGORY AP or APG when only certain ME EQUIPMENT parts are CATEGORY AP or APG** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **G.4** | **Common requirements for CATEGORY AP and CATEGORY APG ME EQUIPMENT** | | **N/A** |
| **G.4.1** | **a) CREEPAGE and CLEARANCES are according to Table 12 for one MEANS OF PATIENT PROTECTION** | -- | **N/A** |
| | **b) Connections protected against accidental disconnection** | -- | **N/A** |
| | **c) CATEGORY AP and APG not provided with a DETACHABLE POWER SUPPLY CORD,** | -- | **N/A** |
| **G.4.2** | **Construction details** | | **N/A** |
| | **a) Opening of an ENCLOSURE protecting against penetration of gases or vapours into ME EQUIPMENT or its parts possible only with a TOOL** | -- | **N/A** |
| | **b) ENCLOSURE complies with..... :** | -- | **N/A** |
| | **– no openings on top covers of ENCLOSURE,** | -- | **N/A** |
| | **– openings in side-covers prevented penetration of a solid cylindrical test rod** | -- | **N/A** |
| | **– openings in base plates prevented penetration of a solid cylindrical test** | -- | **N/A** |
| | **c) Short circuiting conductor(s) to a conductive part (when no explosive gasses) did not result in loss of integrity of the part, an unacceptable temperature, or any HAZARDOUS SITUATION** | -- | **N/A** |
| **G.4.3** | **a) Electrostatic charges prevented on CATEGORY AP and APG ME EQUIPMENT by a combination of appropriate measures** | -- | **N/A** |
| | **– Use of antistatic materials with a limited electrical resistance ..... :** | -- | **N/A** |
| | **– Provision of electrically conductive paths from ME EQUIPMENT or its parts to a conductive floor, protective earth or potential equalization system, or via wheels to an antistatic floor** | -- | **N/A** |
| | **b) Electrical resistance limits of aesthetic tubing, mattresses/ pads, castor tires & other antistatic material comply with ISO 2882..... :** | -- | **N/A** |
| **G.4.4** | **Corona cannot be produced by components or parts of ME EQUIPMENT operating at more than 2000 V a.c. or 2400 V d.c. and not included in ENCLOSURES complying with G.5.4 or G.5.5** | -- | **N/A** |
| **G.5** | **Requirements and tests for CATEGORY AP ME EQUIPMENT, parts and components** | | **N/A** |
| **G.5.1** | **ME EQUIPMENT, its parts or components do not ignite FLAMMABLE AESTHETIC MIXTURES WITH AIR under NORMAL USE and CONDITIONS based on compliance with G.5.2 to G.5.5** | -- | **N/A** |

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Alternatively, ME EQUIPMENT, its parts, and components complied with requirements of IEC 60079-0 for pressurized ENCLOSURES (IEC 60079-2); for sand-filled ENCLOSURES, IEC 60079-5; or for oil immersed equipment, IEC 60079-6; and with this standard excluding G.5.2 to G.5.5 .....:** | -- | **N/A** |
| **G.5.2** | **Temperature limits .....:** | -- | **N/A** |
| **G.5.3** | **ME EQUIPMENT, its parts, and components producing sparks in NORMAL USE and CONDITION complied with temperature requirements of G.5.2, and $U_{max}$ and $I_{max}$ occurring in their circuits, and complied as follows:** | -- | **N/A** |
| | **Measured $U_{max} \leq U_{zR}$ with $I_{zR}$ as in Fig. G.1 .....:** | -- | **N/A** |
| | **Measured $U_{max} \leq U_c$ with $C_{max}$ as in Fig. G.2 ....:** | -- | **N/A** |
| | **Measured $I_{max} \leq I_{zR}$ with $U_{zR}$ as in Fig G.1 .....:** | -- | **N/A** |
| | **Measured $I_{max} \leq I_{zL}$ with $L_{max}$ and a $U_{max} \leq 24$ V as in Fig G.3 .....:** | -- | **N/A** |
| | **– Combinations of currents and corresponding voltages within the limitations IzR.UzR ≤ 50 W extrapolated from Fig G.1** | -- | **N/A** |
| | **No extrapolation made for voltages above 42 V** | -- | **N/A** |
| | **– Combinations of capacitances and corresponding voltages within limitations of $C/2U^2 \leq 1.2$ mJ extrapolated from Fig G.2** | -- | **N/A** |
| | **No extrapolation made for voltages above 242V** | -- | **N/A** |
| | **$U_{max}$ determined using actual resistance R** | -- | **N/A** |
| | **– Combinations of currents and corresponding inductances within limitations $L/2I^2 \leq 0.3$ mJ extrapolated from Fig G.3** | -- | **N/A** |
| | **No extrapolation made for inductances larger than 900 mH** | -- | **N/A** |
| | **– $U_{max}$ was the highest supply voltage occurring in circuit under investigation with sparking contact open** | -- | **N/A** |
| | **– $I_{max}$ was the highest current flowing in circuit under investigation with sparking contact closed** | -- | **N/A** |
| | **– $C_{max}$ and $L_{max}$ taken as values occurring at the component under investigation producing sparks** | -- | **N/A** |
| | **– Peak value considered when a.c. supplied** | -- | **N/A** |
| | **– An equivalent circuit calculated to determine equivalent max capacitance, inductance, and equivalent $U_{max}$ and $I_{max}$, either as d.c. or a.c. peak values in case of a complicated circuit ...:** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Temperature measurements made according to 11.1, and $U_{max}$, $I_{max}$, R, $L_{max}$ , and $C_{max}$ determined with application of Figs G.1-G.3 .. :** | -- | **N/A** |
| | **Alternatively, compliance was verified by examination of design data .....:** | -- | **N/A** |
| **G.5.4** | **External ventilation with internal overpressure** | | **N/A** |
| | **ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with external ventilation by means of internal overpressure complied with the following requirements:** | -- | **N/A** |
| | **a) FLAMMABLE AESTHETIC MIXTURES WITH AIR t removed by ventilation before EQUIPMENT energized,** | -- | **N/A** |
| | **b) Overpressure inside ENCLOSURE was 75 Pa, min., in NORMAL CONDITION (Pa)..... :** | -- | **N/A** |
| | **Overpressure maintained at the site of potential ignition** | -- | **N/A** |
| | **ME EQUIPMENT could be energized only after the required minimum overpressure was present long enough to ventilate the ENCLOSURE** | -- | **N/A** |
| | **ME EQUIPMENT energized at will or repeatedly when overpressure was continuously present** | -- | **N/A** |
| | **c) Ignition sources de-energized automatically when during operation overpressure dropped below 50 Pa (Pa) ..... :** | -- | **N/A** |
| | **d) External surface of ENCLOSURE did not exceed 150 °C in 25 °C ..... :** | -- | **N/A** |
| **G.5.5** | **ENCLOSURES with restricted breathing** | | **N/A** |
| | **ME EQUIPMENT, its parts, and components enclosed in an ENCLOSURE with restricted breathing complied with the following:** | -- | **N/A** |
| | **a) A FLAMMABLE AESTHETIC MIXTURE WITH AIR did not form inside ENCLOSURE with restricted breathing** | -- | **N/A** |
| | **b) Gasket or sealing material used to maintain tightness complied with aging test B-b of IEC 60068-2-2, Clause 15, at 70 °C ± 2 °C and 96 h :** | -- | **N/A** |
| | **c) Gas-tightness of ENCLOSURE containing inlets for flexible cords maintained** | -- | **N/A** |
| | **Cords are fitted with adequate anchorages to limit stresses as determined by test** | -- | **N/A** |
| | **Overpressure not reduced below 200 Pa** | -- | **N/A** |
| | **Tests waived when examination of ENCLOSURE indicated it is completely sealed or gas-tight without a doubt (100 % degree of certainty)** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Operating temperature of external surface of ENCLOSURE was ≤ 150 °C in 25 °C (°C).....:** | -- | **N/A** |
| | **Steady state operating temperature of ENCLOSURE also measured (°C).....:** | -- | **N/A** |
| **G.6** | **CATEGORY APG ME EQUIPMENT, parts and components thereof** | | **N/A** |
| **G.6.1** | **ME EQUIPMENT, its parts, and components did not ignite FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE under NORMAL USE and SINGLE FAULT CONDITION** | -- | **N/A** |
| | **ME EQUIPMENT, its parts, and components not complying with G.6.3 subjected to a CONTINUOUS OPERATION test** | -- | **N/A** |
| **G.6.2** | **Parts and components of CATEGORY APG ME EQUIPMENT operating in a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE supplied from a source isolated from earth by insulation equal to one MEANS OF PATIENT PROTECTION and from electrical parts by insulation twice the MEANS OF PATIENT PROTECTION .....:** | -- | **N/A** |
| **G.6.3** | **Test of G.6.1 waived when the following requirements were met in NORMAL USE and under NORMAL and SINGLE FAULT CONDITIONS .....:** | -- | **N/A** |
| | **a) no sparks produced and temperatures did not exceed 90 °C, or** | -- | **N/A** |
| | **b) a temperature limit of 90 °C not exceeded, sparks produced in NORMAL USE, and SINGLE FAULT CONDITIONS, except $U_{max}$ and $I_{max}$ occurring in their circuits complied with requirements, taking $C_{max}$ and $L_{max}$ into consideration:** | -- | **N/A** |
| | **Measured $U_{max} \leq U_{zR}$ with $I_{zR}$ as in Fig. G.4 .....:** | -- | **N/A** |
| | **Measured $U_{max} \leq U_{zC}$ with $C_{max}$ as in Fig. G.5 ...:** | -- | **N/A** |
| | **Measured $I_{max} \leq I_{zR}$ with $U_{zR}$ as in Fig G.4 .....:** | -- | **N/A** |
| | **Measured $I_{max} \leq I_{zL}$ with $L_{max}$ and a $U_{max} \leq 24$ V as in Fig G.6 .....:** | -- | **N/A** |
| | **– Extrapolation from Figs G.4, G.5, and G.6 was limited to areas indicated** | -- | **N/A** |
| | **– $U_{max}$ was the highest no-load voltage occurring in the circuit under investigation, taking into consideration mains voltage variations as in 4.10** | -- | **N/A** |
| | **– $I_{max}$ was the highest current flowing in the circuit under investigation, taking into account MAINS VOLTAGE variations as in 4.10** | -- | **N/A** |
| | **– $C_{max}$ and $L_{max}$ are values occurring in relevant circuit** | -- | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– $U_{max}$ additionally determined with actual resistance R when equivalent resistance R in Fig G.5 was less than 8000 Ω** | -- | **N/A** |
| | **– Peak value considered when a.c. supplied** | -- | **N/A** |
| | **– An equivalent circuit calculated to determine max capacitance, inductance, and $U_{max}$ and $I_{max}$, either as d.c. or a.c. peak values in case of a complicated circuit ..... :** | -- | **N/A** |
| | **– When energy produced in an inductance or capacitance in a circuit is limited by voltage or current-limiting devices, two independent components applied, to obtain the required limitation even when a first fault (short or open circuit) in one of these components** | -- | **N/A** |
| | **- requirement not applied to transformers complying with this standard** | -- | **N/A** |
| | **- requirement not applied to wire-wound current-limiting resistors provided with a protection against unwinding of the wire in case of rupture** | -- | **N/A** |
| | **Compliance verified by examination of CATEGORY APG ME EQUIPMENT, parts, and components , or** | -- | **N/A** |
| | **Temperature measurements made in accordance with 11.1 ..... :** | -- | **N/A** |
| | **- or $U_{max}$, $I_{max}$, R, $L_{max}$ and $C_{max}$ determined together with application of Figs G.4-G.6 ..... :** | -- | **N/A** |
| | **Alternatively, compliance verified by comparison with design data.....:** | -- | **N/A** |
| **G.6.4** | **ME EQUIPMENT, its parts, and components heating a FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE provided with a non-SELF-RESETTING THERMAL CUT-OUT and complied with 15.4.2.1..... :** | -- | **N/A** |
| | **Current-carrying part of heating element is not in direct contact with FLAMMABLE AESTHETIC MIXTURE WITH OXYGEN OR NITROUS OXIDE** | -- | **N/A** |
| **G.7** | **Test apparatus for flammable mixtures according to this Clause and Fig G.7** | -- | **N/A** |

| | | | |
|---|---|---|---|
| **ANNEX L** | **INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION** | | **N/A** |
| **L.1** | **BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex** | No TIW incorporated within the transformer. | **N/A** |
| **L.2** | **Wire construction** | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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** |
| | **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 with no breakdown:** | -- | **N/A** |
| | **– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V) .....:** | -- | **N/A** |
| | **– 6000 V for REINFORCED INSULATION (V).....:** | -- | **N/A** |
| **L.3.2** | **Flexibility and adherence** | | **N/A** |
| | **Sample subjected to flexibility and adherence** | -- | **N/A** |
| | **Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown** | -- | **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** |
| | **Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa .....:** | -- | **N/A** |
| **L.3.3** | **Heat Shock** | | **N/A** |
| | **Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3** | -- | **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) .....:** | -- | **—** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm$^2$) ..... :** | -- | **N/A** |
| | **Dielectric strength test conducted at room temperature after removal from the oven** | -- | **N/A** |
| **L.3.4** | **Retention of electric strength after bending** | | **N/A** |
| | **Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests** | -- | **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 done by the manufacture per L.4.2 and L.4.3.....:** | -- | **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).....:** | -- | **N/A** |
| | **– 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) .....:** | -- | **N/A** |
| **L.4.3** | **Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1).....:** | -- | **N/A** |
| | **Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than:** | -- | **N/A** |
| | **– 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION ..... :** | -- | **N/A** |
| | **– 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION ..... :** | -- | **N/A** |

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

| 4.2.2 | RM RESULTS TABLE: General requirements for RISK MANAGEMENT | | | P |
|---|---|---|---|---|
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. paragraph/clause, version)** | | **Result - Remarks** | **Verdict** |
| | **General process** | **Particular Medical Device** | | |
| **3.1** | **GTQPR05000; 2016.12.22; cl. 6.1** | — | Risk Management Process (excluding production and post-production) | **P** |
| **3.2** | **GTQPR05000; 2016.12.22; cl. 4** | — | Adequate Resources | **P** |
| **3.2** | **GTQPR05000; 2016.12.22; cl. 4** | — | Assignment of qualified personnel | **P** |
| **3.2** | **GTQPR05000; 2016.12.22; cl. 5** | — | Policy for determining criteria for risk acceptability | **P** |
| **3.3** | — | **GTQPR05000; 2016.12.22; cl. 4** | Qualification of personnel | **P** |
| **3.4a** | — | **GTQPR05000; 2016.12.22; cl. 6.1** | Document name : Attachment B: Risk Management Plan for Device GTM41060 | **P** |
| **3.4b** | — | **GTQPR05000; 2016.12.22; cl. 6.1** | Document name : Attachment B: Risk Management Plan for Device GTM41060 | **P** |
| **3.4c** | — | **GTQPR05000; 2016.12.22; cl. 6.1** | Document name : Attachment B: Risk Management Plan for Device GTM41060 | **P** |
| **3.4d** | — | **GTQPR05000; 2016.12.22; cl. 6.1** | Document name : Attachment B: Risk Management Plan for Device GTM41060 | **P** |
| **3.4e** | — | **GTQPR05000; 2016.12.22; cl. 6.1** | Document name : Attachment B: Risk Management Plan for Device GTM41060 | **P** |
| **3.5** | — | **GTQPR05000; 2016.12.22; cl. 4** | Document name :<br>Risk Management Report; GT-RM2013-008 contains all relevant attachments:<br>Attachment A: ISO 14971 Gap Analysis Checklist<br>Attachment B: Risk Management Plan for Device GTM 41060<br>Attachment C: Risk Management Procedure | **P** |

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

| 4.2.2 | RM RESULTS TABLE: General requirements for RISK MANAGEMENT | | | P |
|---|---|---|---|---|
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. paragraph/clause, version)** | | **Result - Remarks** | **Verdict** |
| | **General process** | **Particular Medical Device** | | |
| **4.1** | — | **GTQPR05000; 2016.12.22; cl. 6** | Risk analysis performed for particular medical device.<br>A description and identification that was analysed is stated.<br>Identification of the person(s) and organization that carried out the risk analysis is stated.<br>The scope and date of risk analysis is stated.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **4.2** | — | **GTQPR05000; 2016.12.22; cl. 6** | Intended use and identification of characteristics related to safety stated.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **4.3** | — | **GTQPR05000; 2016.12.22; cl. 6** | Identification of hazards conducted during risk analysis.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **4.4** | — | **GTQPR05000; 2016.12.22; cl. 6** | Estimation of risk conducted during risk analysis.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **5** | — | **GTQPR05000; 2016.12.22; cl. 6** | Risk evaluation conducted during risk analysis.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **6.2** | — | **GTQPR05000; 2016.12.22; cl. 6.2.3 - 6.2.5** | Risk reduction conducted during risk analysis.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **6.3** | — | **GTQPR05000; 2016.12.22; cl. 6.1** | Implementation of risk control measure(s) conducted during risk analysis.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **6.4** | — | **GTQPR05000; 2016.12.22; cl. 6.2.6** | Residual risk evaluation conducted during risk analysis.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |

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

| 4.2.2 | RM RESULTS TABLE: General requirements for RISK MANAGEMENT | | | P |
|---|---|---|---|---|
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. paragraph/clause, version)** | | **Result - Remarks** | **Verdict** |
| | **General process** | **Particular Medical Device** | | |
| **6.5** | — | **GTQPR05000; 2016.12.22; cl. 6.2.5** | No Risk/benefit analysis required.<br>The residual risk was acceptable.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **6.6a** | — | **GTQPR05000; 2016.12.22; cl. 6** | There were no new risks identified after implementation of risk-reducing measures.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **6.6b** | — | **GTQPR05000; 2016.12.22; cl. 6** | Previously identified hazardous situations were not affected by the introduction of risk control measures.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **6.7** | — | **GTQPR05000; 2016.12.22; cl. 6** | Completeness of risk control conducted during risk analysis.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **7** | — | **GTQPR05000; 2016.12.22; cl. 6.2.6** | Evaluation of overall risk acceptability conducted.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **8** | — | **GTQPR05000; 2016.12.22; cl. 6** | A risk management report was prepared by the manufacturer.<br>Document name : Risk Management Report; GT-RM2013-008 | **P** |
| **Supplementary Information:**<br>**Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.**<br>**(Revision No. 4.0)** | | | | |

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

| 4.3 | TABLE: ESSENTIAL PERFORMANCE | N/A |
|---|---|---|
| **List of ESSENTIAL PERFORMANCE functions** | **MANUFACTURER'S document number reference or reference from this standard or collateral or particular standard(s)** | **Remarks** |
| | | |

**Supplementary Information:**

ESSENTIAL PERFORMANCE is performance, the absence or degradation of which, would result in an unacceptable risk.

Essential performance not defined for power supply unit. End product consideration.

| 4.11 | TABLE: Power Input | | | | P |
|---|---|---|---|---|---|
| **Operating Conditions / Ratings** | **Voltage (V)** | **Frequency (Hz)** | **Current (A)** | **Power (W or VA)** | **Power factor (cos φ)** |
| **Model: GTM41060-1505** | | | | | |
| **Rated load** | **90,0** | **60** | **0,423** | **19,95** | **See 1)** |
| **Rated load** | **100,0** | **60** | **0,400** | **19,85** | **Ditto.** |
| **Rated load** | **110,0** | **60** | **0,381** | **19,75** | **Ditto.** |
| **Rated load** | **120,0** | **60** | **0,356** | **19,65** | **Ditto.** |
| **Rated load** | **132,0** | **60** | **0,327** | **19,59** | **Ditto.** |
| **Rated load** | **216,0** | **50** | **0,231** | **20,16** | **Ditto.** |
| **Rated load** | **220,0** | **50** | **0,227** | **20,12** | **Ditto.** |
| **Rated load** | **230,0** | **50** | **0,220** | **20,20** | **Ditto.** |
| **Rated load** | **240,0** | **50** | **0,213** | **20,22** | **Ditto.** |
| **Rated load** | **253,0** | **50** | **0,206** | **20,35** | **Ditto.** |
| **Rated load** | **264,0** | **50** | **0,199** | **20,42** | **Ditto.** |
| **Model: GTM41060-2512** | | | | | |
| **Rated load** | **90,0** | **60** | **0,580** | **29,40** | **See 2)** |
| **Rated load** | **100,0** | **60** | **0,550** | **29,50** | **Ditto.** |
| **Rated load** | **110,0** | **60** | **0,521** | **29,70** | **Ditto.** |
| **Rated load** | **120,0** | **60** | **0,494** | **29,90** | **Ditto.** |
| **Rated load** | **132,0** | **60** | **0,465** | **30,07** | **Ditto.** |
| **Rated load** | **216,0** | **50** | **0,327** | **30,32** | **Ditto.** |
| **Rated load** | **220,0** | **50** | **0,323** | **30,38** | **Ditto.** |

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

| 4.11 | TABLE: Power Input | | | | | P |
|---|---|---|---|---|---|---|
| Operating Conditions / Ratings | | Voltage (V) | Frequency (Hz) | Current (A) | Power (W or VA) | Power factor (cos φ) |
| Rated load | | 230,0 | 50 | 0,312 | 30,30 | Ditto. |
| Rated load | | 240,0 | 50 | 0,303 | 30,44 | Ditto. |
| Rated load | | 253,0 | 50 | 0,291 | 30,40 | Ditto. |
| Rated load | | 264,0 | 50 | 0,283 | 30,65 | Ditto. |
| Model: GTM41060-2524 | | | | | | |
| Rated load | | 90,0 | 60 | 0,555 | 29,40 | See 3) |
| Rated load | | 100,0 | 60 | 0,521 | 29,30 | Ditto. |
| Rated load | | 110,0 | 60 | 0,495 | 29,25 | Ditto. |
| Rated load | | 120,0 | 60 | 0,476 | 29,27 | Ditto. |
| Rated load | | 132,0 | 60 | 0,458 | 29,35 | Ditto. |
| Rated load | | 216,0 | 50 | 0,335 | 30,14 | Ditto. |
| Rated load | | 220,0 | 50 | 0,328 | 29,92 | Ditto. |
| Rated load | | 230,0 | 50 | 0,320 | 30,05 | Ditto. |
| Rated load | | 240,0 | 50 | 0,309 | 30,15 | Ditto. |
| Rated load | | 253,0 | 50 | 0,296 | 30,00 | Ditto. |
| Rated load | | 264,0 | 50 | 0,290 | 30,31 | Ditto. |
| Model: GTM41060-2530 | | | | | | |
| Rated load | | 90,0 | 60 | 0,575 | 30,2 | See 4) |
| Rated load | | 100,0 | 60 | 0,516 | 30,0 | Ditto. |
| Rated load | | 110,0 | 60 | 0,472 | 29,8 | Ditto. |
| Rated load | | 120,0 | 60 | 0,437 | 29,7 | Ditto. |
| Rated load | | 132,0 | 60 | 0,401 | 29,5 | Ditto. |
| Rated load | | 216,0 | 50 | 0,285 | 30,2 | Ditto. |
| Rated load | | 220,0 | 50 | 0,281 | 30,1 | Ditto. |
| Rated load | | 230,0 | 50 | 0,272 | 30,2 | Ditto. |
| Rated load | | 240,0 | 50 | 0,261 | 30,2 | Ditto. |
| Rated load | | 253,0 | 50 | 0,250 | 30,4 | Ditto. |
| Rated load | | 264,0 | 50 | 0,238 | 30,2 | Ditto. |

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

| 4.11 | TABLE: Power Input | | | | P |
|---|---|---|---|---|---|
| **Operating Conditions / Ratings** | **Voltage (V)** | **Frequency (Hz)** | **Current (A)** | **Power (W or VA)** | **Power factor (cos φ)** |
| **Model: GTM41060-2518-FW** | | | | | |
| **Rated load** | **90,0** | **60** | **0,580** | **31,2** | **See 5)** |
| **Rated load** | **100,0** | **60** | **0,523** | **30,8** | **Ditto.** |
| **Rated load** | **110,0** | **60** | **0,480** | **30,6** | **Ditto.** |
| **Rated load** | **120,0** | **60** | **0,440** | **30,4** | **Ditto.** |
| **Rated load** | **132,0** | **60** | **0,393** | **30,2** | **Ditto.** |
| **Rated load** | **216,0** | **50** | **0,277** | **30,1** | **Ditto.** |
| **Rated load** | **220,0** | **50** | **0,272** | **30,1** | **Ditto.** |
| **Rated load** | **230,0** | **50** | **0,263** | **30,1** | **Ditto.** |
| **Rated load** | **240,0** | **50** | **0,254** | **30,2** | **Ditto.** |
| **Rated load** | **253,0** | **50** | **0,241** | **30,3** | **Ditto.** |
| **Rated load** | **264,0** | **50** | **0,233** | **30,3** | **Ditto.** |
| **Model: GTM41060-2524-FW** | | | | | |
| **Rated load** | **90,0** | **60** | **0,567** | **30,5** | **See 6)** |
| **Rated load** | **100,0** | **60** | **0,512** | **30,2** | **Ditto.** |
| **Rated load** | **110,0** | **60** | **0,434** | **30,0** | **Ditto.** |
| **Rated load** | **120,0** | **60** | **0,470** | **30,0** | **Ditto.** |
| **Rated load** | **132,0** | **60** | **0,389** | **29,8** | **Ditto.** |
| **Rated load** | **216,0** | **50** | **0,225** | **30,1** | **Ditto.** |
| **Rated load** | **220,0** | **50** | **0,231** | **30,2** | **Ditto.** |
| **Rated load** | **230,0** | **50** | **0,214** | **30,2** | **Ditto.** |
| **Rated load** | **240,0** | **50** | **0,205** | **30,3** | **Ditto.** |
| **Rated load** | **253,0** | **50** | **0,197** | **30,3** | **Ditto.** |
| **Rated load** | **264,0** | **50** | **0,189** | **30,5** | **Ditto.** |

**Supplementary Information:**
**1) Nominal output conditions: 4,59 Vdc / 3,0 A**
**2) Nominal output conditions: 11,6 Vdc / 2,08 A**
**3) Nominal output conditions: 24,3 Vdc / 1,04 A**
**4) Nominal output conditions: 30,5 Vdc / 0,83 A**

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

| 4.11 | TABLE: Power Input | | | | | P |
|---|---|---|---|---|---|---|
| **Operating Conditions / Ratings** | **Voltage (V)** | **Frequency (Hz)** | **Current (A)** | **Power (W or VA)** | **Power factor (cos φ)** | |
| **5) Nominal output conditions: 18,2 Vdc / 1,41 A**<br>**6) Nominal output conditions: 24,5 Vdc / 1,04 A**<br>**Rated input:**<br>**100-240 Vac**<br>**50-60 Hz**<br>**0,6 A**<br>**Class II** | | | | | | |

| 5.9.2 | TABLE: Determination of ACCESSIBLE parts | P |
|---|---|---|
| **Location** | **Determination method (NOTE1)** | **Comments** |
| **Power supply unit plastic enclosure** | **Visual, Rigid test finger** | **Plastic enclosure without openings provided.** |
| **Supplementary information:**<br>[1)] NOTE: The determination methods are: visual; rigid test finger; jointed test finger; test hook.<br>Applicable for Direct plug-in Direct Plug-in Power Supply. | | |

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

| 7.1.2 | TABLE: Legibility of Marking | | P |
|---|---|---|---|
| **Markings tested** | **Ambient Illuminance (lx)** | **Remarks** | |
| **Outside Markings (Clause 7.2) ..... :** | **100** | **Legible markings** | |
| **Inside Markings (Clause 7.3) ..... :** | **N/A** | **N/A** | |
| **Controls & Instruments (Clause 7.4) ..... :** | **N/A** | **N/A** | |
| **Safety Signs (Clause 7.5)..... :** | **N/A** | **N/A** | |
| **Symbols (Clause 7.6) ..... :** | **100** | **Legible markings** | |

**Supplementary information:**

Observer, with a visual acuity of 0 on the log Minimum Angle of Resolution (log MAR) scale or 6/6 (20/20) and is able to read N6 of the Jaeger test card in normal room lighting condition (~500lx), reads marking at ambient illuminance least favourable level in the range of 100 lx to 1,500 lx. The ME EQUIPMENT or its part was positioned so that the viewpoint was the intended position of the OPERATOR or if not defined at any point within the base of a cone subtended by an angle of 30° to the axis normal to the centre of the plane of the marking and at a distance of 1 m.

| 7.1.3 | TABLE: Durability of marking test | P |
|---|---|---|
| **Characteristics of the Marking Label tested:** | | **Remarks** |
| **Material of Marking Label .....:** | **Polyester label** | **P** |
| **Ink/other printing material or process .....:** | **Ink; Printed** | **P** |
| **Material (composition) of Warning Label .....:** | **No warning labels provided on the outer side of the EUT.** | **N/A** |
| **Ink/other printing material or process .....:** | **--** | **N/A** |
| **Other .....:** | **--** | **N/A** |
| **Marking Label Tested:** | | **Remarks** |
| **Type label on the outside of the equipment.** | | **--** |

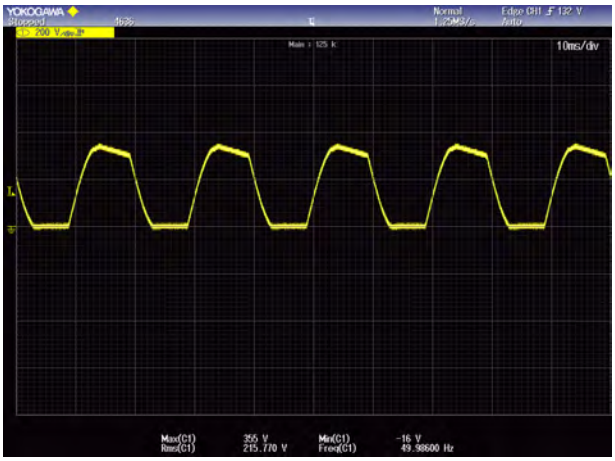
**Supplementary information:**

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.

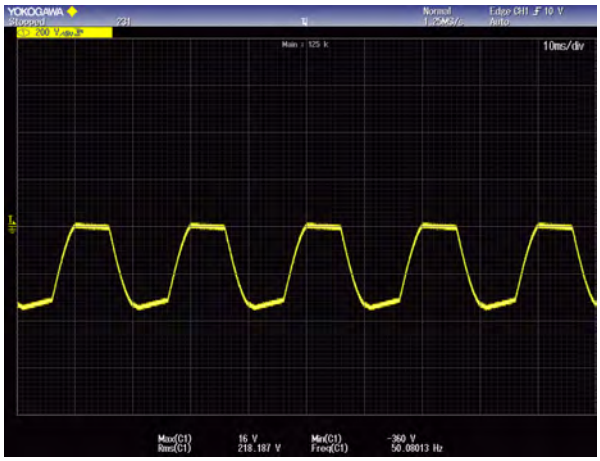
| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | | | | | P |
|---|---|---|---|---|---|---|
| Test supply voltage/frequency (V/Hz)[1)] ..... : | | | | | | 240V/50Hz |
| Location From/To | Measured values | | | | | Remarks |
| | Vrms | Vpk or Vdc | Peak-to-peak ripple[2)] | Power W/VA | Energy (J) | |
| GTM41060-1505 | | | | | | |
| Transformer T1 | | | | | | |
| Pin1 to GND | 216 | 355 | -- | -- | -- | -- |
| Pin2 to GND | 219 | 360 | -- | -- | -- | -- |
| Pin3 to GND | 256 | 496 | -- | -- | -- | Hot pin. |
| Pin4 to GND | 221 | 455 | -- | -- | -- | -- |
| | | | | | | |
| Pin3 to Pin5 | 248 | 488 | -- | -- | -- | -- |
| Pin3 to Pin6 | 255 | 495 | -- | -- | -- | Max. RMS and PEAK |
| Optocoupler PC1 | | | | | | |
| Pin1 to Pin3 | 218 | 360 | -- | -- | -- | -- |
| Pin2 to Pin3 | 212 | 360 | -- | -- | -- | -- |
| Pin1 to Pin4 | 209 | 355 | -- | -- | -- | -- |
| Pin2 to Pin4 | 210 | 352 | -- | -- | -- | -- |
| Y capacitors (CY1 and CY2) | | | | | | |
| Prim.to Sec. | 212 | 356 | -- | -- | -- | -- |
| Pictures from oscilloscope | | | | | | |

**Transformer T1 (Pin1 to GND):**




**Transformer T1 (Pin2 to GND):**



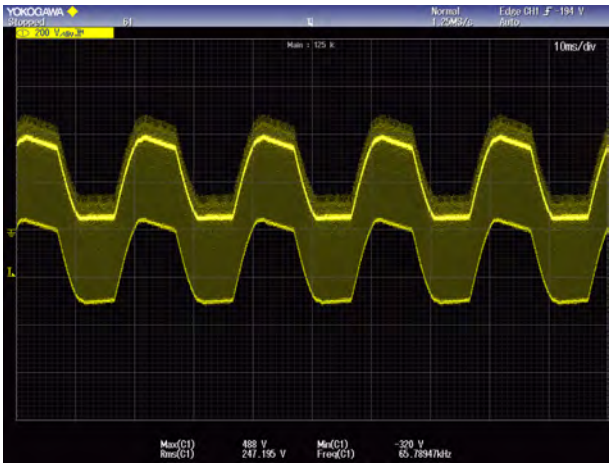

**Transformer T1 (Pin3 to GND):**

**Transformer T1 (Pin4 to GND):**

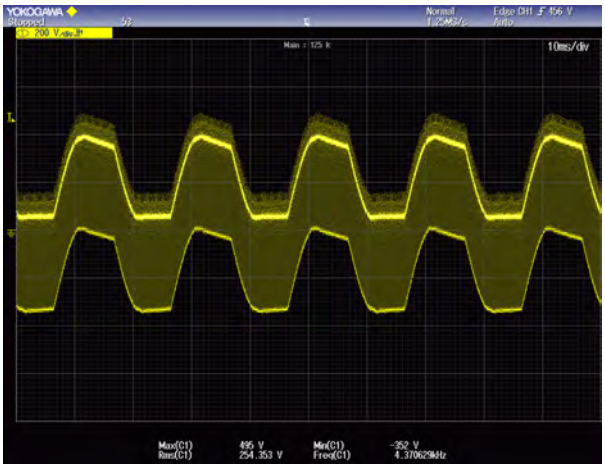
| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | P |
|---|---|---|

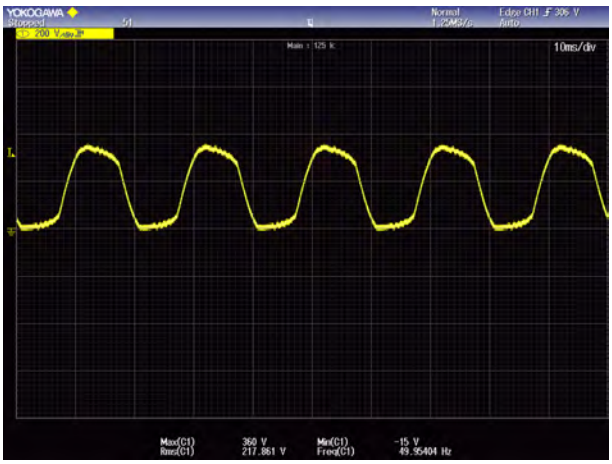
**Transformer T1 (Pin3 to Pin5):**



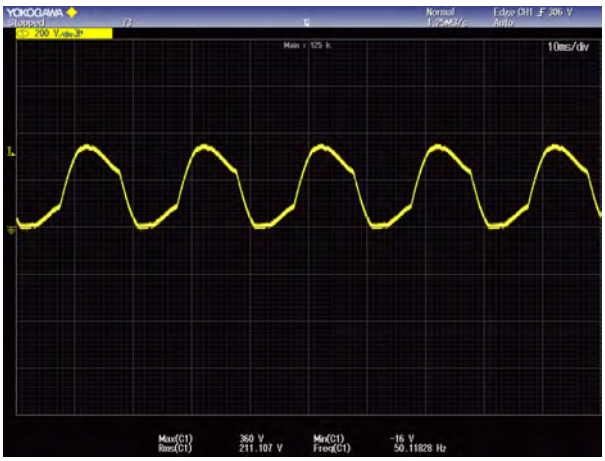

**Transformer T1 (Pin3 to Pin6):**




**Optocoupler PC1 (Pin1 to Pin3):**




**Optocoupler PC1 (Pin2 to Pin3):**

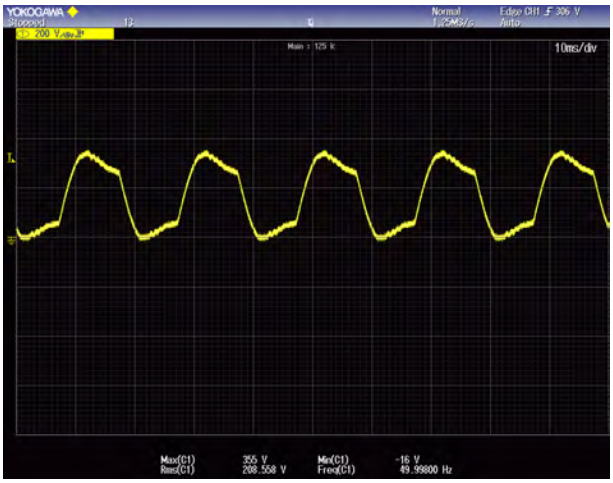


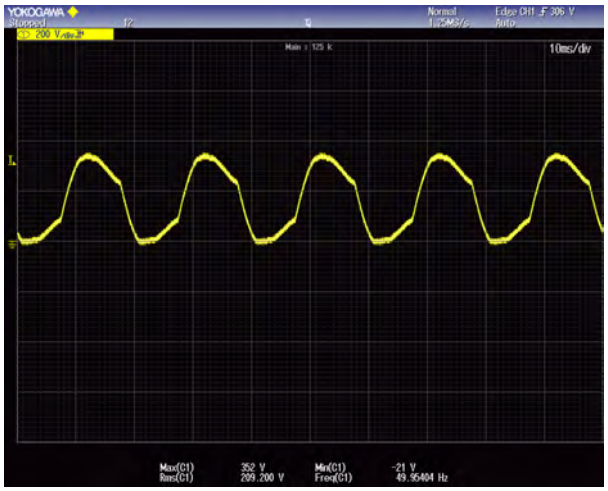

**Optocoupler PC1 (Pin1 to Pin4):**

**Optocoupler PC1 (Pin2 to Pin4):**

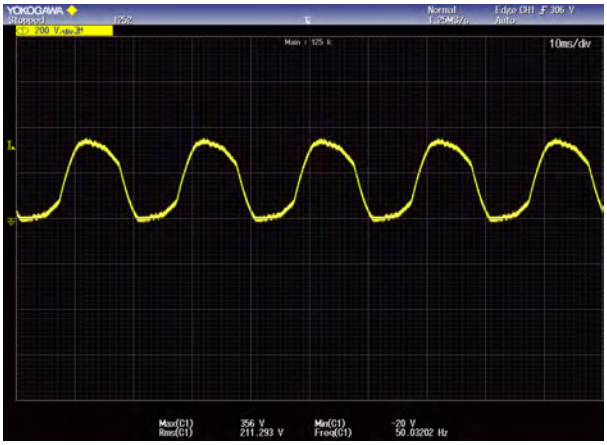
| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | P |
|---|---|---|




**Y capacitors CY1,CY2 (Primary to secondary):**




**Supplementary Information:**

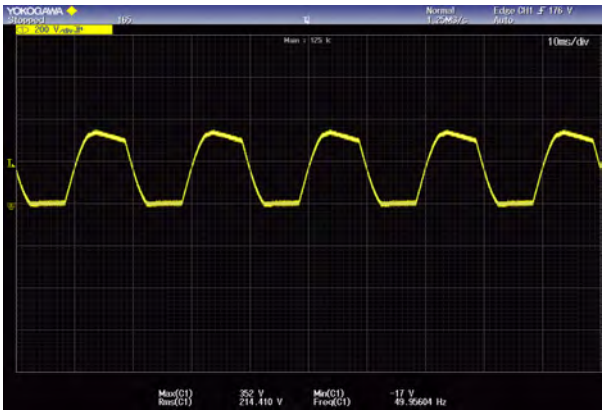
1)The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.

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

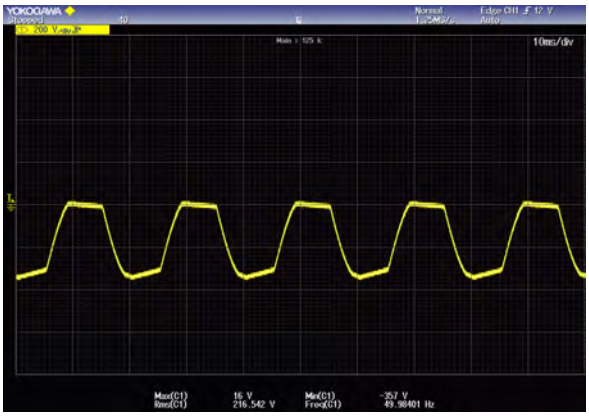
| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | | | | | P |
|---|---|---|---|---|---|---|
| Test supply voltage/frequency (V/Hz)[1] .....: | | | | | | 240V/50Hz |
| Location From/To | Measured values | | | | | Remarks |
| | Vrms | Vpk or Vdc | Peak-to-peak ripple[2] | Power W/VA | Energy (J) | |
| GTM41060-2512 | | | | | | |
| Transformer T1 | | | | | | |
| Pin1 to GND | 215 | 352 | -- | -- | -- | -- |
| Pin2 to GND | 217 | 357 | -- | -- | -- | -- |
| Pin3 to GND | 257 | 488 | -- | -- | -- | Hot pin. |
| Pin4 to GND | 220 | 478 | -- | -- | -- | -- |
| | | | | | | |
| Pin3 to Pin5 | 241 | 470 | -- | -- | -- | -- |
| Pin3 to Pin6 | 257 | 487 | -- | -- | -- | Max. RMS and PEAK |
| Optocoupler PC1 | | | | | | |
| Pin1 to Pin3 | 218 | 368 | -- | -- | -- | -- |
| Pin2 to Pin3 | 222 | 365 | -- | -- | -- | -- |
| Pin1 to Pin4 | 218 | 365 | -- | -- | -- | -- |
| Pin2 to Pin4 | 217 | 364 | -- | -- | -- | -- |
| Y capacitors (CY1 and CY2) | | | | | | |
| Prim.to Sec. | 208 | 358 | -- | -- | -- | -- |
| Pictures from oscilloscope | | | | | | |

**Transformer T1 (Pin1 to GND):**




**Transformer T1 (Pin2 to GND):**



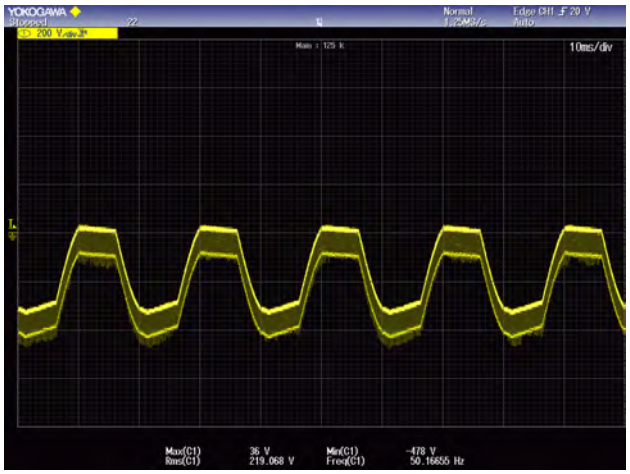

**Transformer T1 (Pin3 to GND):**

**Transformer T1 (Pin4 to GND):**

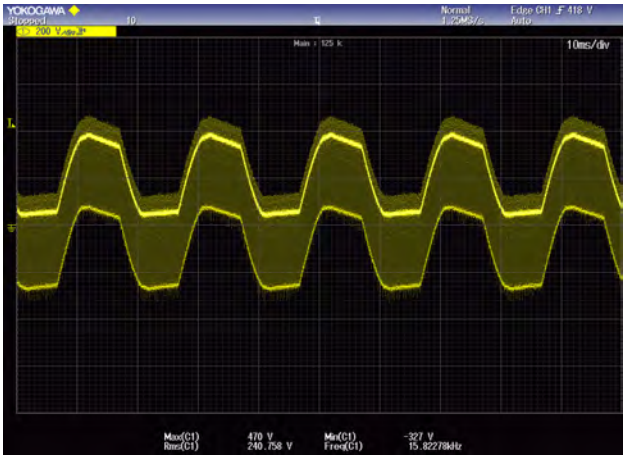
| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | P |
|---|---|---|

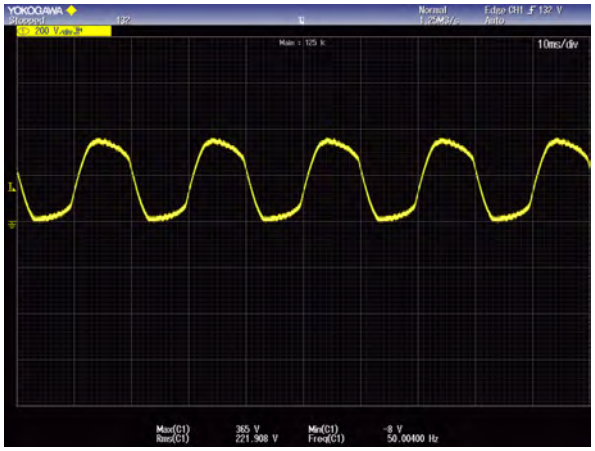
**Transformer T1 (Pin3 to Pin5):**



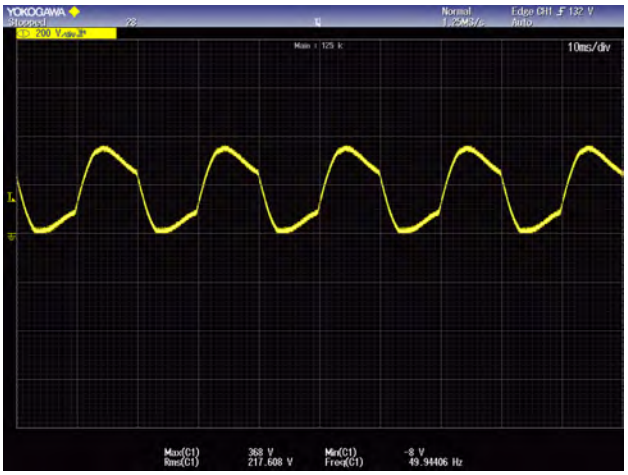

**Transformer T1 (Pin3 to Pin6):**




**Optocoupler PC1 (Pin1 to Pin3):**




**Optocoupler PC1 (Pin2 to Pin3):**



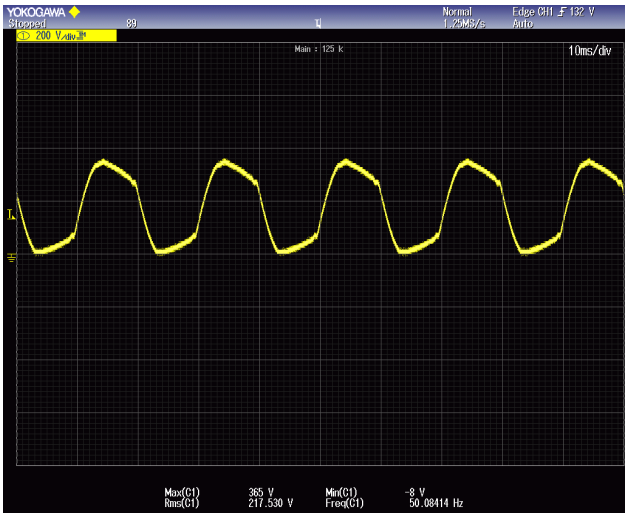

**Optocoupler PC1 (Pin1 to Pin4):**

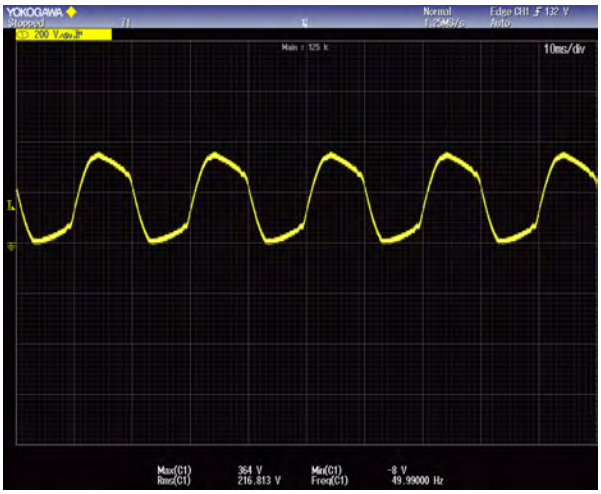



**Optocoupler PC1 (Pin2 to Pin4):**

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

| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | P |
|---|---|---|




**Y capacitors CY1,CY2 (Primary to secondary):**

**Supplementary Information:**

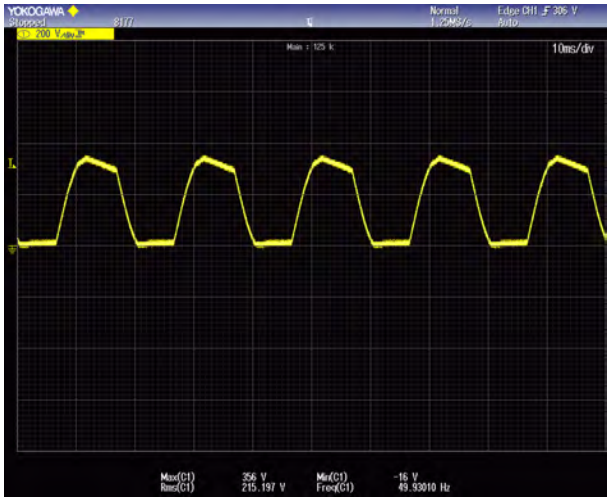
[1)]The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.

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

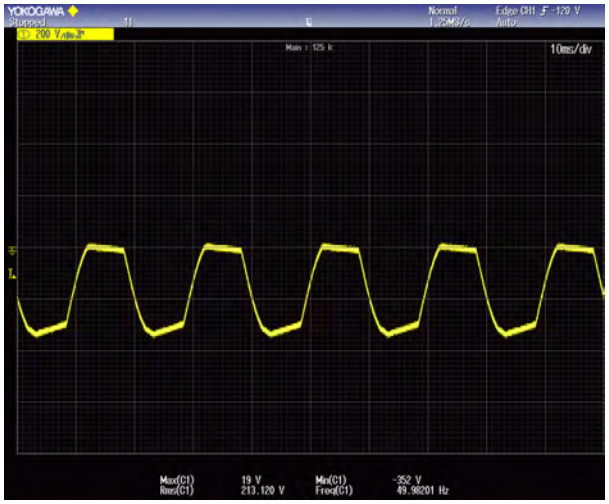
| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | | | | | P |
|---|---|---|---|---|---|---|
| Test supply voltage/frequency (V/Hz)[1] .....: | | | | | | 240V/50Hz |
| Location From/To | Measured values | | | | | Remarks |
| | Vrms | Vpk or Vdc | Peak-to-peak ripple[2] | Power W/VA | Energy (J) | |
| GTM41060-2524 | | | | | | |
| Transformer T1 | | | | | | |
| Pin1 to GND | 216 | 356 | -- | -- | -- | -- |
| Pin2 to GND | 214 | 352 | -- | -- | -- | -- |
| Pin3 to GND | 264 | 480 | -- | -- | -- | Hot pin. |
| Pin4 to GND | 217 | 506 | -- | -- | -- | Hot pin. |
| | | | | | | |
| Pin3 to Pin5 | 236 | 454 | -- | -- | -- | -- |
| Pin3 to Pin6 | 264 | 480 | -- | -- | -- | Max. RMS |
| Pin4 to Pin5 | 212 | 360 | -- | -- | -- | -- |
| Pin4 to Pin6 | 216 | 508 | -- | -- | -- | Max.PEAK. |
| Optocoupler PC1 | | | | | | |
| Pin1 to Pin3 | 231 | 384 | -- | -- | -- | -- |
| Pin2 to Pin3 | 230 | 376 | -- | -- | -- | -- |
| Pin1 to Pin4 | 229 | 376 | -- | -- | -- | -- |
| Pin2 to Pin4 | 228 | 372 | -- | -- | -- | -- |
| Y capacitors (CY1 and CY2) | | | | | | |
| Prim.to Sec. | 212 | 352 | -- | -- | -- | -- |
| Pictures from oscilloscope | | | | | | |

**Transformer T1 (Pin1 to GND):**




**Transformer T1 (Pin2 to GND):**

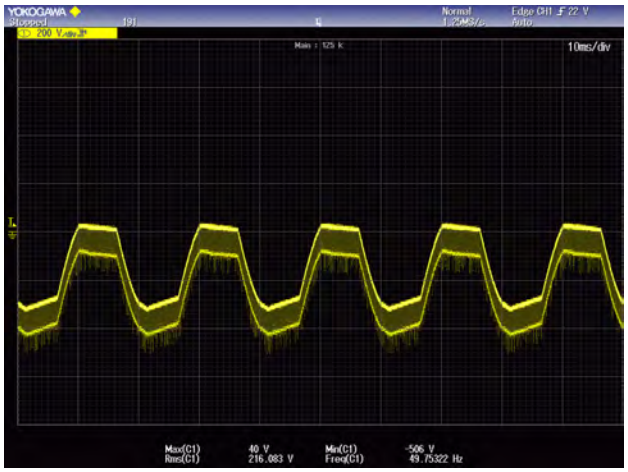


| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | P |
|---|---|---|

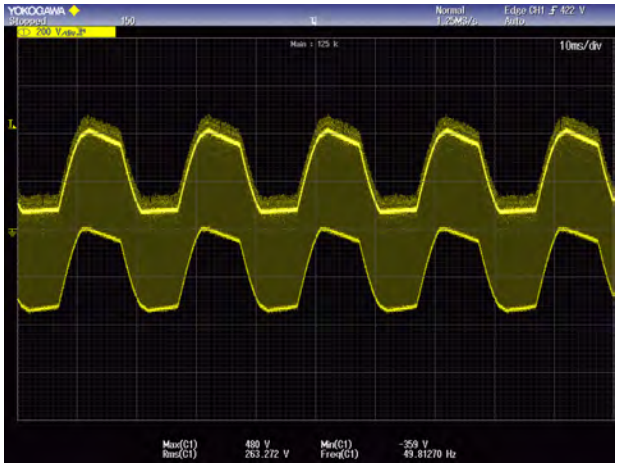
**Transformer T1 (Pin3 to GND):**

**Transformer T1 (Pin4 to GND):**



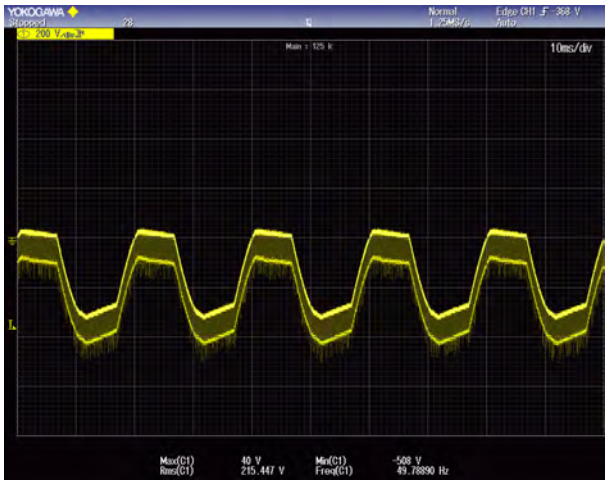

**Transformer T1 (Pin3 to Pin5):**

**Transformer T1 (Pin3 to Pin6):**




**Transformer T1 (Pin4 to Pin5):**

**Transformer T1 (Pin4 to Pin6):**

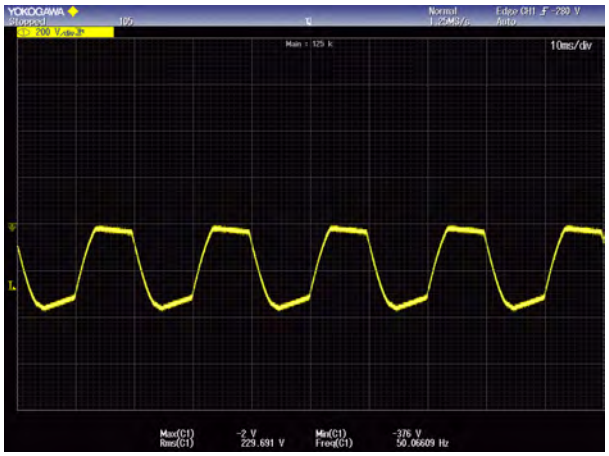



**Optocoupler PC1 (Pin1 to Pin3):**

**Optocoupler PC1 (Pin2 to Pin3):**

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

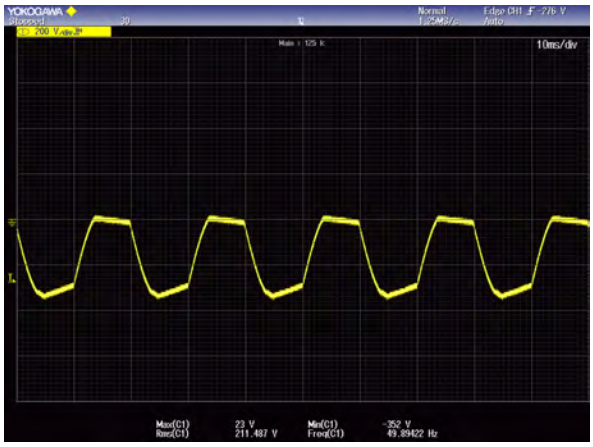
| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | P |
|---|---|---|



**Optocoupler PC1 (Pin1 to Pin4):**

**Optocoupler PC1 (Pin2 to Pin4):**

**Y capacitors CY1,CY2 (Primary to secondary):**




**Supplementary Information:**

[1)]The input supply voltage to the ME EQUIPMENT was the RATED voltage or the voltage within the RATED voltage range which results in the highest measured value. See clause 8.5.4.

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

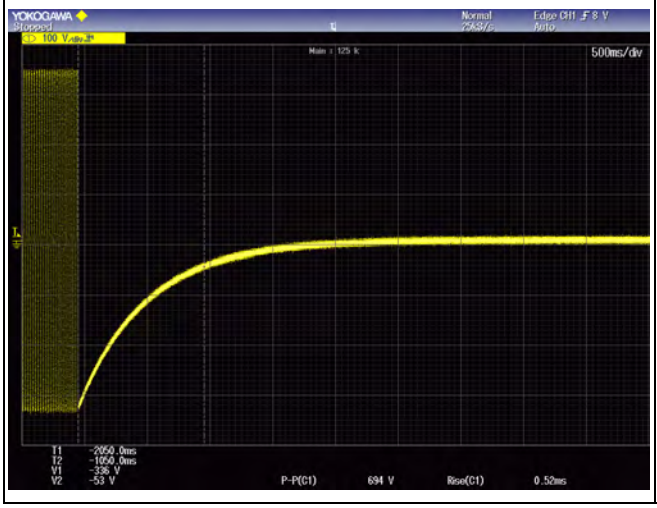
| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

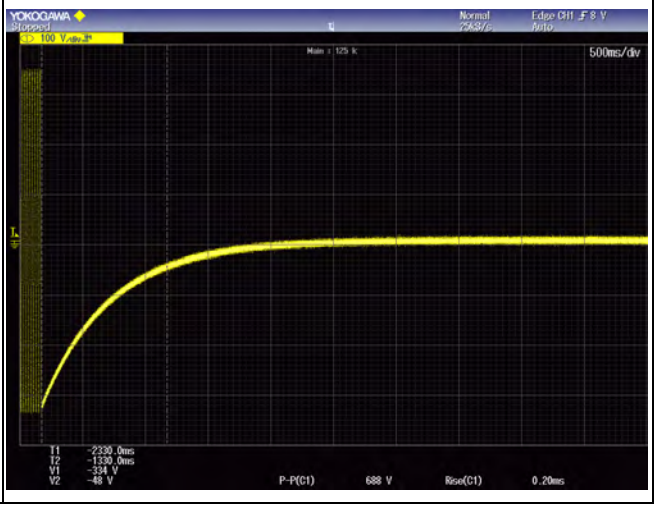
| 8.4.3 | TABLE: ME EQUIPMENT for connection to a power source by a plug - measurement of voltage or calculation of stored charge 1 s after disconnection of plug from mains supply | | | | | | | | | | P |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Maximum allowable voltage (V) ..... : | | | | | | | | | | | 60 |
| Voltage measured (V) | | | | | | | | | | | |
| Voltage Measured Between: | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
| Plug pins 1 and 2 | 53 | 48 | 50 | 56 | 48 | 50 | 59 | 48 | 49 | 50 | |
| Plug pin 1 and plug earth pin | - | - | - | - | - | - | - | - | - | - | |
| Plug pin 2 and plug earth pin | - | - | - | - | - | - | - | - | - | - | |
| Plug pin 1 and enclosure | - | - | - | - | - | - | - | - | - | - | |
| Plug pin 2 and enclosure | - | - | - | - | - | - | - | - | - | - | |
| Maximum allowable stored charge when measured voltage exceeded 60 v (µc) .....: | | | | | | | | | | | 45 |
| Calculated stored charge (µc) | | | | | | | | | | | |
| Voltage Measured Between: | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | |
| Plug pins 1 and 2 | - | - | - | - | - | - | - | - | - | - | |
| Plug pin 1 and plug earth pin | - | - | - | - | - | - | - | - | - | - | |
| Plug pin 2 and plug earth pin | - | - | - | - | - | - | - | - | - | - | |
| Plug pin 1 and enclosure | - | - | - | - | - | - | - | - | - | - | |
| Plug pin 2 and enclosure | - | - | - | - | - | - | - | - | - | - | |

**Supplementary information:**

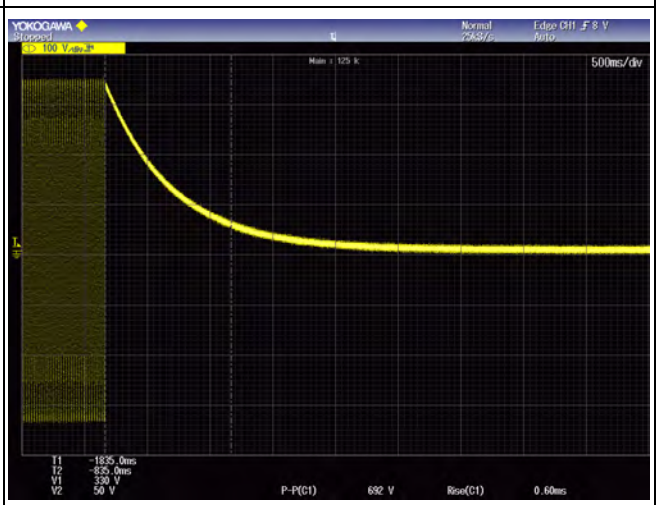
**A triggering circuit was used. EUT is class II.**

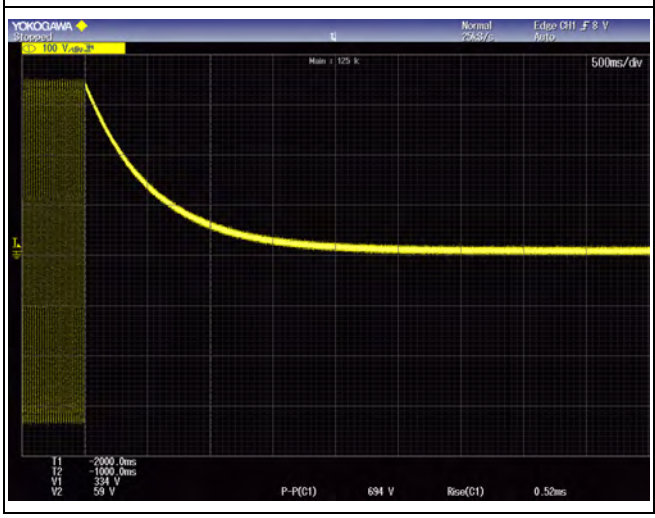
**See pictures from oscilloscope below.**

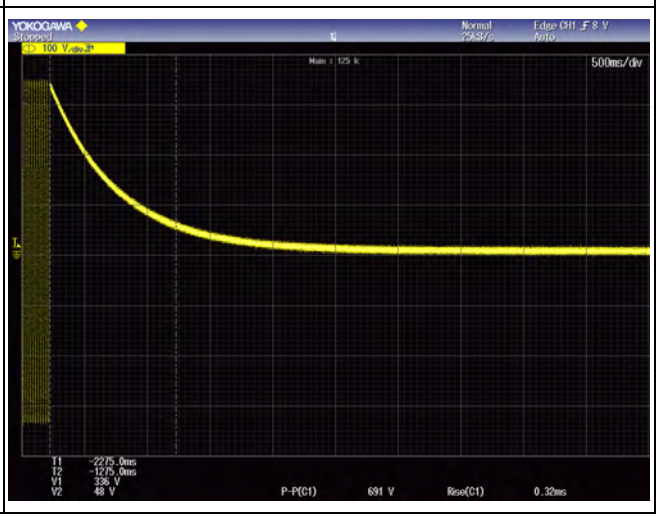


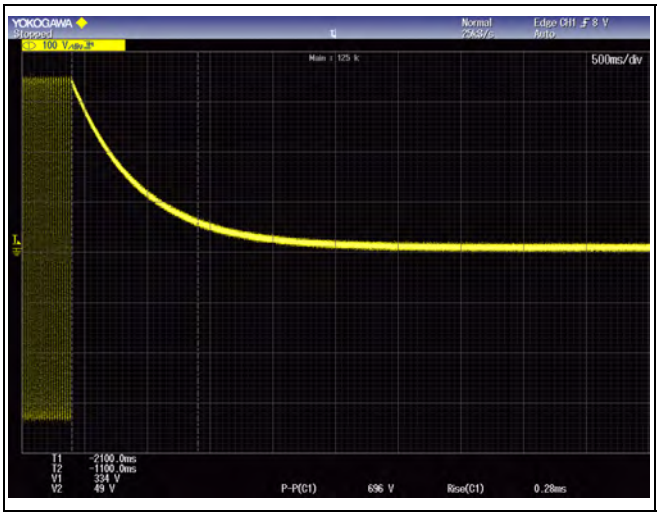
| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

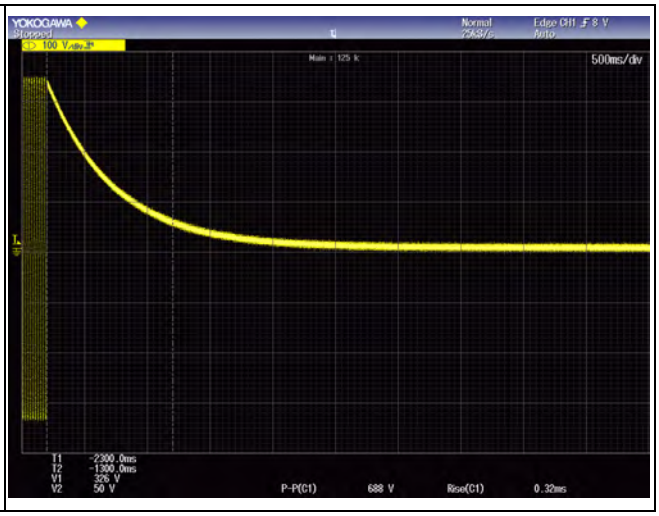


| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |



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

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

| 8.5.5.1a | TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies | | | | N/A |
|---|---|---|---|---|---|
| Test Condition: Figs. 9 & 10 | Measurement made on accessible part | Applied part with test voltage | Test voltage polarity | Measured voltage between Y1 and Y2 (mV) | Remarks |
| | | | | | |
| Supplementary information:<br>No applied parts provided. | | | | | |

| 8.5.5.1b | TABLE: defibrillation-proof applied parts – verification of recovery time | | | N/A |
|---|---|---|---|---|
| Applied part with test voltage | Test voltage polarity | Recovery time from documents (s) | Measured recovery time (s) | Remarks |
| | | | | |
| Supplementary information:<br>No applied parts provided. | | | | |

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

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

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

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

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

| Type of ME EQUIPMENT & impedance measured between parts | Test current (A) /Duration (s) | Voltage drop measured between parts (V) | Maximum calculated impedance (mΩ) | Maximum allowable impedance (mΩ) |
|---|---|---|---|---|
| | | | | |

**Supplementary information:**

**PERMANENTLY INSTALLED ME EQUIPMENT, impedance between PROTECTIVE EARTH TERMINAL and a PROTECTIVELY EARTHED part - Limit 100 mΩME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the APPLIANCE INLET and a PROTECTIVELY EARTHED part - Limit 100 mΩ**
**ME EQUIPMENT with an APPLIANCE INLET, impedance between earth pin in the protective earth pin on the DETACHABLE POWER SUPPLY CORD and a PROTECTIVELY EARTHED part - Limit 200 mΩ**
**ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, impedance between the protective earth pin in the MAINS PLUG and a PROTECTIVELY EARTHED part - Limit 200 mΩ**

**No protective earthing provided.**

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

| 8.7 | TABLE: leakage current | P |
|---|---|---|

| Type of leakage current and test condition (including single faults) | Supply voltage (V) | Supply frequency (Hz) | Measured max. value (µA) | Remarks |
|---|---|---|---|---|
| **Power supply unit evaluated for Means of Operator Protection (MOOP)**<br>**(Single Y1 capacitor (1 nF) provided between primary and secondary circuit)** | | | | |
| Fig. 13 - Earth Leakage (ER) | — | — | — | Maximum allowed values:<br>5 mA NC; 10 mA SFC |
| | | | | |
| Fig. 14 - Touch Current (TC) | — | — | — | Maximum allowed values:<br>100 µA NC; 500 µA SFC |
| **Touch Leakage Current on output plus** | | | | |
| **Normal condition, normal polarity** | **264** | **60** | **89,7** | **--** |
| **Normal condition, reverse polarity** | **264** | **60** | **90,1** | **--** |
| **Single fault condition (supply interruption), normal polarity** | **264** | **60** | **136,0** | **--** |
| **Single fault condition (supply interruption), reverse polarity** | **264** | **60** | **136,1** | **--** |
| **Touch Leakage Current on output minus** | | | | |
| **Normal condition, normal polarity** | **264** | **60** | **89,7** | **--** |
| **Normal condition, reverse polarity** | **264** | **60** | **90,1** | **--** |
| **Single fault condition (supply interruption), normal polarity** | **264** | **60** | **136,0** | **--** |
| **Single fault condition (supply interruption), reverse polarity** | **264** | **60** | **136,1** | **--** |
| **Touch Leakage Current on enclosure wrapped in aluminium foil** | | | | |
| **Normal condition, normal polarity** | **264** | **60** | **3,90** | **--** |
| **Normal condition, reverse polarity** | **264** | **60** | **4,10** | **--** |
| **Single fault condition (supply interruption), normal polarity** | **264** | **60** | **6,30** | **--** |
| **Single fault condition (supply interruption), reverse polarity** | **264** | **60** | **6,30** | **--** |

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

| Type of leakage current and test condition (including single faults) | Supply voltage (V) | Supply frequency (Hz) | Measured max. value (µA) | Remarks |
|---|---|---|---|---|
| | | | | |
| Fig. 15 - Patient Leakage Current (P) | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current);<br>100 µA NC; 500 µA SFC (a.c.)<br>Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current) |
| | | | | |
| Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM) | — | — | — | Maximum allowed values:<br>Type B: N/A<br>Type BF AP: 5000 µA<br>Type CF AP: 50 µA |
| | | | | |
| Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP) | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current);<br>100 µA NC; 500 µA SFC (a.c.) ;<br>Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current) |
| | | | | |
| Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed | — | — | — | Maximum allowed values:<br>Type B or BF AP: 500 µA<br>Type CF: N/A |
| | | | | |
| Fig. 19 – Patient Auxiliary Current | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current);<br>100 µA NC; 500 µA SFC (a.c.) ;<br>Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current) |
| | | | | |
| Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together | — | — | — | Maximum allowed values:<br>Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current);<br>500 µA NC; 1000 µA SFC (a.c.);<br>Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current) |
| | | | | |
| Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP | — | — | — | Maximum allowed values:<br>Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current);<br>500 µA NC;1000 µA SFC (a.c.);<br>Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current) |
| | | | | |
| Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP | — | — | — | Maximum allowed values:<br>Type B: NA<br>Type BF: 5000 µA<br>Type CF: 100 µA |
| | | | | |

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

| Type of leakage current and test condition (including single faults) | Supply voltage (V) | Supply frequency (Hz) | Measured max. value (µA) | Remarks |
|---|---|---|---|---|
| Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed | — | — | — | Maximum allowed values:<br>Type B & BF: 1000 µA<br>Type CF: N/A |
| | | | | |
| Function Earth Conductor Leakage Current (FECLC) | — | — | — | Maximum allowed values:<br>5 mA NC; 10 mA SFC |
| | | | | |
| **Power supply unit evaluated for Means of Patient Protection (MOPP)**<br>**(Models additionally marked with 2MOPP near model name)**<br>**(2 x Y1 capacitors (2 x 1 nF) in series provided between primary and secondary circuit)** | | | | |
| Fig. 13 - Earth Leakage (ER) | — | — | — | Maximum allowed values:<br>5 mA NC; 10 mA SFC |
| | | | | |
| Fig. 14 - Touch Current (TC) | — | — | — | Maximum allowed values:<br>100 µA NC; 500 µA SFC |
| **Touch Leakage Current on output plus** | | | | |
| **Normal condition, normal polarity** | **264** | **60** | **44,0** | **--** |
| **Normal condition, reverse polarity** | **264** | **60** | **44,1** | **--** |
| **Single fault condition (supply interruption), normal polarity** | **264** | **60** | **65,4** | **--** |
| **Single fault condition (supply interruption), reverse polarity** | **264** | **60** | **65,0** | **--** |
| **Touch Leakage Current on output minus** | | | | |
| **Normal condition, normal polarity** | **264** | **60** | **44,4** | **--** |
| **Normal condition, reverse polarity** | **264** | **60** | **44,5** | **--** |
| **Single fault condition (supply interruption), normal polarity** | **264** | **60** | **65,3** | **--** |
| **Single fault condition (supply interruption), reverse polarity** | **264** | **60** | **65,1** | **--** |
| **Touch Leakage Current on enclosure wrapped in aluminium foil** | | | | |
| **Normal condition, normal polarity** | **264** | **60** | **3,90** | **--** |
| **Normal condition, reverse polarity** | **264** | **60** | **4,10** | **--** |
| **Single fault condition (supply interruption), normal polarity** | **264** | **60** | **6,30** | **--** |
| **Single fault condition (supply interruption), reverse polarity** | **264** | **60** | **6,30** | **--** |

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

| Type of leakage current and test condition (including single faults) | Supply voltage (V) | Supply frequency (Hz) | Measured max. value (µA) | Remarks |
|---|---|---|---|---|
| | | | | |
| Fig. 15 - Patient Leakage Current (P) | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current);<br>100 µA NC; 500 µA SFC (a.c.)<br>Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current) |
| | | | | |
| Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM) | — | — | — | Maximum allowed values:<br>Type B: N/A<br>Type BF AP: 5000 µA<br>Type CF AP: 50 µA |
| | | | | |
| Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP) | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current);<br>100 µA NC; 500 µA SFC (a.c.) ;<br>Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current) |
| | | | | |
| Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed | — | — | — | Maximum allowed values:<br>Type B or BF AP: 500 µA<br>Type CF: N/A |
| | | | | |
| Fig. 19 – Patient Auxiliary Current | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current);<br>100 µA NC; 500 µA SFC (a.c.) ;<br>Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current) |
| | | | | |
| Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together | — | — | — | Maximum allowed values:<br>Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current);<br>500 µA NC; 1000 µA SFC (a.c.);<br>Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current) |
| | | | | |
| Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP | — | — | — | Maximum allowed values:<br>Type B or BF AP: 50 µA NC; 100µA SFC (d.c. current);<br>500 µA NC;1000 µA SFC (a.c.);<br>Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current) |
| | | | | |
| Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP | — | — | — | Maximum allowed values:<br>Type B: NA<br>Type BF: 5000 µA<br>Type CF: 100 µA |
| | | | | |

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

| Type of leakage current and test condition (including single faults) | Supply voltage (V) | Supply frequency (Hz) | Measured max. value (µA) | Remarks |
|---|---|---|---|---|
| Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed | — | — | — | Maximum allowed values:<br>Type B & BF: 1000 µA<br>Type CF: N/A |
| | | | | |
| Function Earth Conductor Leakage Current (FECLC) | — | — | — | Maximum allowed values:<br>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;

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

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

**Measurement was performed before and after humidity treatment with identical result.**

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

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

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

| 8.8.3 | TABLE: Dielectric strength test of solid insulating materials with safety function – MEANS OF OPERATOR PROTECTION (MOOP) / MEANS OF PATIENT PROTECTION (MOPP) | | | | P |
|---|---|---|---|---|---|
| **Insulation under test (area from insulation diagram)** | **Insulation Type (1 or 2 MOOP/MOPP)** | **Reference Voltage** | | **A.C. test voltages in V r.m.s[1)]** | **Dielectric breakdown after 1 minute Yes/No[2)]** |
| | | **PEAK WORKING VOLTAGE (U) $V_{peak}$** | **PEAK WORKING VOLTAGE (U) V d.c.** | | |
| **Power supply unit evaluated for Means of Operator Protection (MOOP)**<br>**(Single Y1 capacitor provided between primary and secondary circuit)** | | | | | |
| **Primary to secondary**<br>**(Direct plug-in power Supply)** | **2 x MOOP** | **508** | **--** | **3.000 Vac** | **No BD** |
| **Primary to plastic enclosure**<br>**(Direct plug-in power Supply)** | **2 x MOOP** | **508** | **--** | **3.000 Vac** | **No BD** |
| **Primary to secondary**<br>**(Open-frame Power Supply)** | **2 x MOOP** | **508** | **--** | **3.000 Vac** | **No BD** |
| **2 layers of insulation tape provided within transformer** | **2 x MOOP** | **508** | **--** | **3.000 Vac** | **No BD** |
| **Power supply unit evaluated for Means of Patient Protection (MOPP)**<br>**(Models additionally marked with 2MOPP near model name)**<br>**(2 x Y1 capacitors in series provided between primary and secondary circuit)** | | | | | |
| **Primary to secondary**<br>**(Direct plug-in power Supply)** | **2 x MOPP** | **508** | **--** | **4.440 Vac** | **No BD** |
| **Primary to plastic enclosure**<br>**(Direct plug-in power Supply)** | **2 x MOPP** | **508** | **--** | **4.440 Vac** | **No BD** |
| **Primary to secondary**<br>**(Open-frame Power Supply)** | **2 x MOPP** | **508** | **--** | **4.440 Vac** | **No BD** |
| **2 layers of insulation tape provided within transformer** | **2 x MOPP** | **508** | **--** | **4.440 Vac** | **No BD** |

| IEC 60601-1 | | | |
|---|---|---|---|
| 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).

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

| **Part/material** | **Test temperature (°C)** | **Impression diameter (mm)** |
|---|---|---|
| **Transformer bobbin Chang Chun Plastics Co., Ltd, T375J** | **125** | **0,9** |

**Supplementary information:**

**Approved thermoplastic materials used. See table 8.10.**

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

| 8.9.2 | TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4 | | P |
|---|---|---|---|
| **Specific areas of circuits short-circuited and test conditions** | **Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1)]** | **HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No** | **Remarks** |
| **Between parts of opposite polarity (after primary fuses)** | | | |
| **Varistor MOV1, Capacitor CX1**<br>**Short circuit**<br>**90 Vac / 60 Hz** | **AC** | **No** | **Primary fuses F1, F2 opened immediately.** |
| **Varistor MOV1, Capacitor CX1**<br>**Short circuit**<br>**264 Vac / 50 Hz** | **AC** | **No** | **Primary fuses F1, F2 opened immediately.** |
| **Resistor R1, Short circuit**<br>**90 Vac / 60 Hz** | **AC** | **No** | **No effect on function.** |
| **Resistor R1, Short circuit**<br>**264 Vac / 50 Hz** | **AC** | **No** | **No effect on function.** |
| **Capacitor C1, Short circuit**<br>**90 Vac / 60 Hz** | **AC** | **No** | **Primary fuses F1, F2 opened immediately.** |
| **Capacitor C1, Short circuit**<br>**264 Vac / 50 Hz** | **AC** | **No** | **Primary fuses F1, F2 opened immediately.** |
| **Transformer T1**<br>**Short circuit**<br>**90 Vac / 60 Hz** | **AC** | **No** | **Unit switched off immediately.** |
| **Transformer T1**<br>**Short circuit**<br>**264 Vac / 50 Hz** | **AC** | **No** | **Unit switched off immediately.** |
| **Supplementary information:**<br>[1)] Note: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE<br>**Sufficient creepage and air 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.** | | | |

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

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

**Supplementary information:**

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

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

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

**Supplementary information:**

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

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

| 8.10 | TABLE: List of critical components | | | | | P |
|---|---|---|---|---|---|---|
| **Component/ Part No.** | **Manufacturer/ Trademark** | **Type No./model No./** | **Technical data** | **Standard No./, Edition** | **Mark(s) & Certificates of conformity[1)]** | |
| **Enclosure (electrical, mechanical, fire)** | **+ Sabic Innovative Plastics China Co., Ltd.** | **SE1X** | **min. 94V-1 at min. 1,5 mm thickness; overall approx. 84 by 56 by 40 mm, min. 2,0 mm thick; 105°C** | **IEC/EN 60601-1**<br>**UL 746**<br>**Complies to IEC 60695-11-4** | **Checked with appliance.**<br>**UL E45329** | |
| | **+ Sabic Innovative Plastics China Co., Ltd.** | **SE100** | **min. 94V-1 at min. 1,5 mm thickness; overall approx. 84 by 56 by 40 mm, min. 2,0 mm thick; 95°C** | **IEC/EN 60601-1**<br>**UL 746**<br>**Complies to IEC 60695-11-4** | **Checked with appliance.**<br>**UL E45329** | |
| | **+ Sabic Innovative Plastics China Co., Ltd.** | **C2950** | **min. 94V-1 at min. 1,5 mm thickness; overall approx. 84 by 56 by 40 mm, min. 2,0 mm thick; 85°C** | **IEC/EN 60601-1**<br>**UL 746**<br>**Complies to IEC 60695-11-4** | **Checked with appliance.**<br>**UL E45329** | |
| | **+ Sabic Innovative Plastics China Co., Ltd.** | **SE1** | **min. 94V-1 at min. 0,75 mm thickness; overall approx. 84 by 56 by 40 mm, min. 2,0 mm thick; 105°C** | **IEC/EN 60601-1**<br>**UL 746**<br>**Complies to IEC 60695-11-4** | **Checked with appliance.**<br>**UL E45329** | |
| | **+ Sabic Innovative Plastics China Co., Ltd.** | **HF500R** | **min. 94V-10at min. 1,5 mm thickness; overall approx. 84 by 56 by 40 mm, min. 2,0 mm thick; 125°C** | **IEC/EN 60601-1**<br>**UL 746**<br>**Complies to IEC 60695-11-4** | **Checked with appliance.**<br>**UL E45329** | |
| | **+ Sabic Innovative Plastics China Co., Ltd.** | **CX7211** | **min. 94V-0 at min. 1,5 mm thickness; overall approx. 84 by 56 by 40 mm, min. 2,0 mm thick; 90°C** | **IEC/EN 60601-1**<br>**UL 746**<br>**Complies to IEC 60695-11-4** | **Checked with appliance.**<br>**UL E45329** | |

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

| | | | | | |
|---|---|---|---|---|---|
| | **+ Sabic Innovative Plastics China Co., Ltd.** | **EXCY0098** | **min. 94V-0 at min. 1,5 mm thickness; overall approx. 84 by 56 by 40 mm, min. 2,0 mm thick; 85°C** | **IEC/EN 60601-1**<br>**UL 746**<br>**Complies to IEC 60695-11-4** | **Checked with appliance.**<br>**UL E45329** |
| | **+ Sabic Innovative Plastics China Co., Ltd.**<br>**Rev. No.: 4.0** | **945** | **min. 94V-0 at min. 1,5 mm thickness; overall approx. 84 by 56 by 40 mm, min. 2,0 mm thick; 120°C** | **IEC/EN 60601-1**<br>**UL 746**<br>**(QMFZ2)** | **Accepted**<br>**UR E45329** |
| | **+ Chi Mei** | **PA-765A** | **min. 94V-1 at min. 1,5 mm thickness; overall approx. 84 by 56 by 40 mm, min. 2,0 mm thick; 80°C** | **IEC/EN 60601-1**<br>**UL 746**<br>**Complies to IEC 60695-11-4** | **Checked with appliance.**<br>**UL E56070** |
| **Blade holder** | **+ Sabic Innovative Plastics China Co., Ltd.** | **SE1X** | **Min. V-1, min. 1,5 mm thick, 105°C** | **IEC/EN 60601-1**<br>**UL 746**<br>**Complies to IEC 60695-11-4** | **Checked with appliance.**<br>**UL E45329** |
| **Output cable with moulded connector, ferrite core and strain relief or stripped and tinned** | **+ Yong Hao Electrical Industry Co., Ltd** | **Various** | **Min. 18AWG; VW-1; 80°C; 300V; one conductor and shield or two conductor minimum; polarized connector or open ends.** | **IEC/EN 60601-1**<br>**UL758 (AVLV2)** | **Checked with appliance**<br>**UR E240426** |
| | **+ Dongguan Guneetal Wire & Cable Co., Ltd.** | **Various** | **Min. 18AWG; VW-1; 80°C; 300V; one conductor and shield or two conductor minimum; polarized connector or open ends.** | **IEC/EN 60601-1**<br>**UL758 (AVLV2)** | **Checked with appliance**<br>**UR E204204** |
| **PCB (plug-in version)** | **+ Yuanman Printed Circuit Co. Ltd.** | **1V0** | **OD: 77,3 by 50 mm**<br>**Min. 1,5 mm** | **IEC/EN 60601-1**<br>**(ZPMV2)** | **Accepted.**<br>**UR E74757** |

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

| | | | | | |
|---|---|---|---|---|---|
| | | | thick<br>Min. UL94 V-0<br>Min. 130°C | | |
| PCB (FW open frame version) | + Yuanman Printed Circuit Co. Ltd. | 1V0 | OD: 98,2 by 50 mm<br>Min. 1,5 mm thick<br>Min. UL94 V-0<br>Min. 130°C | IEC/EN 60601-1<br>(ZPMV2) | Accepted.<br>UR E74757 |
| Fuse (F1, F2) | + Littelfuse | Microfuse, TE5, Type 392 | Time delay 1A; 250Vac; soldered to PCB | IEC/EN 60127-3/4<br>(JDYX2) | VDE 126983<br>UL E67006 |
| | + Conquer | Microfuse, TE5, Type MST | Time delay 1A; 250Vac; soldered to PCB | IEC/EN 60127-3/4<br>(JDYX2) | VDE 40017118<br>UL E82636 |
| | + Walter | 2010 | Time delay 1A; 250Vac; soldered to PCB | IEC/EN 60127-3/4<br>(JDYX2) | VDE 40018781<br>UL E56092 |
| Varistor (ZNR) (line to line) | + Centra Science Corp. | CNR-10D471K | 300 V rms; 385 V dc<br>diameter: 10 mm | IEC/EN 61051-2<br>(VZCA2) | VDE 40008220<br>UR E316325 |
| | + Centra Science Corp. | CNR-14D471K | 300 V rms; 385 V dc<br>diameter: 14 mm | IEC/EN 61051-2<br>(VZCA2) | VDE 40008220<br>UR E316325 |
| Bleeder resistors (RA, RB) | + Compostar or equivalent | 1206 | 0,25W; 510 kΩ | IEC/EN 60601-1 | Checked with appliance |
| X-capacitor (CX1) (line to neutral) | Ultra Tech Xiphi Enterprise Co., Ltd. | HQX | Min. 250Vac, 0,47µF; min. X2 | IEC/EN 60384-14<br>(FOWX2) | VDE 40015608<br>UR E183780 |
| | + Cheng Tung Industrial Co., Ltd. | CTX | Min. 250Vac, 0,47µF; min. X2 | IEC/EN 60384-14<br>(FOWX2) | VDE 40022642<br>UR E193049 |
| | + Tenta Electric Industrial Co., Ltd. | MEX | Min. 250Vac, 0,47µF; min. X2 | IEC/EN 60384-14<br>(FOWX2) | VDE 123198<br>UR E222911 |
| | + Pilkor Electronics Co., Ltd. | PCX2 | Min. 250Vac, 0,47µF; min. X2 | IEC/EN 60384-14 | Checked with appliance |

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

| | | | | | |
|---|---|---|---|---|---|
| | | | | **(FOWX2)** | **UR E165646** |
| | **+ Panasonic** | **ECQUL** | **Min. 250Vac, 0,47µF; min. X2** | **IEC/EN 60384-14**<br>**(FOWX2)** | **VDE 121548**<br>**UR E62674** |
| | **+ EVOX RIFA GROUP OYJ** | **PHE** | **Min. 250Vac, 0,47µF; min. X2** | **IEC/EN 60384-14**<br>**(FOWX2)** | **Checked with appliance**<br>**UR E73869** |
| | **+ Okaya Electri Industries Co., Ltd.** | **LE** | **Min. 250Vac, 0,47µF; min. X2** | **IEC/EN 60384-14**<br>**(FOWX2)** | **VDE 40021020**<br>**UR E47474** |
| | **+ Vishay BC components** | **339** | **Min. 250Vac, 0,47µF; min. X2** | **IEC/EN 60384-14**<br>**(FOWX2)** | **VDE 40031978**<br>**UR E354331** |
| **EMC common mode choke (NF1)** | **YAO Sheng Electronic, Top Nation Electronic, Ensign Electronic,GlobTek or equivalent**<br>**NF00009B**<br>**Open type construction**<br>**20 mH; 1,1 Ω**<br>**core: ferrite; UU10,5**<br>**coil: copper magnet wire wound on bobbin**<br>**bobbin (QMFZ2, min 94V-2): + Chang Chun, T373J and T375J, RTI, 94V-0, min. thickness (UL E59481S)**<br>**Temperature Class: 130°C** | | | **IEC/EN 60601-1** | **Checked with appliance** |
| **Bridge rectifier (BD1)** | **+ Various** | **DF06M or equivalent** | **1A; 600V** | **IEC/EN 60601-1** | **Accepted** |
| **Bulk (C2)** | **+ Samxon or equivalent** | **KM or equivalent** | **400V; 33 µF to 47 µF; 105°C** | **IEC/EN 60601-1** | **Accepted** |
| **Transformer (T1) for models: 5 Vdc - 30 Vdc (primary to secondary) (reinforced insulation)** | **YOUNG SHANG Electronic Co., Ltd.**<br>**Alternative: GlobTek**<br>**Models:**<br>**XF00290 (5 Vdc)**<br>**XF00290A (5,1-6 Vdc)**<br>**XF00328 (6,1-10 Vdc)**<br>**XF00291 (10,1-15 Vdc)**<br>**XF00318 (15,1-18 Vdc)** | | | **IEC/EN 60601-1** | **Accepted** |

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

| | | | | | |
|---|---|---|---|---|---|
| | **XF00295 (18,1-20 Vdc)**<br>**XF00230 (20,1-24 Vdc)**<br>**XF00292 (24,1-30 Vdc)**<br>**Open type construction**<br>**-core: ferrite, EF-25**<br>**-coil, primary: polyurethane enamelled magnet copper wire wound on bobbin; magnet wire: +Pacific Electric Wire & Cable Co., Ltd (OBMW2.E201757)**<br>**-coil, secondary: polyurethane enamelled magnet copper wire wound on bobbin; magnet wire: +Pacific Electric Wire & Cable Co., Ltd (OBMW2.E201757)**<br>**Insulation tape placed on the shield.**<br>**Temperature class: Class B (130°C)** | | | | |
| **-- bobbin** | **Chang Chun Plastics Co., Ltd.** | **T375J** | **Phenolic**<br>**V-0 at min. 0,45 mm**<br>**Min. 150°C** | **(QMFZ2)** | **UL E59481** |
| | **Chang Chun Plastics Co., Ltd.** | **T375HF** | **Phenolic**<br>**V-0 at min. 0,43 mm**<br>**Min. 150°C** | **(QMFZ2)** | **UL E59481** |
| | **Sumitomo Bakelite Co., Ltd.** | **PM-9820** | **Phenolic**<br>**V-0 at min. 0,16 mm**<br>**Min. 150°C** | **(QMFZ2)** | **UL E41429** |
| | **Sumitomo Bakelite Co., Ltd.** | **PM-9630** | **Phenolic**<br>**V-0 at min. 0,16 mm**<br>**Min. 150°C** | **(QMFZ2)** | **UL E41429** |
| **-- UL insulation system** | **GlobTek** | **GTX-130-TM** | **Class B (130°C)** | **(OBJY2)** | **UL E243347** |
| | **Yao Sheng** | **M7AGHB** | **Class B (130°C)** | **(OBJY2)** | **UL E173643** |
| | **Yao Sheng** | **YCI-130** | **Class B (130°C)** | **(OBJY2)** | **UL E173643** |
| | **BOAM** | **BOAM-01** | **Class B (130°C)** | **(OBJY2)** | **UL E252329** |
| | | | **Class B (130°C)** | **(OBJY2)** | **UL E308897** |
| **Bridging** | **+ Murata MFG** | **KX** | **250V; X1/Y1** | **IEC/EN 60384-** | **VDE 40002831** |

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

| | | | | | |
|---|---|---|---|---|---|
| **capacitor (CY1) (reinforced)**<br>**(between primary and secondary)**<br>**(single capacitor for MOOP)** | **Co., Ltd** | | **1nF max.** | **14**<br>**(FOWX2)** | **UL E37921** |
| | **+ TDK Corp.** | **CD** | **250V; X1/Y1 1nF max.** | **IEC/EN 60384-14**<br>**(FOWX2)** | **VDE 40029780**<br>**UL E37861** |
| | **+ Welson Industrial Co., Ltd** | **WD** | **250V; X1/Y1 1nF max.** | **IEC/EN 60384-14**<br>**(FOWX2)** | **VDE 40016157**<br>**UL E104572** |
| | **+ Chyun Fuh Electronic Co., Ltd** | **CD** | **250V; X1/Y1 1nF max.** | **IEC/EN 60384-14** | **VDE 40001223** |
| | **+ JYA-NAY Co., Ltd** | **JN** | **250V; X1/Y1 1nF max.** | **IEC/EN 60384-14**<br>**(FOWX2)** | **VDE 40001831**<br>**UL E201384** |
| **Bridging capacitor (CY1, CY2)**<br>**(reinforced)**<br>**(in series between primary and secondary)**<br>**(for models marked with 2MOPP)** | **+ Murata MFG Co., Ltd** | **KX** | **250V; X1/Y1 1nF max.** | **IEC/EN 60384-14**<br>**(FOWX2)** | **VDE 40002831**<br>**UL E37921** |
| | **+ TDK Corp.** | **CD** | **250V; X1/Y1 1nF max.** | **IEC/EN 60384-14**<br>**(FOWX2)** | **VDE 40029780**<br>**UL E37861** |
| | **+ Welson Industrial Co., Ltd** | **WD** | **250V; X1/Y1 1nF max.** | **IEC/EN 60384-14**<br>**(FOWX2)** | **VDE 40016157**<br>**UL E104572** |
| | **+ Chyun Fuh Electronic Co., Ltd** | **CD** | **250V; X1/Y1 1nF max.** | **IEC/EN 60384-14** | **VDE 40001223** |
| | **+ JYA-NAY Co., Ltd** | **JN** | **250V; X1/Y1 1nF max.** | **IEC/EN 60384-14**<br>**(FOWX2)** | **VDE 40001831**<br>**UL E201384** |
| **Optical isolator (PC1)**<br>**(primary to secondary)** | **LITE-ON** | **LTV-817C** | **Thermal cycling test performed (Clause 8.9.3)**<br>**Grid: 10,16 mm**<br>**External clearance / creepage distance: ≥ 8,0 mm**<br>**DTI: ≥ 0,4 mm**<br>**5000 Vac** | **IEC/EN 60601-1**<br>**IEC/EN 60747-5-2**<br>**(FPQU2)** | **T223-0437/12**<br>**VDE 40015248**<br>**SGS FI 24426 M3**<br>**UL E113898** |
| | **EVERLIGHT** | **EL817** | **Thermal cycling test** | **IEC/EN 60601-1**<br>**IEC/EN 60747-5-** | **T223-0106/13** |

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

| | | | | | |
|---|---|---|---|---|---|
| | | | **performed (Clause 8.9.3)**<br>**Grid: 10,16 mm**<br>**External clearance / creepage distance: ≥ 8,0 mm**<br>**DTI: ≥ 0,4 mm**<br>**5000 Vac** | **2**<br>**(FPQU2)** | **VDE 132249**<br>**CQC 08001022762**<br>**UL E214129** |
| **Inductor (L1)** | **+ Ensign Electronics or Globtek**<br>**RC00002**<br>**Open type construction**<br>**4,2 µH; 2A**<br>**Core: ferrite; 6mm OD by 15mm**<br>**Coil/magnet wire: +Pacific Electric Wire & Cable Co., Ltd (OBMW2.E84081) Class B (130°C); + TAI-I Electric Wire & Cable Co., Ltd (OBMW2.E85640)**<br>**Class B (130°C);** | | | **IEC/EN 60601-1** | **Accepted** |

**Supplementary information:**
1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

| **8.10 b** | **TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS** | | | | **N/A** |
|---|---|---|---|---|---|
| **Component/ Part No.** | **Manufacturer/ Trademark** | **Type No./model No./** | **Technical data** | **Standard No./, Edition** | **Mark(s) & Certificates of conformity[1)]** |
| | | | | | |

**Supplementary information:**
1) Indicates a mark which assures the agreed level of surveillance. See Licenses and Certificates of Conformity for verification.

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

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

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

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

| 9.2.3.2 | TABLE: Over-travel End Stop Test | N/A |
|---|---|---|
| **ME EQUIPMENT end stop** | **Test Condition (cycles, load, speed)** | **Remarks** |
| | | |
| **Supplementary information: No moving part.** | | |

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

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

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

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

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

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

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

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

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

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

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

| 9.7.5 | TABLE: Pressure vessels | | | | N/A |
|---|---|---|---|---|---|
| **Hydraulic, Pneumatic or Suitable Media and Test Pressure** | **Vessel Burst** | **Permanent Deformation** | **Leaks** | **Vessel fluid substance** | **Remarks** |
| | | | | | |
| **Supplementary Information: No pressure vessels provided.** | | | | | |

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

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

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

| 10.1.1 | TABLE: Measurement of X - radiation | | N/A |
|---|---|---|---|
| **Maximum allowable radiation pA/kg ( µSv/h) (mR/h)** | | **36 (5 µSv/h) (0.5 mR/h)** | |
| **Surface area under test Surface no./ Description[1)]** | | **Measured Radiation, pA/kg (µSv/h) (mR/h)** | **Remarks** |
| **1/ /** | | | |
| **2/ /** | | | |
| **3/ /** | | | |
| **4/ /** | | | |
| **5/ /** | | | |
| **6/ /** | | | |
| **7/ /** | | | |
| **8/ /** | | | |
| **9/ /** | | | |
| **10/ /** | | | |
| | | | |

**Supplementary information:**
[1)] Measurements made at a distance of 5 cm from any surface to which OPERATOR (other than SERVICE PERSONNEL) can gain access without a TOOL, is deliberately provided with means of access, or is instructed to enter regardless of whether or not a TOOL is needed to gain access

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

| 11.1.1 | TABLE: Excessive temperatures in ME EQUIPMENT | | | | | P |
|---|---|---|---|---|---|---|
| Model No. ..... : | | 1 | 2 | 3 | 4 | — |
| Test ambient (°C) ..... : | | 40 | 40 | 40 | 40 | — |
| Test supply voltage/frequency (V/Hz)[4].. : | | 90/60 | 264/50 | 90/60 | 264/50 | — |
| Model No. | Thermo-couple No. | Thermocouple location[3] | Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C) | Max measured temperature[2], (°C) | Remarks | |
| GTM41060-1505 | | | | | | |
| 1 | 1 | Transformer core | 120 | 94,9 | -- | |
| | 2 | Transformer winding outer wrap | 120 | 88,0 | -- | |
| | 3 | Bulk capacitor – Top | 105 | 84,6 | -- | |
| | 4 | Inductor NF1 winding – primary side | 120 | 85,5 | -- | |
| | 5 | Inductor L1 core (top) and Output lead (+ inside enclosure) | 95 | 86,7 | -- | |
| | 6 | Enclosure top (See note 1) | 71 | 61,1 | -- | |
| | 7 | Enclosure bottom – detachable blade assembly (See note 2) | 86 | 65,7 | -- | |
| 2 | 1 | Transformer core | 120 | 96,3 | -- | |
| | 2 | Transformer winding outer wrap | 120 | 88,3 | -- | |
| | 3 | Bulk capacitor – Top | 105 | 80,8 | -- | |
| | 4 | Inductor NF1 winding – primary side | 120 | 78,8 | -- | |
| | 5 | Inductor L1 core (top) and Output lead (+ inside enclosure) | 95 | 87,0 | -- | |
| | 6 | Enclosure top (See note 1) | 71 | 61,8 | -- | |
| | 7 | Enclosure bottom – detachable blade assembly (See note 2) | 86 | 57,5 | -- | |
| GTM41060-2512 | | | | | | |
| 3 | 1 | Transformer core | 120 | 116,8 | -- | |
| | 2 | Transformer winding outer wrap | 120 | 104,0 | -- | |

| IEC 60601-1 | | | | | |
|---|---|---|---|---|---|
| Clause | Requirement + Test | | Result - Remark | | Verdict |
| | **3** | **Bulk capacitor – Top** | **105** | **102,0** | **--** |
| | **4** | **Inductor NF1 winding – primary side** | **120** | **119,9 *)** | **--** |
| | **5** | **Inductor L1 core (top) and Output lead (+ inside enclosure)** | **95** | **87,4** | **--** |
| | **6** | **Enclosure top (See note 1)** | **71** | **70,9 *)** | **--** |
| | **7** | **Enclosure bottom – detachable blade assembly (See note 2)** | **86** | **83,9 *)** | **--** |
| **4** | **1** | **Transformer core** | **120** | **112,8** | **--** |
| | **2** | **Transformer winding outer wrap** | **120** | **99,2** | **--** |
| | **3** | **Bulk capacitor – Top** | **105** | **94,3** | **--** |
| | **4** | **Inductor NF1 winding – primary side** | **120** | **93,2** | **--** |
| | **5** | **Inductor L1 core (top) and Output lead (+ inside enclosure)** | **95** | **89,2** | **--** |
| | **6** | **Enclosure top (See note 1)** | **71** | **70,4 *)** | **--** |
| | **7** | **Enclosure bottom – detachable blade assembly (See note 2)** | **86** | **77,0** | **--** |

**Supplementary information:**

1) Maximum allowable temperature on surfaces of test corner is 90 °C
2) Max temperature determined in accordance with 11.1.3e)
3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
4) Supply voltage:

- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.

- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

5) **APPLIED PARTS** intended to supply heat to a **PATIENT - S**ee RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

**Information from Risk Management, as applicable:**

**Note 1: External surface that is likely to be touched for the time less than 1 second.**

**Note 2: External surface that is likely to be touched for the time between 1 and 10 seconds.**

**Power supply unit is not end medical product, contact time for different external parts shall be additionally evaluated during end medical product approval.**

***) It is not possible to state compliance using a 95% coverage probability for the expanded uncertainty. Expanded uncertainty: U = 3°C (coverage factor kp = 2; confidence level: 95 %).**

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

| 11.1.1 | TABLE: Excessive temperatures in ME EQUIPMENT | | | | P |
|---|---|---|---|---|---|
| Model No. ..... : | 1 | 2 | 3 | 4 | — |
| Test ambient (°C) ..... : | 40 | 40 | 40 | 40 | — |
| Test supply voltage/frequency (V/Hz)[4].. : | 90/60 | 264/50 | 90/60 | 264/50 | — |

| Model No. | Thermo-couple No. | Thermocouple location[3] | Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C) | Max measured temperature[2], (°C) | Remarks |
|---|---|---|---|---|---|
| GTM41060-2524 | | | | | |
| 1 | 1 | Transformer core | 120 | 97,0 | -- |
| | 2 | Transformer winding outer wrap | 120 | 95,0 | -- |
| | 3 | Bulk capacitor – Top | 105 | 91,3 | -- |
| | 4 | Inductor NF1 winding – primary side | 120 | 103,1 | -- |
| | 5 | Inductor L1 core (top) and Output lead (+ inside enclosure) | 95 | 72,7 | -- |
| | 6 | Enclosure top (See note 1) | 71 | 67,1 | -- |
| | 7 | Enclosure bottom – detachable blade assembly (See note 2) | 86 | 63,1 | -- |
| 2 | 1 | Transformer core | 120 | 101,7 | -- |
| | 2 | Transformer winding outer wrap | 120 | 96,7 | -- |
| | 3 | Bulk capacitor – Top | 105 | 83,6 | -- |
| | 4 | Inductor NF1 winding – primary side | 120 | 82,7 | -- |
| | 5 | Inductor L1 core (top) and Output lead (+ inside enclosure) | 95 | 79,8 | -- |
| | 6 | Enclosure top (See note 1) | 71 | 69,4 *) | -- |
| | 7 | Enclosure bottom – detachable blade assembly (See note 2) | 86 | 62,0 | -- |
| GTM41060-2530 | | | | | |
| 3 | 1 | Transformer core | 120 | 98,9 | -- |
| | 2 | Transformer winding outer wrap | 120 | 90,8 | -- |

| IEC 60601-1 | | | | | |
|---|---|---|---|---|---|
| Clause | Requirement + Test | | Result - Remark | | Verdict |
| | **3** | **Bulk capacitor – Top** | **105** | **90,8** | **--** |
| | **4** | **Inductor NF1 winding – primary side** | **120** | **101,9** | **--** |
| | **5** | **Inductor L1 core (top) and Output lead (+ inside enclosure)** | **95** | **68,2** | **--** |
| | **6** | **Enclosure top (See note 1)** | **71** | **70,0 *)** | **--** |
| | **7** | **Enclosure bottom – detachable blade assembly (See note 2)** | **86** | **71,1** | **--** |
| **4** | **1** | **Transformer core** | **120** | **107,0** | **--** |
| | **2** | **Transformer winding outer wrap** | **120** | **94,1** | **--** |
| | **3** | **Bulk capacitor – Top** | **105** | **84,2** | **--** |
| | **4** | **Inductor NF1 winding – primary side** | **120** | **84,4** | **--** |
| | **5** | **Inductor L1 core (top) and Output lead (+ inside enclosure)** | **95** | **76,4** | **--** |
| | **6** | **Enclosure top (See note 1)** | **71** | **70,3 *)** | **--** |
| | **7** | **Enclosure bottom – detachable blade assembly (See note 2)** | **86** | **68,4** | **--** |

**Supplementary information:**

1) Maximum allowable temperature on surfaces of test corner is 90 °C
2) Max temperature determined in accordance with 11.1.3e)
3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
4) Supply voltage:

- ME EQUIPMENT with heating elements - 110 % of the maximum RATED voltage;
- Motor operated ME EQUIPMENT - least favourable voltage between 90 % of the minimum RATED and 110 % of the maximum RATED voltage. ME EQUIPMENT operated under normal load and normal DUTY CYCLE.

- Combined heating and motor operated and other ME EQUIPMENT - tested both at 110 % of the maximum RATED voltage and at 90 % of the minimum RATED voltage.

5) **APPLIED PARTS** intended to supply heat to a **PATIENT - S**ee RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

**Information from Risk Management, as applicable:**

**Note 1: External surface that is likely to be touched for the time less than 1 second.**

**Note 2: External surface that is likely to be touched for the time between 1 and 10 seconds.**

**Power supply unit is not end medical product, contact time for different external parts shall be additionally evaluated during end medical product approval.**

***) It is not possible to state compliance using a 95% coverage probability for the expanded uncertainty. Expanded uncertainty: U = 3°C (coverage factor kp = 2; confidence level: 95 %).**

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

| 11.1.1 | TABLE: Excessive temperatures in me equipment | | | | P |
|---|---|---|---|---|---|
| Model No. ..... : | 1 | 2 | 3 | 4 | — |
| Test ambient (°C) ..... : | 40 | 40 | 40 | 40 | — |
| Test supply voltage/frequency (V/Hz)[4].. : | 90/60 | 264/50 | 90/60 | 264/50 | — |

| Model No. | Thermo-couple No. | Thermocouple location[3] | Max allowable temperature[1] from Table 22, 23 or 24 or RM file for AP[5] (°C) | Max measured temperature[2], (°C) | Remarks |
|---|---|---|---|---|---|
| GTM41060-2518-FW | | | | | |
| 1 | 1 | Transformer core | 120 | 77,3 | -- |
| | 2 | Transformer winding outer wrap | 120 | 71,3 | -- |
| | 3 | Bulk capacitor – Top | 105 | 72,0 | -- |
| | 4 | Inductor NF1 winding – primary side | 120 | 83,5 | -- |
| | 5 | Inductor L1 core (top) and Output lead (+ inside enclosure) | 95 | 52,6 | -- |
| | 6 | Primary heat sink | -- | 64,4 | -- |
| | 7 | Secondary heat sink | -- | 66,2 | -- |
| 2 | 1 | Transformer core | 120 | 87,8 | -- |
| | 2 | Transformer winding outer wrap | 120 | 79,5 | -- |
| | 3 | Bulk capacitor – Top | 105 | 69,3 | -- |
| | 4 | Inductor NF1 winding – primary side | 120 | 65,9 | -- |
| | 5 | Inductor L1 core (top) and Output lead (+ inside enclosure) | 95 | 63,8 | -- |
| | 6 | Primary heat sink | -- | 69,5 | -- |
| | 7 | Secondary heat sink | -- | 68,0 | -- |
| GTM41060-2524-FW | | | | | |
| 3 | 1 | Transformer core | 120 | 97,0 | -- |
| | 2 | Transformer winding outer wrap | 120 | 95,0 | -- |
| | 3 | Bulk capacitor – Top | 105 | 91,3 | -- |
| | 4 | Inductor NF1 winding – primary side | 120 | 103,1 | -- |

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

| | | | | | |
|---|---|---|---|---|---|
| | **5** | **Inductor L1 core (top) and Output lead (+ inside enclosure)** | **95** | **72,7** | **--** |
| | **6** | **Primary heat sink** | **--** | **67,1** | **--** |
| | **7** | **Secondary heat sink** | **--** | **63,1** | **--** |
| **4** | **1** | **Transformer core** | **120** | **93,0** | **--** |
| | **2** | **Transformer winding outer wrap** | **120** | **83,5** | **--** |
| | **3** | **Bulk capacitor – Top** | **105** | **67,7** | **--** |
| | **4** | **Inductor NF1 winding – primary side** | **120** | **65,3** | **--** |
| | **5** | **Inductor L1 core (top) and Output lead (+ inside enclosure)** | **95** | **63,7** | **--** |
| | **6** | **Primary heat sink** | **--** | **64,8** | **--** |
| | **7** | **Secondary heat sink** | **--** | **80,6** | **--** |

**Supplementary information:**

1) Maximum allowable temperature on surfaces of test corner is 90 °C
2) Max temperature determined in accordance with 11.1.3e)
3) When thermocouples used to determine temperature of windings, limits of Table 22 reduced by 10 °C.
4) Supply voltage:

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

5) **APPLIED PARTS** intended to supply heat to a **PATIENT - S**ee RISK MANAGEMENT FILE containing temperatures and clinical effects. Also, see instructions for use.

**Information from Risk Management, as applicable:**

**No external enclosure provided.**

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

| 11.1.3d | TABLE: Temperature of windings by change-of-resistance method | | | | | | | N/A |
|---|---|---|---|---|---|---|---|---|
| Temperature T of winding: | | $t_1$ (°C) | $R_1$ (Ω) | $t_2$ (°C) | $R_2$ (Ω) | T (°C) | Allowed $T_{max}$ (°C) | Insulation class |
| | | | | | | | | |
| **Supplementary information:**<br>**Switch mode transformer incorporated. Temperature rise measured was measured on the transformer windings by thermocouple.** | | | | | | | | |

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

| 11.2.2.1 | TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source | | N/A |
|---|---|---|---|
| **Areas where sparking might cause ignition:** | | **Remarks** | |
| **1.** | | | |
| **2.** | | | |
| **3.** | | | |
| **4.** | | | |
| **5.** | | | |
| **6.** | | | |
| **Materials of the parts between which sparks could occur (Composition, Grade Designation, Manufacturer):** | | **Remarks** | |
| **1.** | | | |
| **2.** | | | |
| **3.** | | | |
| **4.** | | | |
| **5.** | | | |
| **6.** | | | |
| **Test parameters selected representing worst case conditions for ME EQUIPMENT:** | | **Remarks** | |
| **Oxygen concentration (%) ..... :** | | | |
| **Fuel..... :** | | | |
| **Current (A)..... :** | | | |
| **Voltage (V)..... :** | | | |
| **Capacitance (μF) ..... :** | | | |
| **Inductance or resistance (h or Ω) .... :** | | | |
| **No. of trials (300 Min)..... :** | | | |
| **Sparks resulted in ignition (Yes/No) :** | | | |
| **Supplementary information:** Test procedure of 11.2.2.1 a) 5) & Figs 35-37 used for tests. For circuits not in Figs 35-37, test voltage or current set at 3 times the worst case values with other parameters set at worst case values to determine if ignition can occur.<br>**Information from Risk Management, as applicable:** | | | |

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

| 11.6.1 | TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances | | N/A |
|---|---|---|---|
| **Clause / Test Name** | **Test Condition** | **Part under test** | **Remarks** |
| | | | |
| **Supplementary information:**<br><br>**Information from Risk Management, as applicable:** | | | |

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

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

| 13.2 | TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive | | P |
|---|---|---|---|
| **Clause No.** | **Description of SINGLE FAULT CONDITION** | **Results observed** | **HAZARDOUS SITUATION (Yes/No)** |
| **13.2.2** | **Electrical SINGLE FAULT CONDITIONS per Cl. 8.1:** | **—** | **—** |
| | **Varistor MOV1, Capacitor CX1 shorted** | **F1, F2 opened immediately.**<br>**No hazard.** | **NO** |
| | **Resistor R1 shorted** | **No effect on function.**<br>**No defect. No hazard.** | **NO** |
| | **Capacitor C1 shorted** | **F1, F2 opened immediately.**<br>**No hazard.** | **NO** |
| | **Capacitor C2 shorted** | **Power supply folds back**<br>**Duration of test 4 h.**<br>**No defect. No hazard.**<br>**Normal operation after short removed.** | **NO** |
| | **Diode D4 shorted (30 V model)** | **Unit switched off immediately.**<br>**No defect. No hazard.** | **NO** |
| | **Capacitor C6 shorted** | **Power supply does not operate.**<br>**No defect. No hazard.**<br>**Normal operation after short removed.** | **NO** |
| | **Capacitor C7 shorted** | **Power supply folds back.**<br>**Duration of test 1 h.**<br>**No defect. No hazard.**<br>**Normal operation after short removed.** | **NO** |
| | **Capacitor C8 shorted** | **Power supply folds back.**<br>**Duration of test 1 h.**<br>**No defect. No hazard.**<br>**Normal operation after short removed.** | **NO** |
| | **Capacitor C9, C12, Diode ZD1 shorted** | **Power supply folds back.**<br>**Duration of test 1 h.**<br>**No defect. No hazard.**<br>**Normal operation after short removed.** | **NO** |

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

| Clause No. | Description of SINGLE FAULT CONDITION | Results observed | HAZARDOUS SITUATION (Yes/No) |
|---|---|---|---|
| | **Capacitor C13 shorted GTM41060-2524** | **Output voltage dropped to 5,4V due short on feedback ref. voltage amplifier.**<br>**Duration of test 1 h.**<br>**No defect. No hazard.**<br>**Normal operation after short removed.** | **NO** |
| | **Capacitor C15 shorted GTM41060-2524** | **Output voltage dropped to 1,2V due short on feedback ref. voltage amplifier.**<br>**Duration of test 1 h.**<br>**No defect. No hazard.**<br>**Normal operation after short removed.** | **NO** |
| | **Output overload GTM41060-1505** | **Output voltage: 3,70 Vdc.**<br>**Output current: 4,03 A max.**<br>**Maximum temperature on transformer: 89,4°C at 22,8°C ambient temperature.**<br>**No hazard. No defect.** | **NO** |
| | **Output shorted GTM41060-1505** | **Unit switched off.**<br>**No hazard. No defect.** | **NO** |
| | **Output overload GTM41060-2512** | **Output voltage: 9,70 Vdc.**<br>**Output current: 2,33 A max.**<br>**Maximum temperature on transformer: 107,6°C at 24,7°C ambient temperature.**<br>**No hazard. No defect.** | **NO** |
| | **Output shorted GTM41060-2512** | **Unit switched off.**<br>**No hazard. No defect.** | **NO** |
| | **Output overload GTM41060-2524** | **Output voltage: 16,3 Vdc.**<br>**Output current: 1,55 A max.**<br>**Maximum temperature on transformer: 102,6°C at 24,7°C ambient temperature.**<br>**No hazard. No defect.** | **NO** |
| | **Output shorted GTM41060-2524** | **Unit switched off.**<br>**No hazard. No defect.** | **NO** |

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

| Clause No. | Description of SINGLE FAULT CONDITION | Results observed | HAZARDOUS SITUATION (Yes/No) |
|---|---|---|---|
| | **Output overload GTM41060-2530** | **Output voltage: 12,0 Vdc.**<br>**Output current: 1,21 A max.**<br>**Maximum temperature on transformer: 80,1°C at 24,7°C ambient temperature.**<br>**No hazard. No defect.** | **NO** |
| | **Output shorted GTM41060-2530** | **Unit switched off.**<br>**No hazard. No defect.** | **NO** |
| | **Output overload GTM41060-2518-FW** | **Output voltage: 17,6 Vdc.**<br>**Output current: 2,20 A max.**<br>**Maximum temperature on transformer: 126,8°C at 22,3°C ambient temperature.**<br>**No hazard. No defect.** | **NO** |
| | **Output shorted GTM41060-2518-FW** | **Unit switched off.**<br>**No hazard. No defect.** | **NO** |
| | **Output overload GTM41060-2524-FW** | **Output voltage: 24,3 Vdc.**<br>**Output current: 1,85 A max.**<br>**Maximum temperature on transformer: 122,5°C at 22,8°C ambient temperature.**<br>**No hazard. No defect.** | **NO** |
| | **Output shorted GTM41060-2524-FW** | **Unit switched off.**<br>**No hazard. No defect.** | **NO** |
| | **Opto isolator PC1, shorted pins 1, 2 (GTM41060-2530)** | **Output voltage: 36,0 Vdc.**<br>**No hazard. No defect.** | **NO** |
| | **Opto isolator PC1, shorted pins 3, 4 (GTM41060-2530)** | **Output voltage: 0,2 Vdc.**<br>**No hazard. No defect.** | **NO** |
| **13.2.3** | **Overheating of transformers per Clause 15.5:** | **—** | **—** |
| | **Transformer short circuit** | **See Clause 15.5.1.2 for details.** | **NO** |
| | **Transformer overload** | **See Clause 15.5.1.3 for details.** | **NO** |
| **13.2.4** | **Failure of THERMOSTATS according to 13.2.13 & 15.4.2, overloading - THERMOSTATS short circuited or interrupted, the less favourable of the two:** | **—** | **—** |
| | **No thermostats incorporated** | **--** | **--** |

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

| Clause No. | Description of SINGLE FAULT CONDITION | Results observed | HAZARDOUS SITUATION (Yes/No) |
|---|---|---|---|
| 13.2.5 | Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two: | — | — |
| | No temperature limiting devices incorporated. | -- | -- |
| 13.2.6 | Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted) | — | — |
| | No liquid used. | -- | -- |
| 13.2.7 | Impairment of cooling that could result in a HAZARD using test method of 11.1: | — | — |
| | Single ventilation fans locked consecutively | No fan provided. | -- |
| | Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls | No opening provided. | -- |
| | 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: | — | — |
| | No moving part provided. | -- | -- |
| 13.2.9 | Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1)] – Also see 13.10 | — | — |
| | -- | V measured = | -- |
| 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 motor 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 motor provided. | -- |
| | Temperatures measured as specified in 11.1.3 d) | No motor provided. | -- |
| | Temperatures did not exceed limits of Table 26 | No motor provided. | -- |
| 13.2.11 | Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS: | — | — |
| | MEE is not intended to be used in an oxygen rich environment. | -- | -- |

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

| Clause No. | Description of SINGLE FAULT CONDITION | Results observed | HAZARDOUS SITUATION (Yes/No) |
|---|---|---|---|
| **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.**

**Information from Risk Management, as applicable:**

| **15.3** | **TABLE: Mechanical Strength tests 1)** | | **P** |
|---|---|---|---|
| **Clause** | **Name of Test** | **Test conditions** | **Observed results/Remarks** |
| **15.3.2** | **Push Test** | **Force = 250 N ± 10 N for 5 s** | **No damage on the plastic enclosure.**<br>**Test conducted on plug in version.** |
| **15.3.3** | **Impact Test** | **Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m** | **No damage on the plastic enclosure.**<br>**Test conducted on plug in version.** |
| **15.3.4.1** | **Drop Test (hand-held)** | **Free fall height (m) = 1 m** | **No damage on the plastic enclosure.**<br>**Test conducted on plug in version.** |
| **15.3.4.2** | **Drop Test (portable)** | **Drop height: 5 cm** | **No damage on the plastic enclosure.**<br>**Test conducted on plug in version.** |
| **15.3.6** | **Mould Stress Relief** | **7 h in oven at temperature (°C) = 94°C** | **No damage on the plastic enclosure.**<br>**Test conducted on plug in version.** |
| **15.3.2** | **Push Test** | **Force = 250 N ± 10 N for 5 s** | **No damage on the plastic enclosure.**<br>**Test conducted on plug in version.** |
| **15.3.3** | **Impact Test** | **Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m** | **No damage on the plastic enclosure.**<br>**Test conducted on plug in version.** |

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

**Supplementary information:** 1) As applicable, Push, Impact, Drop, Mould Stress Relief and Rough Handling Tests (delete not applicable rows or state N/A in Remarks field).

| 15.4.6 | TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests | | | | N/A |
|---|---|---|---|---|---|
| **Rotating control under test** | **Gripping diameter "d" of control knob (mm)1)** | **Torque from Table 30 (Nm)** | **Axial force applied (N)** | **Unacceptable RISK occurred Yes/No** | **Remarks** |
| | | | | | |

**Supplementary information:** 1) Gripping diameter (d) is the maximum width of a control knob regardless of its shape (e.g. control knob with pointer)

**No such parts provided.**

| 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 | | | | | | P |
|---|---|---|---|---|---|---|---|
| **Primary voltage (most adverse value from 90 % to 110 % of RATED voltage)(V)1) ...:** | | | | | **264 V** | | **—** |
| **RATED input 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)** | **Maximum allowed temp from Table 31 (ºC)** | **Maximum winding temp measured (ºC)** | **Ambient (ºC)** |
| **Pin 5-6** | **B** | **Inherently** | **No** | **--** | **165** | **27,2** | **22,3** |

**Supplementary information:**
1) Loads on other windings between no load and their NORMAL USE load. Short-circuit applied at end of windings or at the first point that could be short circuited under SINGLE FAULT CONDITION.

**Short circuit of the transformer was performed between pin 5 and pin 6 of T1. EUT switched off immediately, therefore no temperature rise was observed during performing short circuit. Maximum allowed temperature from Table 31 is reduced for 10°C for TC measuring method.**

| 15.5.1.3 | TABLE: transformer overload test – conducted only when protective device under short-circuit test operated | | | | | P |
|---|---|---|---|---|---|---|
| **Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)1) ..... :** | | | | | | **264 V** |
| **RATED input frequency (Hz) ..... :** | | | | | | **50 Hz** |
| **Test current just below minimum current that would activate protective device and achieve THERMAL STABILITY under method a) (A) ..... :** | | | | | | **Inherently protection** |
| **Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A) ..... :** | | | | | | **--** |
| **Winding tested** | **Class of insulation (A, B, E, F, H)** | **Type of protective device used (fuse, circuit breaker)/Ratings** | **Maximum allowed temp from Table 31 (ºC)** | **Maximum winding temp measured (ºC)** | **Ambient (ºC)** | |
| **GTM41060-1505** | | | | | | |
| **Pin 5-6** | **B** | **Inherently** | **165** | **89,4** | **22,8** | |

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

| | | | | | |
|---|---|---|---|---|---|
| **GTM41060-2512** | | | | | |
| **Pin 5-6** | **B** | **Inherently** | **165** | **107,6** | **24,7** |
| **GTM41060-2524** | | | | | |
| **Pin 5-6** | **B** | **Inherently** | **165** | **102,6** | **24,7** |
| **GTM41060-2530** | | | | | |
| **Pin 5-6** | **B** | **Inherently** | **165** | **80,1** | **24,7** |
| **GTM41060-41060-2518-FW** | | | | | |
| **Pin 5-6** | **B** | **Inherently** | **165** | **126,8** | **22,3** |
| **GTM41060-2524-FW** | | | | | |
| **Pin 5-6** | **B** | **Inherently** | **165** | **122,5** | **22,8** |

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

| **15.5.2** | **TABLE: Transformer dielectric strength after humidity preconditioning of 5.7** | | | | **N/A** |
|---|---|---|---|---|---|
| **Transformer Model/Type/ Part No** | **Test voltage applied between** | **Test voltage, (V)** | **Test frequency (Hz)** | **Breakdown Yes/No** | **Deterioration Yes/No** |
| | **Primary & secondary windings** | | | | |
| | **Primary winding & frame** | | | | |
| | **Secondary winding & frame** | | | | |

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

**Switch mode transformers provided; therefore this test not relevant.**

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

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

| SP | TABLE: Additional or special tests conducted | | P |
|---|---|---|---|
| **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** | |
| **Supplementary information:** | | | |

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

| | TABLE: evaluation of voltage limiting components in SELV circuits | | | P |
|---|---|---|---|---|
| **Component (measured between)** | | **max. voltage (V) (normal operation)** | | **Voltage Limiting Components** |
| **Transformer identification** | **Transformer output winding** | **V peak** | **V d.c.** | |
| **Power supply GTM41060-1505** | | | | |
| **Secondary winding of T1** | **Pin 5 – 6** | **35,2Vpk/ 8,1Vrms** | | **--** |
| **--** | **Pin 6 to cathode of D4** | **33,3 Vpk/ 30,2 Vdc** | | **D4** |
| **Power supply GTM41060-2512** | | | | |
| **Secondary winding of T1** | **Pin 5 – 6** | **88,8 Vpk/ 22,3 Vrms** | | **--** |
| **--** | **Pin 6 to cathode of D4** | **13,0 Vpk/ 12,5 Vdc** | | **D4** |
| **Power supply GTM41060-2524** | | | | |
| **Secondary winding of T1** | **Pin 5 – 6** | **156 Vpk/ 51,4 Vrms** | | **--** |
| **--** | **Pin 6 to cathode of D4** | **25,0 Vpk/ 24,7 Vdc** | | **D4** |
| **Power supply GTM41060-2530** | | | | |
| **Secondary winding of T1** | **Pin 5 – 6** | **204 Vpk/ 62,0 Vrms** | | **--** |
| **--** | **Pin 6 to cathode of D4** | **31,0 Vpk/ 30,7 Vdc** | | **D4** |
| **Power supply GTM41060-2518-FW** | | | | |
| **Secondary winding of T1** | **Pin 5 – 6** | **130 Vpk/ 40,2 Vrms** | | **--** |
| **--** | **Pin 6 to cathode of D4** | **19,0 Vpk/ 18,4 Vdc** | | **D4** |
| **Power supply GTM41060-2524-FW** | | | | |
| **Secondary winding of T1** | **Pin 5 – 6** | **168 Vpk/ 51,1 Vrms** | | **--** |
| **--** | **Pin 6 to cathode of D4** | **25,2 Vpk/ 24,7 Vdc** | | **D4** |
| **Fault test performed on voltage limiting components** | | **Voltage measured (V) in SELV circuits (V peak or V d.c.)** | | |
| | | | | |
| **Supplementary information:**<br>**SELV reliability test was required. See appended table 13.2.** | | | | |

# Enclosure No. 1

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

(10 pages including this cover page)

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Clause | Result - Remark | Verdict |

| CANADA NATIONAL DIFFERENCES to IEC 60601-1 Third edition<br>National standard CAN/CSA-C22.2 No. 60601-1:08 | | | |
|---|---|---|---|
| 1.1 | Scope | -- | P |
| | 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.<br>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. | Considered. | P |
| 1.3 | Collateral standards | -- | P |
| | Applicable Canadian collateral standards become normative at the date of their publication and apply together with this standard.<br>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 | Considered. | P |
| 1.4 | Particular standards | -- | P |
| | A requirement of a Canadian-particular safety standard takes precedence over this standard. | Considered. | P |
| 2 | Normative references<br>The following referenced documents are indispensable for the application of this document.<br>For dated references, the applicable corresponding Canadian adopted IEC standards shall take precedence. For undated references, the latest edition of the referenced document (including any amendments) applies. All Canadian adopted IEC part 2 standards are referenced with the date of publication. | Considered. | P |
| | CSA (Canadian Standards Association)<br>B51-03: Boiler, pressure vessel, and pressure piping code<br>C22.1-06: Canadian Electrical Code, Part I<br>CAN/CSA-C22.2 No. 0-M91 (R2006): General | Considered. | P |

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

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Clause | Result - Remark | Verdict |
| | V-1-2005: Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections<br>V-5-2005: Diameter Index Safety System (Non interchangeable Low Pressure Connections for Medical Gas Applications) | | |
| | ISO (International Organization for Standardization)<br>32:1977: Gas cylinders for medical use — Marking for identification of content<br>407:2004: Small medical gas cylinders — Pin-index yoke-type valve connections | -- | N/A |
| 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 | -- | P |
| | a) the applicable safety requirements of a relevant CSA, IEC, or ISO standard;<br>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. | Considered. | P |
| | b) where there is no relevant CSA, IEC, or ISO standard, the requirements of this standard have to be applied<br>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. | Considered. | P |
| 4.10.2 | SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS | -- | P |
| | and shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1: | -- | P |
| 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. | -- | N/A |
| 8.7.3 | Allowable values<br>Allowable values shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA | Considered.<br>Touch current did not exceed 100 µA in NC and 300 | P |

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Clause | Result - Remark | Verdict |
| | C22.1. | µA in SFC. | |
| 8.11.3.2 | POWER SUPPLY CORDS Types | No power supply cord provided. | N/A |
| | a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENT shall be<br>i) if molded-on type, hospital grade mains plug complying with CSA C22.2 No. 21;<br>j) hospital grade disassembly attachment plug type complying with CSA C22.2 No. 42; or<br>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:<br>1- the centre contact of an Edison base lamp holder;<br>2- a single pole switch;<br>3- an automatic control with a marked off position;<br>4- a solitary fuse/fuse holder; or<br>5- any other single pole over-current protective device | -- | N/A |
| | b) Detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type that<br>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;<br>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<br>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 | -- | N/A |
| | c) A detachable POWER SUPPLY CORD shall<br>i) comply with the applicable requirements of | -- | N/A |

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Clause | Result - Remark | Verdict |
| | CSA C22.2 No. 21; and<br>j) not be smaller than No. 18 AWG, and the mechanical serviceability shall be not less than<br>1) Type SJ or equivalent for mobile or exposed to abuse ME EQUIPMENT; and<br>2) Type SV or equivalent for ME EQUIPMENT not exposed to abuse (or Type HPN if required because of temperature).<br>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.<br>Connecting cords between equipment parts shall meet the requirements of the Canadian Electrical Code, Part I, as applicable. | -- | N/A |
| 8.11.5 | Mains fuses and OVER-CURRENT RELEASES<br>Mains fuses and OVER-CURRENT RELEASES shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1. | See appended table 8.10. | P |
| 9.7.5 | Pressure vessels<br>Pressure vessels shall comply with the requirements of CSA B51, as applicable. | No pressure vessels provided. | N/A |
| 9.7.7 | Pressure-relief device<br>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<br>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<br>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<br>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.<br>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 | No gas cylinders provided. | N/A |

| IEC 60601-1 | | | |
|---|---|---|---|
| **Clause** | **Clause** | **Result - Remark** | **Verdict** |
| | **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**<br>**Internal wiring of ME EQUIPMENT shall be in accordance with the Canadian Electrical Code (CEC), Part I, CSA C22.1.** | **--** | **P** |
| **16.1** | **MULTIPLE SOCKET OUTLET**<br>**The MULTIPLE SOCKET-OUTLET shall comply with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and the following requirements.**<br>**- The separating transformer shall comply with the requirements of CAN/CSA-E61558-2-1 with a rated output not exceeding**<br>**- 1 kVA for single-phase transformers; and**<br>**- 5 kVA for polyphase transformers**<br>**The separating transformer shall also have a degree of protection not exceeding IPX4.** | **No multiple socket outlets provided.** | **N/A** |

| IEC 60601-1 | | | |
|---|---|---|---|
| **Clause** | **Clause** | **Result - Remark** | **Verdict** |

| | | | |
|---|---|---|---|
| **SWITZERLAND NATIONAL DIFFERENCES to IEC 60601-1 Third edition<br>National standard SN EN 60601-1:06** | | | |
| 4 | Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7,<br>Mercury - Annex 1.7 of SR 814.81 applies for mercury. | No mercury used during normal use of the equipment. | N/A |
| | 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:<br>- SEV 6533-2:2009 Plug type 11, L + N, 250V 10A<br>- SEV 6534-2:2009 Plug type 12, L + N + PE, 250V 10A<br>- SEV 6532-2:2009 Plug type 15, 3L + N + PE, 250/400V 10A | Power supply cord not part of the investigation. | N/A |
| 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,<br>SEV 1011 and one of the following dimension sheets:<br>- SEV 5933-2:2009 Plug type 21 L + N, 250 V, 16A<br>- SEV 5934-2:2009 Plug type 23 L + N + PE, 250 V, 16A<br>- SEV 5932-2:2009 Plug type 25 3L + N + PE, 250/400V 16A | Power supply cord not part of the investigation.. | N/A |
| | 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 |

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Clause | Result - Remark | Verdict |

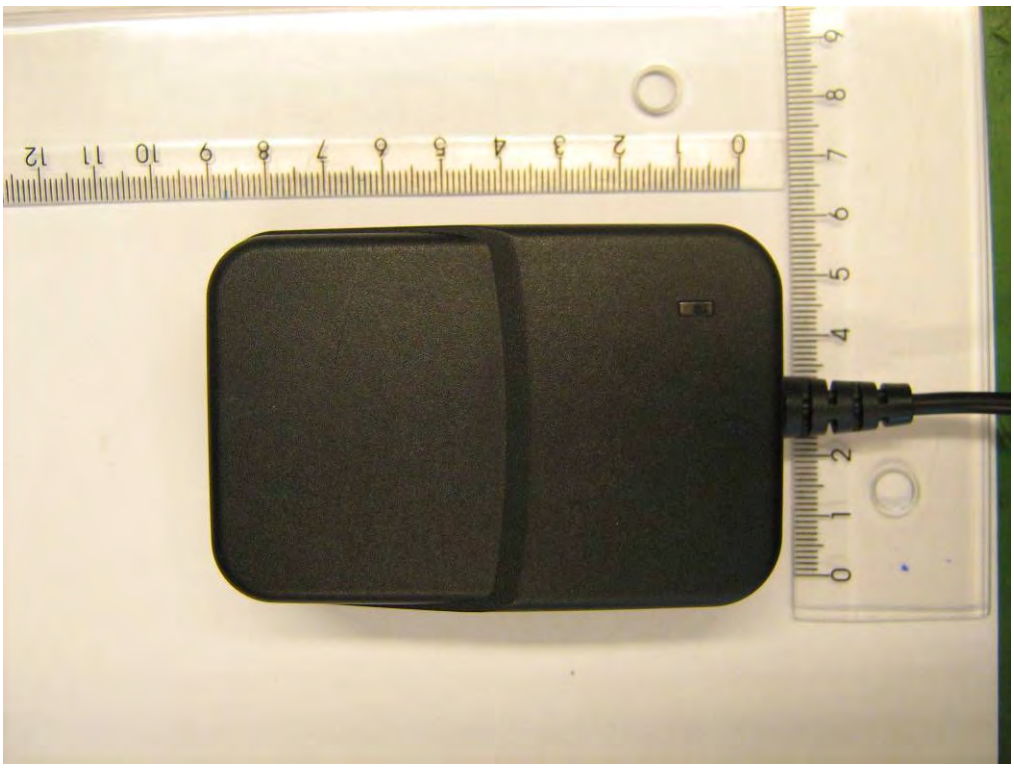
| US NATIONAL DIFFERENCES to IEC 60601-1 Third edition<br>National standard ANSI/AAMI ES60601-1: 2005 | | | |
|---|---|---|---|
| 4.8 | Components of ME EQUIPMENT | -- | P |
| | When no relevant US ANSI standard existed, the requirements of this standard applied | Considered. | P |
| 4.10.2. | SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS | -- | P |
| | 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. | P |
| 8.2 | Requirements related to power sources | -- | N/A |
| | Addition to agree with NEC: The requirement, “ALL FIXED ME EQUIPMENT and PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT” | EUT is not fixed or permanently installed equipment. | N/A |
| 8.7.3 | Allowable values: | -- | N/A |
| | 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: | -- | N/A |
| | d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION | -- | N/A |
| 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”<br>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: | EUT is not permanently connected equipment. | N/A |
| | Installation of connecting cords between EQUIPMENT parts comply with NEC, as applicable | No connecting cord between equipment parts provided.<br>Only output cable provided. | N/A |
| | Cable used as external interconnection between units was: | -- | N/A |

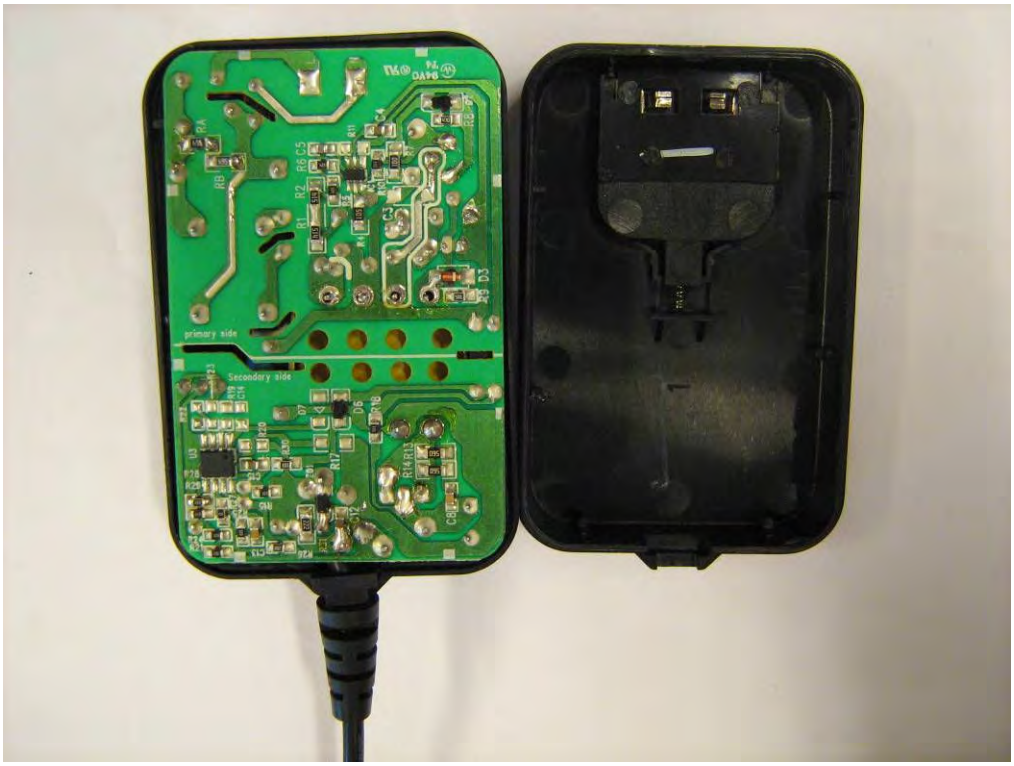
| IEC 60601-1 | | | |
|---|---|---|---|
| **Clause** | **Clause** | **Result - Remark** | **Verdict** |
| | **1) Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord when exposed to abuse, or similar multiple-conductor appliance-wiring material such as computer cable:**<br>**2) The cable was as in item 1) above when not exposed to abuse, or it was**<br>**i) Type SPT-2, SP-2, or SPE-2, or equivalent**<br>**ii) Type SVr, SVRO, SVE, or equivalent flexible cord or similar multiple-conductor appliance wiring material,**<br>**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** | **--** | **N/A** |
| **8.11.3.2.** | **Addition to agree with NEC:** | **Power supply cord not part of the investigation.** | **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** |

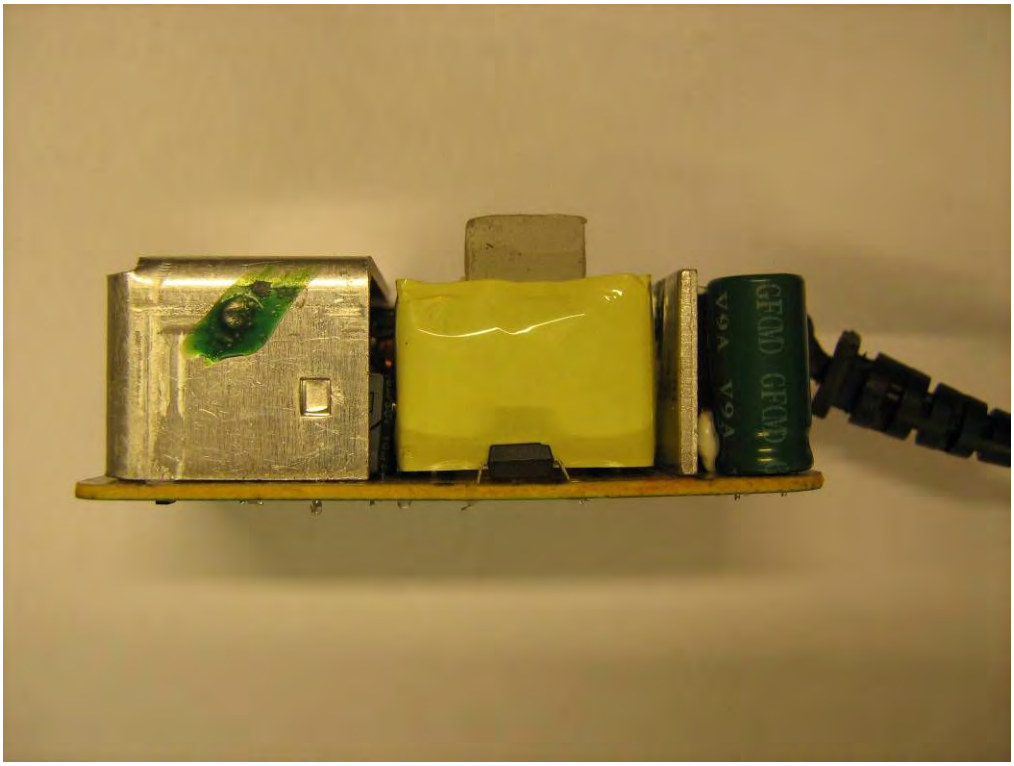
# Enclosure No. 2

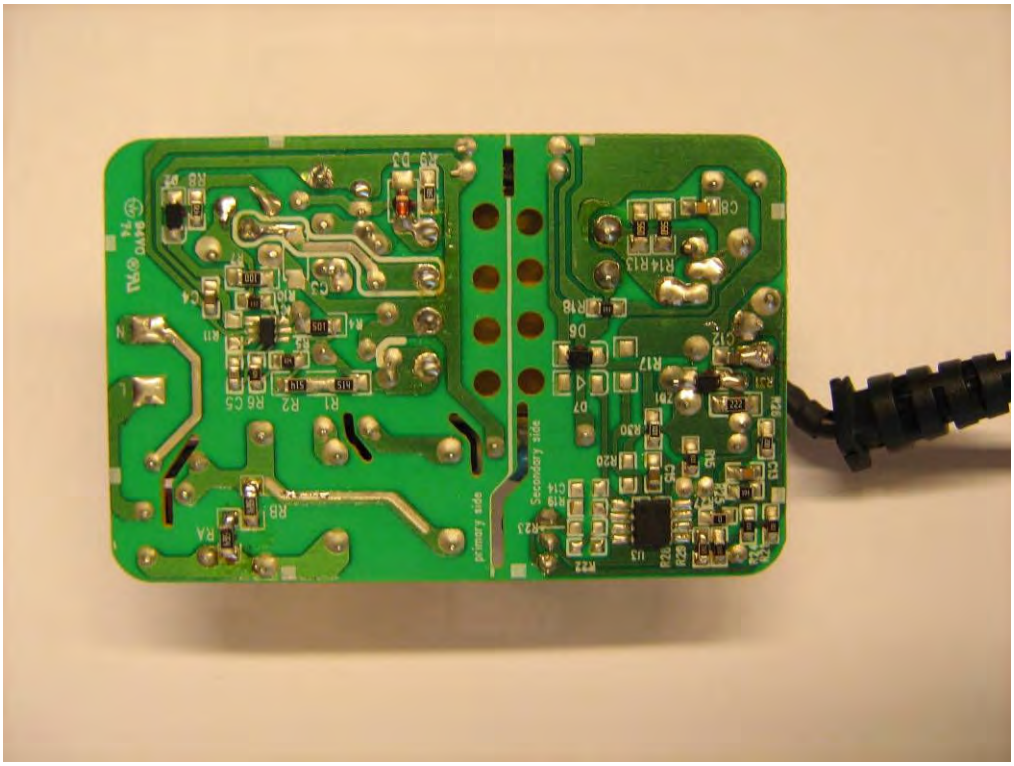
Photo documentation

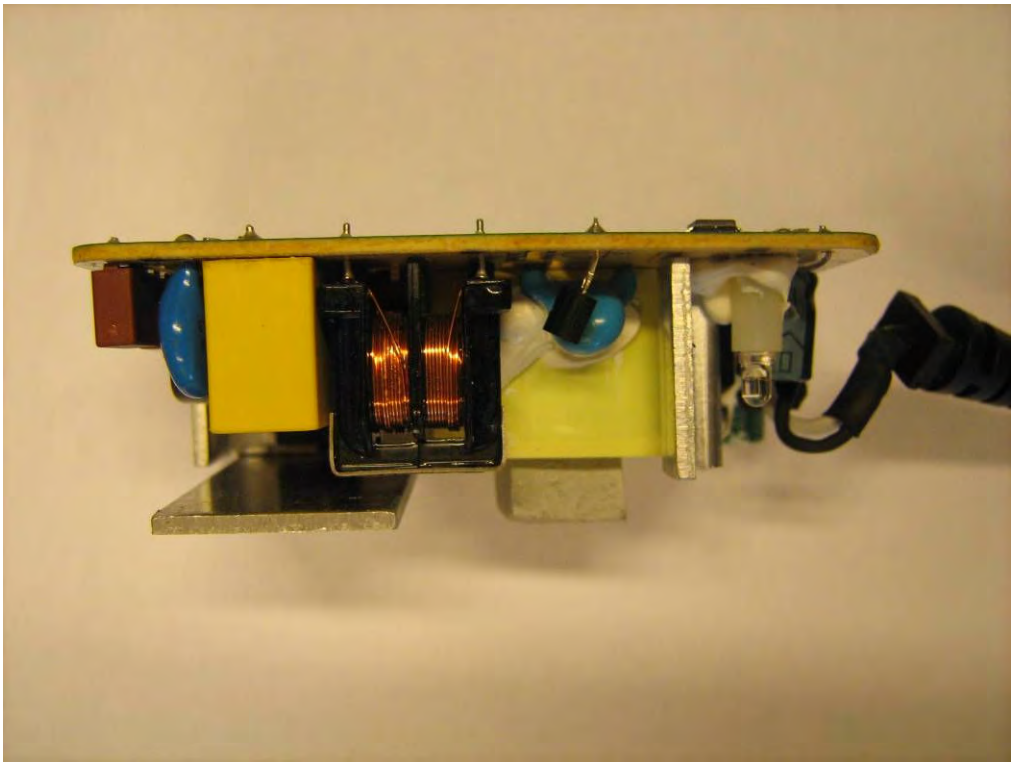
(16 pages including this cover page)

| Power supply unit evaluated for Means of Operator Protection (MOOP)<br>(Single Y1 capacitor provided between primary and secondary circuit) |
|---|
| Direct plug-in Power Supply |
| |
|  |

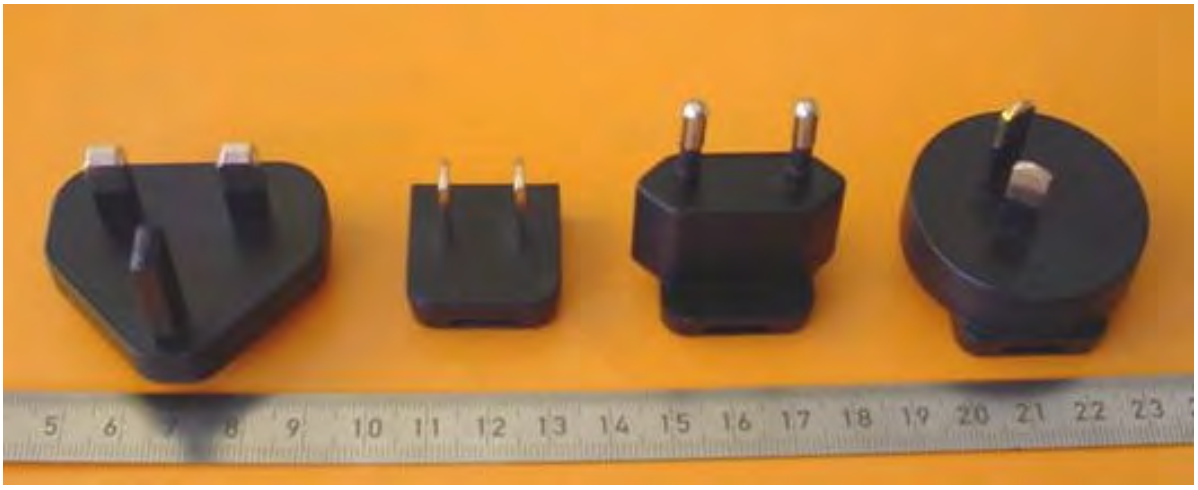

primary side
Secondary side

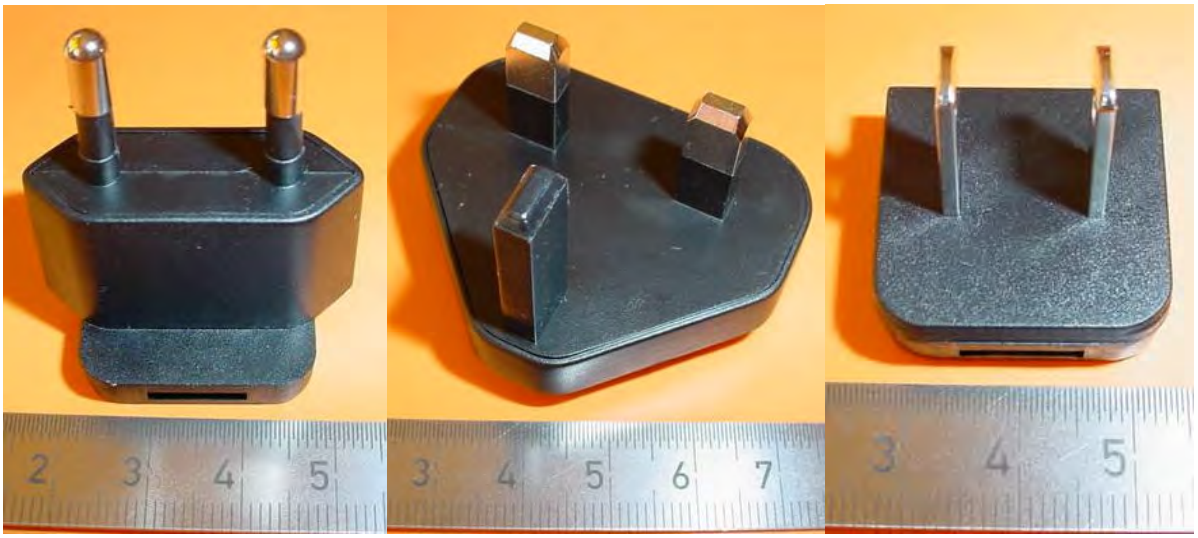

GFCMD GFCMD
V9A V9A

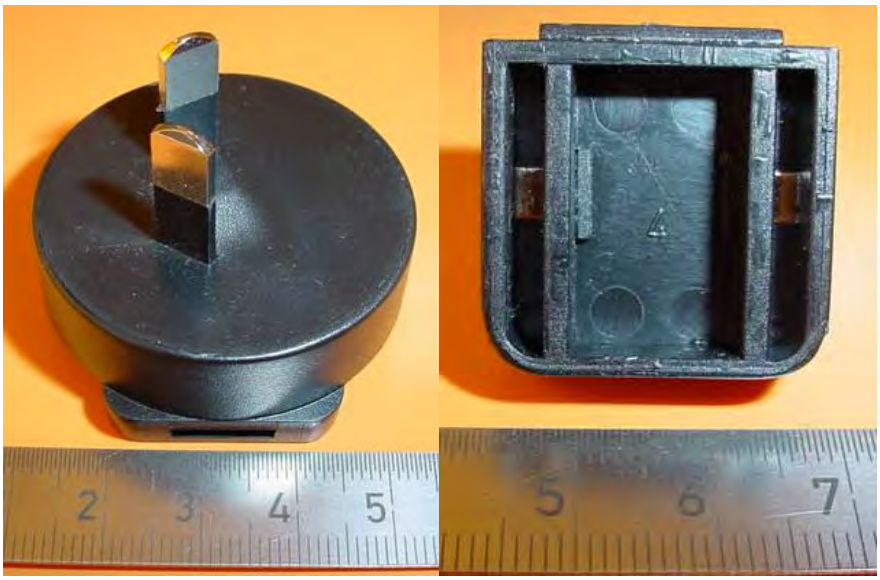

primary side
Secondary side

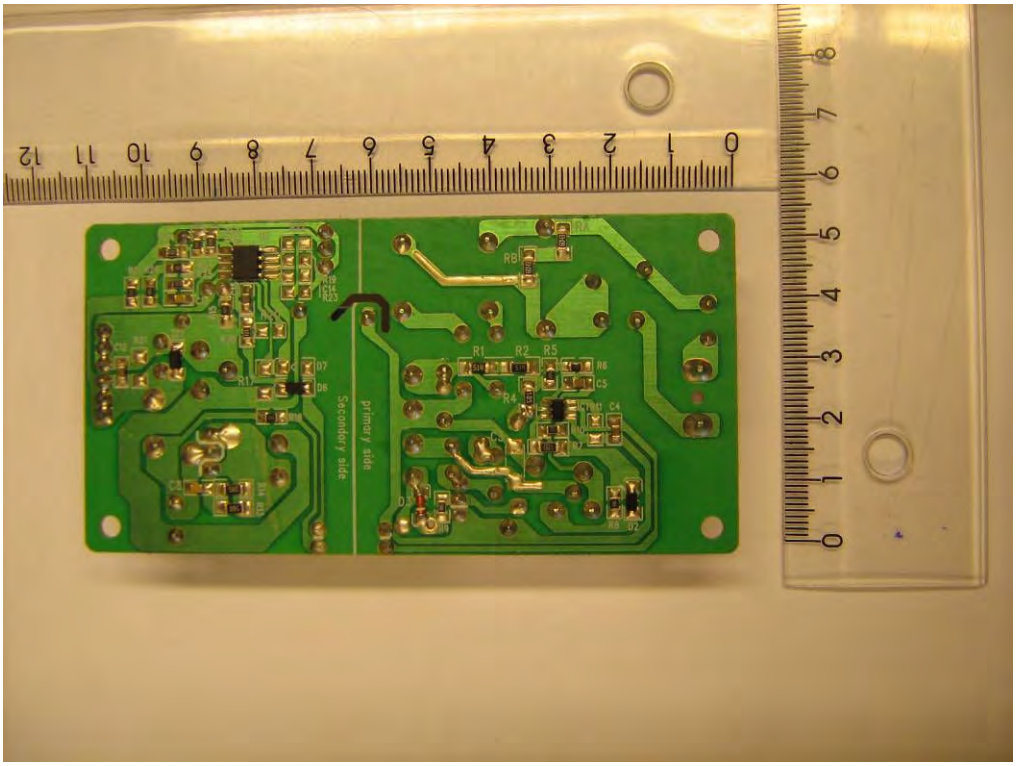


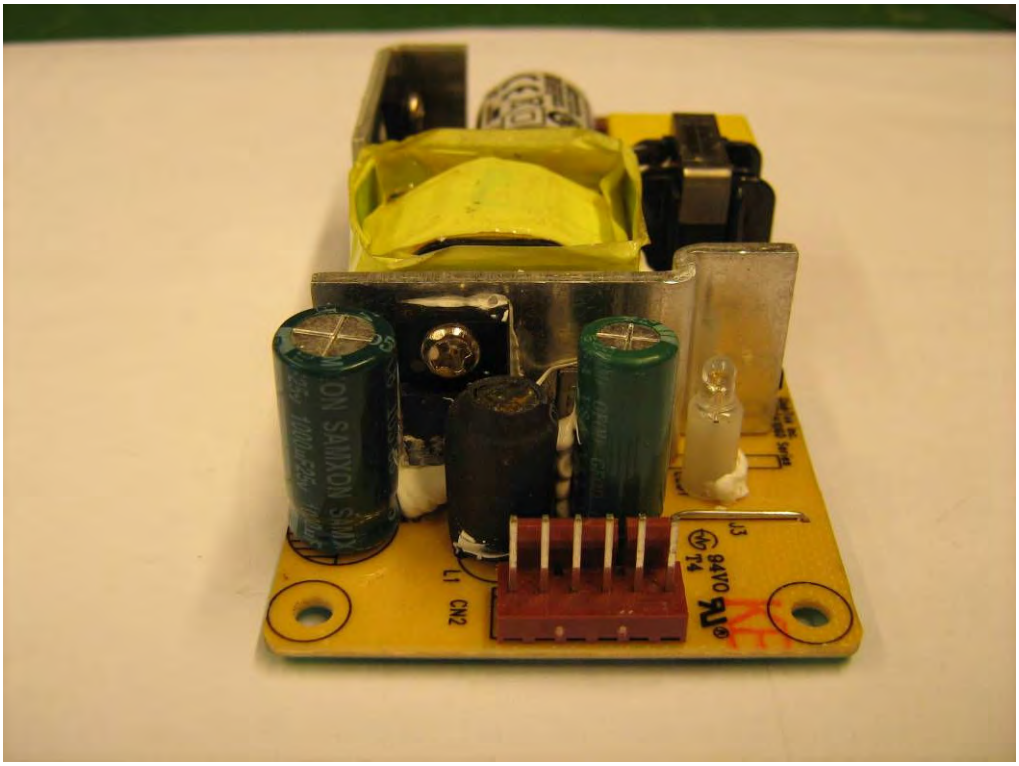
0 1 2 3 4 5 6

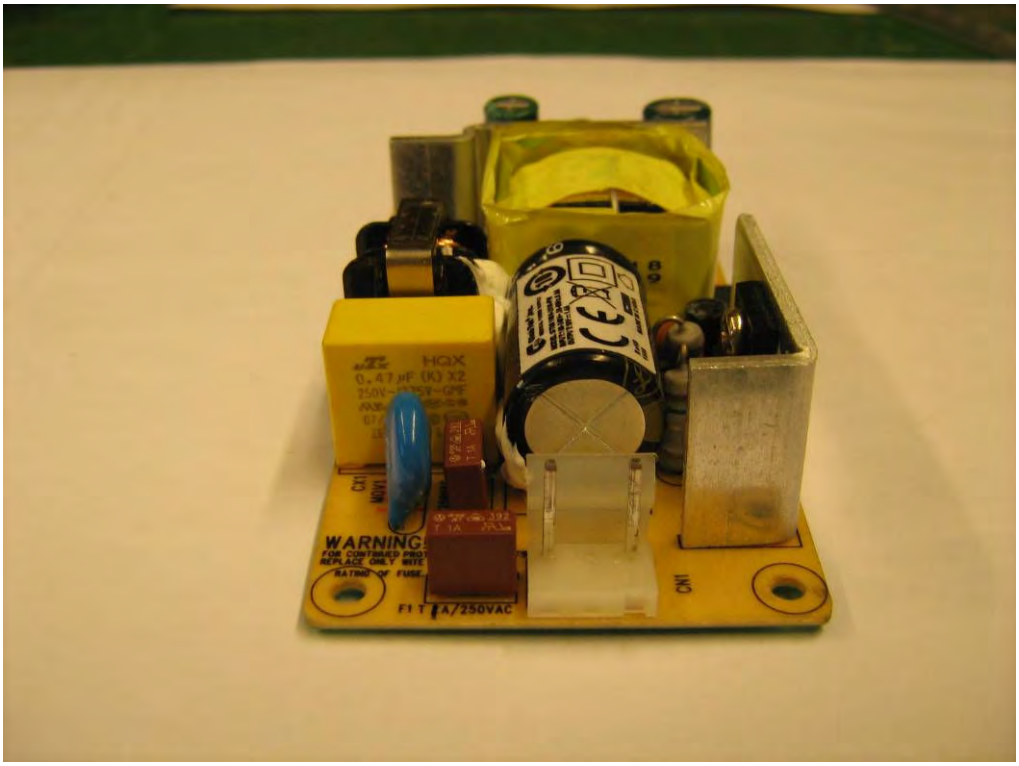






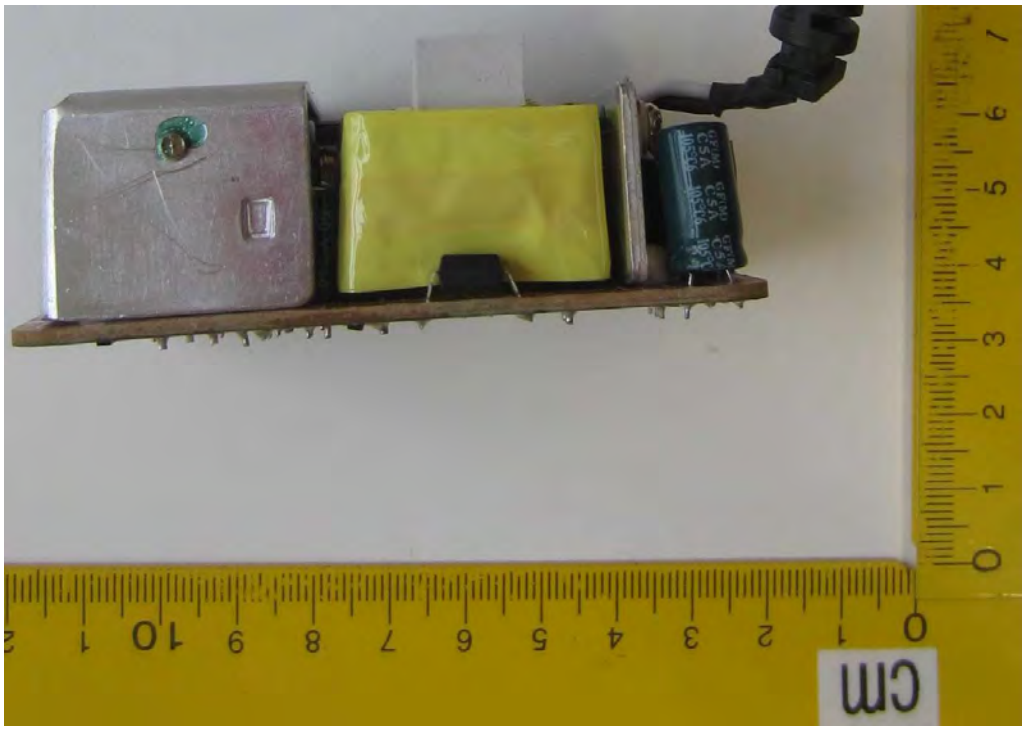
| Open frame Power Supply |
| --- |
| |
|  |

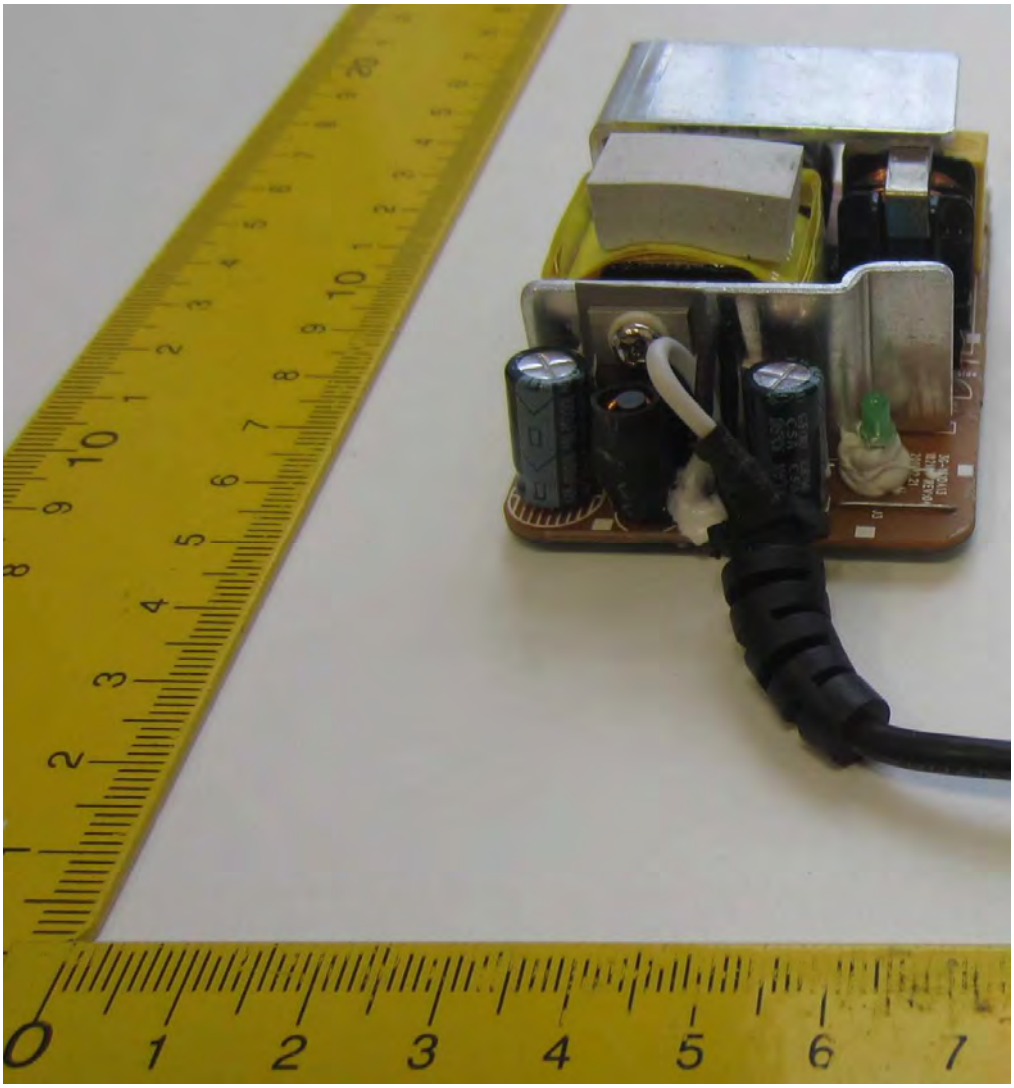

ON SANYO
L1
CN2
94V0

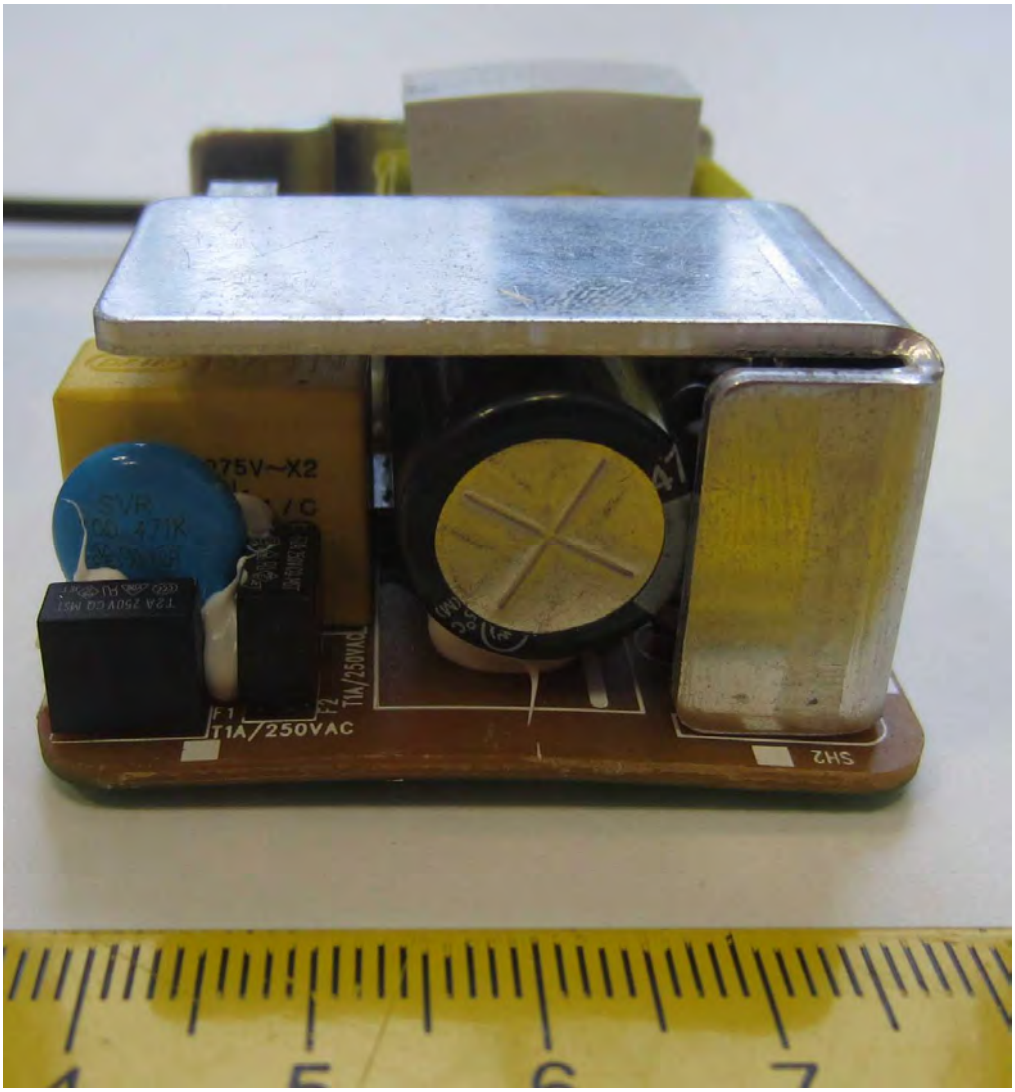

WARNING
F1 T 1A/250VAC

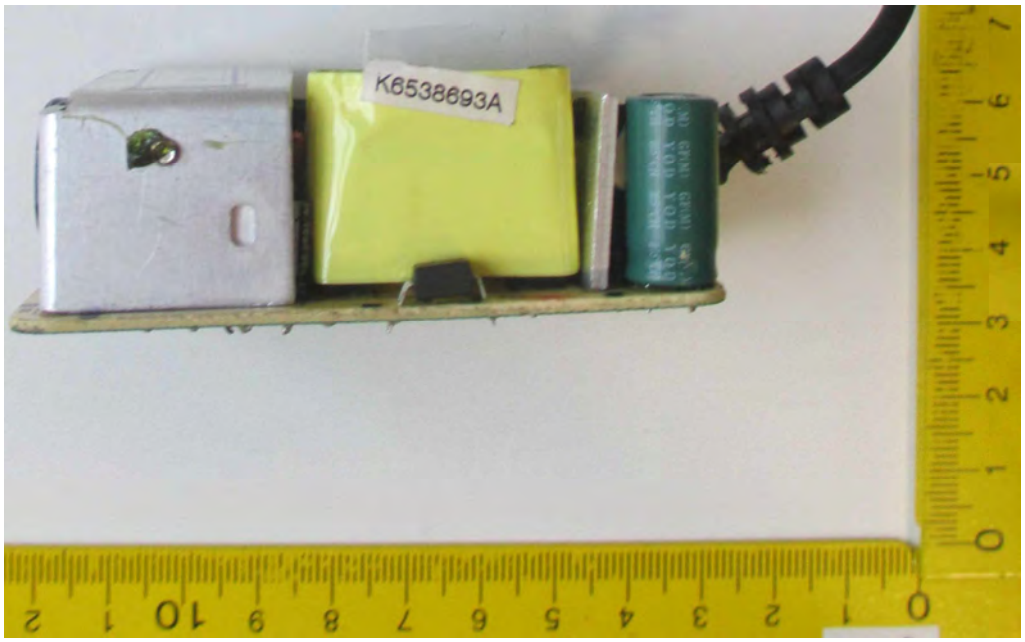
| |
|---|
| **Power supply unit evaluated for Means of Patient Protection (MOPP)**<br>**(Models additionally marked with 2MOPP near model name)**<br>**(2 x Y1 capacitors in series provided between primary and secondary circuit)** |
| |

S201344A2






F1
T1A/250VAC
F2
T1A/250VAC
SH2

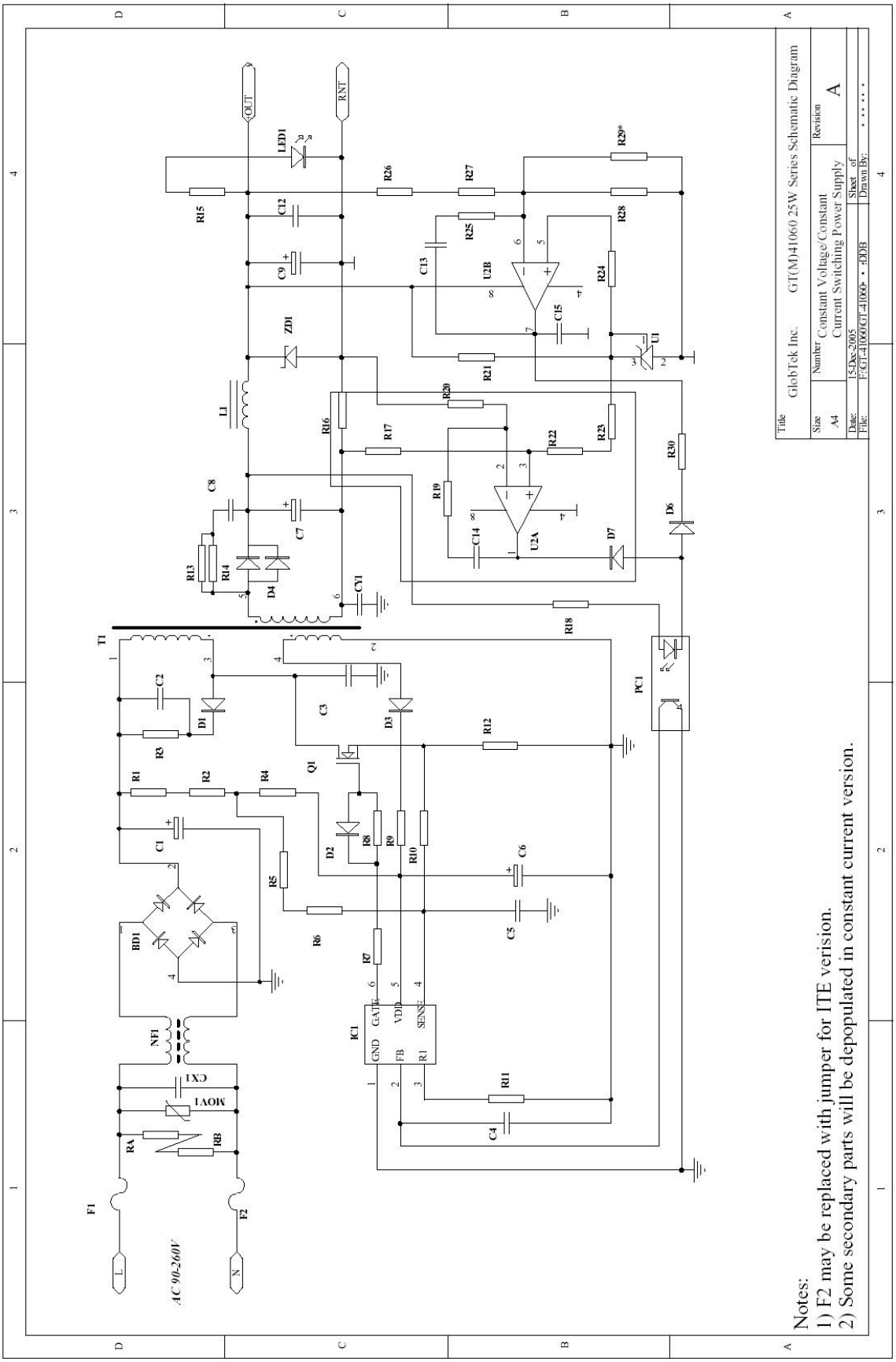

K6538693A

# Enclosure No. 3

# Schematics, layouts and transformer drawings

(35 pages including this cover page)

**Power supply unit evaluated for Means of Operator Protection (MOOP)**
**(Single Y1 capacitor provided between primary and secondary circuit)**



Sheet1

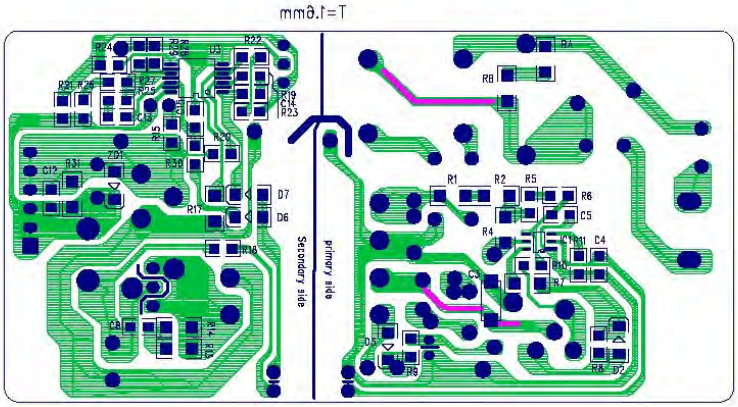
| GlobTek Inc. BOM LIST GT(M)41060-2524 REV01 | | | | | |
|---|---|---|---|---|---|
| ITEM NO: | PART NAME | SPECIFICATION | SYMBOL | Q"TY (pcs) | MARK |
| 1 | RESISTOR | 47K 1W±5% | R3 | 1 | |
| 2 | capacitor | 2200pF/1KV ±10% | C2 | 1 | |
| 3 | RESISTOR | 0.56Ω 1W ±5% | R12 | 1 | |
| 4 | ele capacitor | 47uF/400V 105℃ ±20% | C1 | 1 | |
| 5 | ele capacitor | 10uF/50V 105℃ Φ5X11 | C6 | 1 | |
| 6 | ele capacitor | 560uF/35V 105℃ L-ESR | C7 | 1 | |
| 7 | ele capacitor | 270uF/35V 105℃ L-ESR | C9 | 1 | |
| 8 | X CAPACITOR | 0.47uF/275V ±10% P=15mm | CX1 | 1 | |
| 9 | Y CAPACITOR | 3300pF/250V P=10mm | CY1 | 1 | |
| 10 | DIODE | DI106 1A/600V DIP | BD1 | 1 | |
| 11 | DIODE | FR107 1A/1000V DO-41 | D1 | 1 | |
| 12 | DIODE | ER1002 | D4 | 1 | |
| 13 | LED | φ 3x5.3mm LA304B2CA-X-01-P | LED1 | 1 | |
| 14 | IC | KA431AZTA_NL ±1% TO-92 | U1 | 1 | |
| 15 | IC | PC817X2NSZW DIP-4 SHARP | PC1 | 1 | |
| 16 | MOSFET | FQPF8N60C 7.5A/600V/1.2Ω TO-220F | Q1 | 1 | |
| 17 | LINE CHOKE | NF00009B | NF1 | 1 | |
| 18 | INDUCTOR | RC00002 R6X15 | L1 | 1 | |
| 19 | FUSE | 2A/250V(ITE POWER SUPPLY F2 USE JUMP) | F1 F2 | 2 | |
| 20 | VARISTOR | CNR-10D471K | MOV1 | 1 | |
| 21 | RESISTOR | 0.1Ω/2W | R16 | 1 | CV model use jump |
| 22 | JUMP | 0.6φ x5x4mm (MEDICAL POWER SUPPLY USE FUSE) | F2 | 1 | |
| 23 | JUMP | 0.6φ x10x4mm | J1 | 1 | |
| 24 | JUMP | 0.6φ x12x4mm | J2.J3 | 2 | |
| 25 | BEAD | RH 3.5X2.5X1.6 | D4 | 2 | |
| 26 | TRANSFORMER | XF00230 | T1 | 1 | |
| 27 | HEAT SINK | H02-182103-003 | Q1 | 1 | |
| 28 | HEAT SINK | H02-182103-002 | D4 | 1 | |
| 29 | PCB | CEM-1 94V-0 REV(02) 1.6mm | | 1 | |
| 30 | RESISTOR | SMD 1206 1M 1/4W ±5% | RA RB R4 | 3 | |
| 31 | RESISTOR | SMD 1206 510K 1/4W ±5% | R1.R2 | 2 | |
| 32 | RESISTOR | SMD 0805 820K 1/8W ±5% | R5.R6 | 2 | |
| 33 | RESISTOR | SMD 1206 10Ω 1/4W ±5% | R7 | 1 | |
| 34 | RESISTOR | SMD 0805 47Ω 1/8W ±5% | R8 | 1 | |
| 35 | RESISTOR | SMD 0805 5.1Ω 1/8W ±5% | R9 | 1 | |
| 36 | RESISTOR | SMD 0805 1.3K 1/8W ±5% | R10 | 1 | |
| 37 | RESISTOR | SMD 1206 56Ω 1/4W ±5% | R13.R14 | 2 | |
| 38 | RESISTOR | SMD 0805 100K 1/8W ±5% | R15 | 1 | |
| 39 | RESISTOR | SMD 0805 10K 1/8W ±5% | R19.R20.R 24.R25 | 3 | CV modle R19 R20 open |
| 40 | RESISTOR | SMD 0805 240Ω 1/8W ±5% | R18 | 1 | |
| 41 | RESISTOR | SMD 0805 27K 1/8W ±5% | R21 | 1 | |
| 42 | RESISTOR | SMD 0805 300K 1/8W ±5% | R29 | 1 | |
| 43 | RESISTOR | SMD 0805 100Ω 1/8W ±5% | R30 | 1 | |
| 44 | RESISTOR | SMD 0805 75K 1/8W ±1% | R26 | 1 | |
| 45 | RESISTOR | SMD 0805 11KΩ 1/8W ±1% | R27 | 1 | |

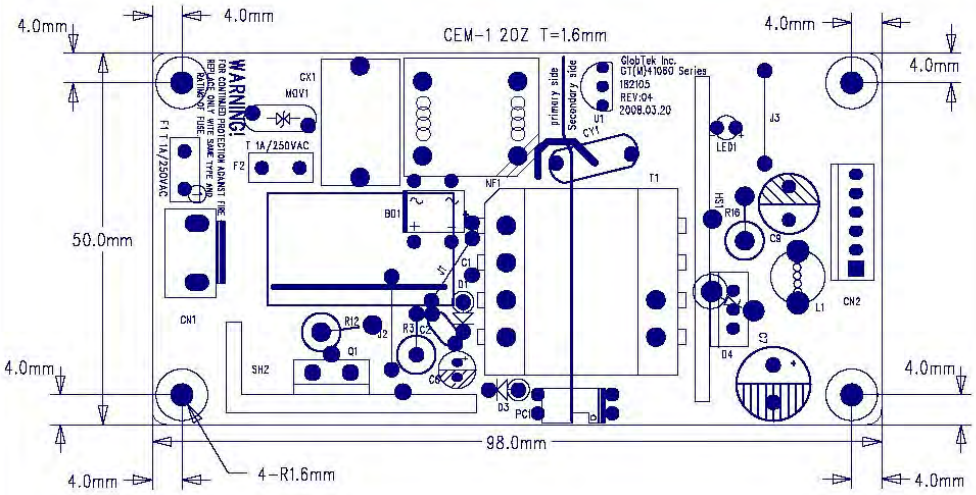
Page 1

Sheet1

| | | | | | |
|---|---|---|---|---|---|
| 46 | RESISTOR | SMD 0805 10K 1/8W ±1% | R28 | 1 | |
| 47 | RESISTOR | SMD 1206 2K 1/4W ±1% | R17 | 1 | CV model open |
| 48 | RESISTOR | SMD 0805 37.4K 1/8W ±1% | R22 | 1 | |
| 49 | RESISTOR | SMD 0805 5.1K 1/8W ±1% | R23 | 1 | |
| 50 | CAPACITOR | SMD 0805 0.1uF/50V(104) ±10% | C14 | 1 | |
| 51 | CAPACITOR | SMD 0805 0.001uF/50V(102) ±10% | C4.12.15 | 3 | |
| 52 | CAPACITOR | SMD 0805 0.0001uF/50V(101) ±10% | C5 | 1 | |
| 53 | CAPACITOR | SMD 0805 0.001uF/200V(102) ±10% X7R | C8 | 1 | |
| 54 | CAPACITOR | SMD 0805 0.0018uF/50V(182) ±10% | C13 | 1 | |
| 55 | DIODE | SMD RLS245 0.2A/220V LLDS | D3 | 1 | |
| 56 | DIODE | SMD 1N4148W 150mA/75V SOD-123 | D2.D6.D7 | 3 | CC model D7 open |
| 57 | DIODE | SMD ZENER 27V 1/2W SOD-123 | ZD1 | 1 | |
| 58 | IC | SMD SG6849-65T SOT-26 | IC1 | 1 | |
| 59 | IC | SMD LM358 SOP-8 | U3 | 1 | |
| 60 | Output cord | UL1185(or SPT-1) with ferrite core(14.2*28.5*8.2) | | | |
| 61 | Top case | ENG-20--06-00 | | | 251WP12-024 |
| 62 | Bottom case | ENG-20--06-15 | | | |
| 63 | Thermal pad | Per GT drawing PN:800-0965 REV:02 | T1 | 1 | |
| 64 | RTV | CN8603 | | | |

Page 2

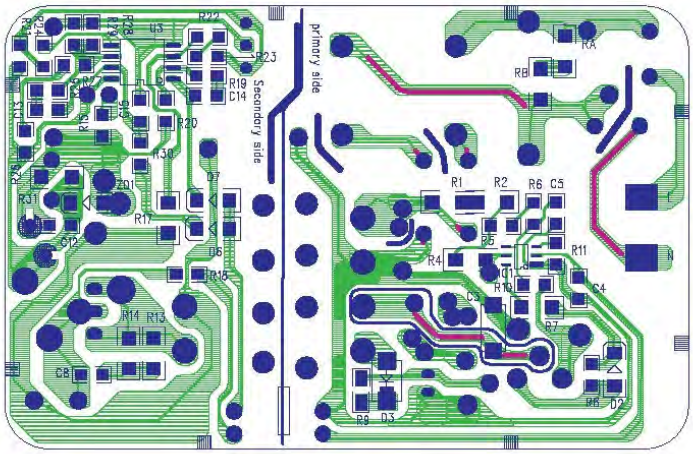


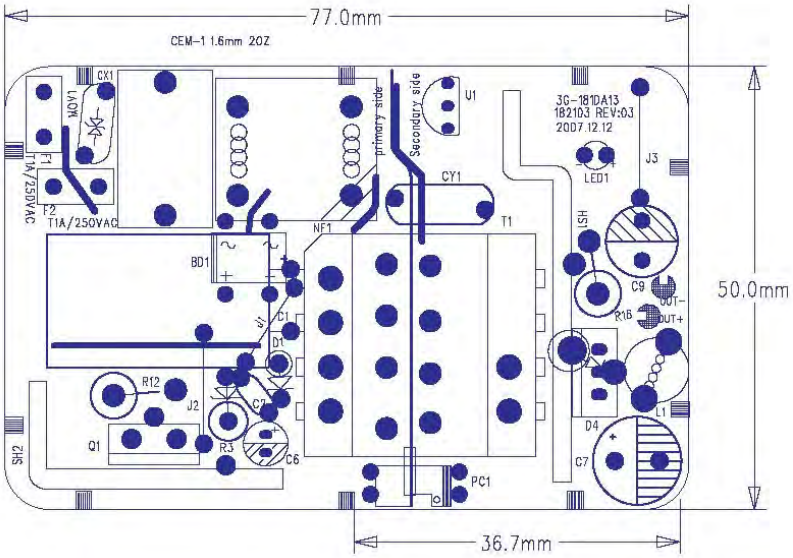




| TOLERANCE | | |
|---|---|---|
| 0<X≤100 | 100<X≤300 | 300< X |
| ±0.1 | ±0.2 | ±0.3 |

| DESIGNED | CHECKED | APPROVED | | TITLE | DATE |
|---|---|---|---|---|---|
| tangwm | zhoujg | zhurg | UNITS mm | PCB | |
| | | | SCALE | DRAWING NO. W182105-01 | 08.04.11 |
| GlobTek Inc. | | | | DRAWING NAME 182105 | REVISION 04 |

RDS-041 07.03

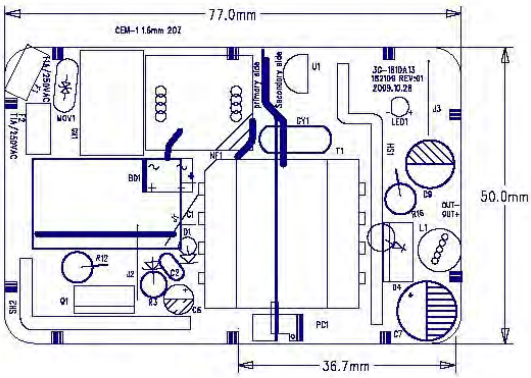


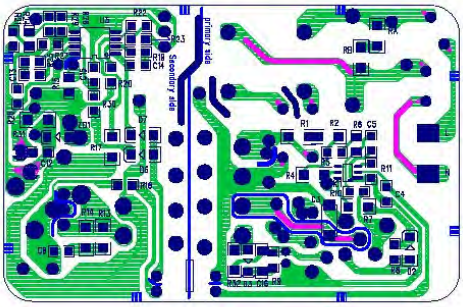

| TOLERANCE | | |
|---|---|---|
| 0<X≤100 | 100<X≤300 | 300< X |
| ±0.1 | ±0.2 | ±0.3 |

| DESIGNED | CHECKED | APPROVED | | TITLE | DATE |
|---|---|---|---|---|---|
| tangwm | zhoujg | zhurg | UNITS mm | GT(M)41060 PCB | 07.12.14 |
| | | | SCALE | DRAWING NO. | |
| GlobTek Inc. | | | | DRAWING NAME | REVISION 03 |

RDS-041 07.03




GlobTek Inc.
GT(M)41060 Enclosed Power Supply Series
PCB Layout


primary side
secondary side

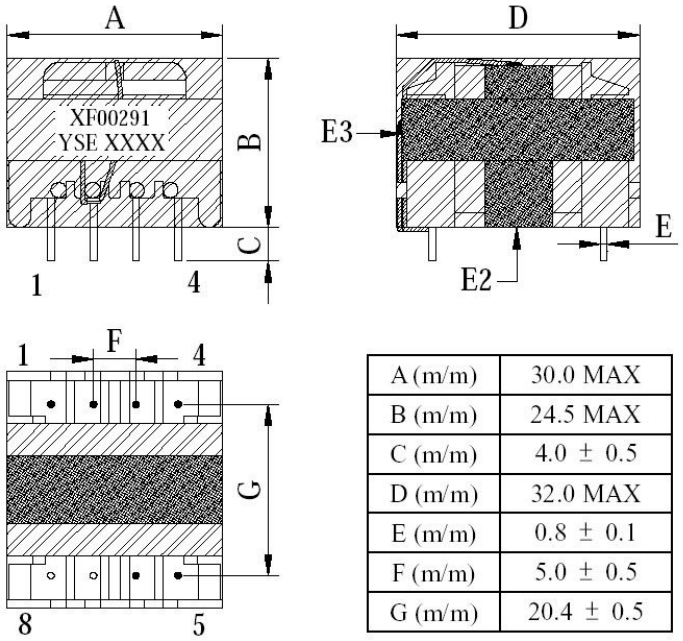
# SPECIFICATION FOR APPROVAL

Y.S.E

PAGE 1 OF 4

| CUSTOMER | 英 格 爾 | Y.S.E. NO | EF25-05081409-5 |
|---|---|---|---|
| PART NO | XF00291 | PART NAME | TRANSFORMER |
| REV NO | E | ISSUE DATE | 2006/6/5 |

1. CONFIGURATION & DIMENSIONS: (UNITE: mm)




| | |
|---|---|
| A (m/m) | 30.0 MAX |
| B (m/m) | 24.5 MAX |
| C (m/m) | 4.0 ± 0.5 |
| D (m/m) | 32.0 MAX |
| E (m/m) | 0.8 ± 0.1 |
| F (m/m) | 5.0 ± 0.5 |
| G (m/m) | 20.4 ± 0.5 |

NOTE:
1. CORE FIXED BY MYLAR TAPE 2Ts.
2. At first wrapped 3Ts 15.5mm tape around the side of x'fmr.
   1). E2: 0.025t*8w+1 layer 3M 1350T-1 tape around the coil and lead wire Ø0.3 (white tube) on top to pin2. then wrapped 1Ts 15.5mm tape again.
   2). E3: Copper film: 0.025t*15w(max)+1 layer 3M 1350T-1 tape) wrapped 1 layer 18mm tape around the E3 copper film.
   3). E3: Around the core and lead Ø0.3 (white tube) to pin2.
   4). Wrapped 1Ts 18mm tape around the side of x'fmr.
   5). PIN7,8 CUT OFF.
3. PIN1-4 朝機臺內繞線.

| REPORTED BY | CHECKED BY | APPROVED BY | 3. | |
|---|---|---|---|---|
| 毛嘉美 | 唐 亮 | 曹志宏 | 2. | |
| | | | RECV 1. | |

YOUNG-SHANG ELECTRONIC PLANT. TEL:0752—6663113

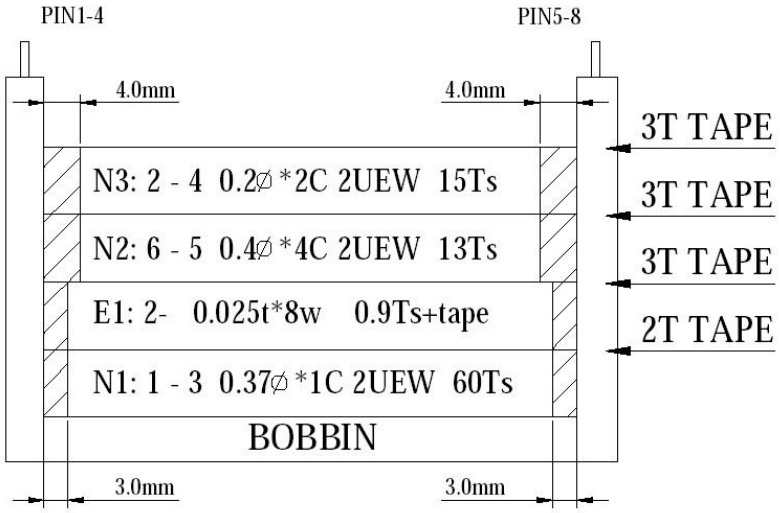
# SPECIFICATION FOR APPROVAL

Y.S.E

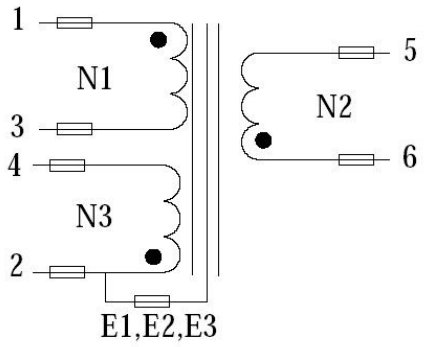


| CUSTOMER | 英 格 爾 | Y.S.E. NO | EF25-05081409-5 |
|---|---|---|---|
| PART NO | XF00291 | PART NAME | TRANSFORMER |
| REV NO | E | ISSUE DATE | 2006/6/5 |

2. WINDING SEQUENCE:




3. SCHEMATIC:




| REPORTED BY | CHECKED BY | APPROVED BY | 3. | |
|---|---|---|---|---|
| | | | 2. | |
| 毛嘉美 | 唐 亮 | 曹志宏 | REV 1. | |

# SPECIFICATION FOR APPROVAL

Y.S.E

PAGE 3 OF 4

| CUSTOMER | 英 格 爾 | Y.S.E. NO | EF25-05081409-5 |
|---|---|---|---|
| PART NO | XF00291 | PART NAME | TRANSFORMER |
| REV NO | E | ISSUE DATE | 2006/6/5 |

4. ELECTRONICAL CHARACTER:

| TEST INSTRUMENT | INDUCTANCE(L) @ 1KHZ 0.25VRMS CH-1061 | DCR 502AC |
|---|---|---|
| 1-3 | 1.0mH ± 5%<br>LK: 65uH MAX (PIN2,4,5,6 Short) | 0.6Ω MAX |
| 6-5 | | 45mΩ MAX |
| 2-4 | | 0.3Ω MAX |

5. HI-POT : (CH9071)

APPLY AC 4000V 5mA BETWEEN PRI. TO SEC. FOR 60 SEC.

APPLY AC 1800V 5mA BETWEEN PRI. TO CORE FOR 60 SEC.

APPLY AC 1800V 5mA BETWEEN SEC. TO CORE FOR 60 SEC.

6. MATERIAL LIST:

| # | ITEM | MATERIAL | SUPPLIER |
|---|---|---|---|
| 1. | CORE | EF25 PC40<br>PL-7 | TDK<br>SAM WHA CO., LTD |
| 2. | BOBBIN | PHENOLIC T375J 94V-0<br>150℃ | CHANG CHUN PLASTICS CO.,LTD.<br>E59481(S) |
| 3. | WIRE | POLYURETHANE ENAMELD<br>COPPER WIRE 130℃ | PACIFIC ELECTRIC WIRE & CABLE<br>CO.,LTD E201757 |
| 4. | INSULATION TAPE | POLYESTER #1350T-1 130℃ | MINNESO TAMINING& MFG 3M<br>CENTER E17385(N) |
| | | TAPE CT 130℃ | YAHUA PRESSURE SENSITIVE GLUE<br>Co.,LTD E165111 |
| 5. | VARNISH | V-1630FS 130℃ | VIKING PRODUCTS E73071 |
| 6. | TUBE | TEFLON TUBE 150V 200℃ | GREAT HOLDING INDUSTRIES CO.,LTD<br>E156256 |
| 7. | MARGIN TAPE | COMPOSITE FILM<br>NO.44 130℃ | MINNESOTAMINING& MFG 3M CENTER<br>E17385(N) |
| | | TAPE CT 130℃ | YAHUA PRESSURE SENSITIVE GLUE<br>Co.,LTD E165111 |
| 8. | SHIELD | COPPER FOIL | OPTION |

| REPORTED BY | CHECKED BY | APPROVED BY | 3. | |
|---|---|---|---|---|
| | | | 2. | |
| 毛嘉美 | 唐 亮 | 曹志宏 | REV 1. | |

YOUNG-SHANG ELECTRONIC PLANT. TEL:0752—6663113

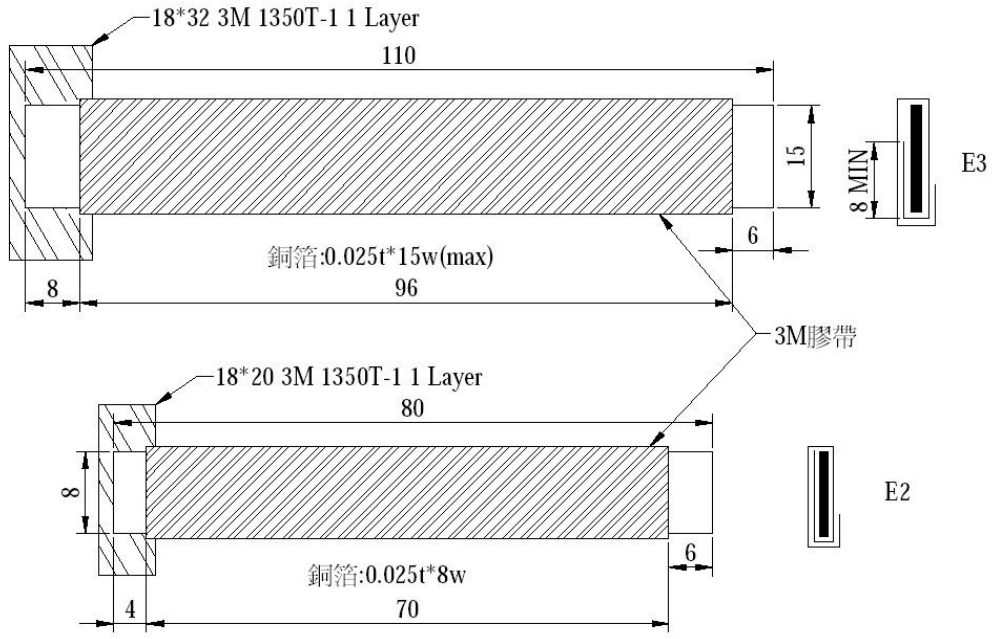
# SPECIFICATION FOR APPROVAL

Y.S.E

PAGE 4 OF 4

| | | | |
|---|---|---|---|
| CUSTOMER | 英 格 爾 | Y.S.E. NO | EF25-05081409-5 |
| PART NO | XF00291 | PART NAME | TRANSFORMER |
| REV NO | E | ISSUE DATE | 2006/6/5 |

7. 銅箔圖: (UNITE: mm)




公差:±0.5mm

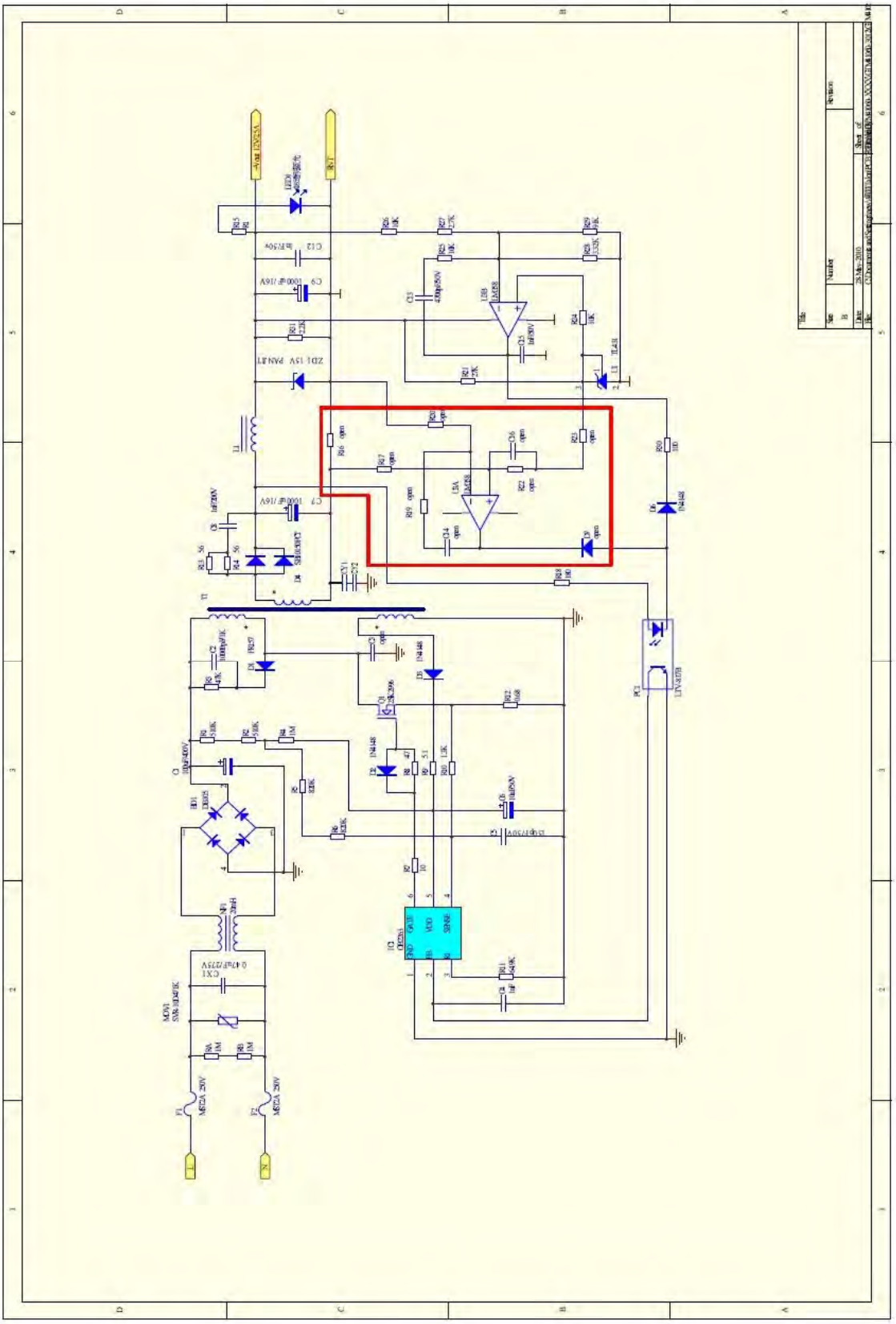
| REPORTED BY | CHECKED BY | APPROVED BY | 3. | |
|---|---|---|---|---|
| | | | 2. | |
| 毛嘉美 | 唐 亮 | 曹志宏 | RECV 1.0 | |

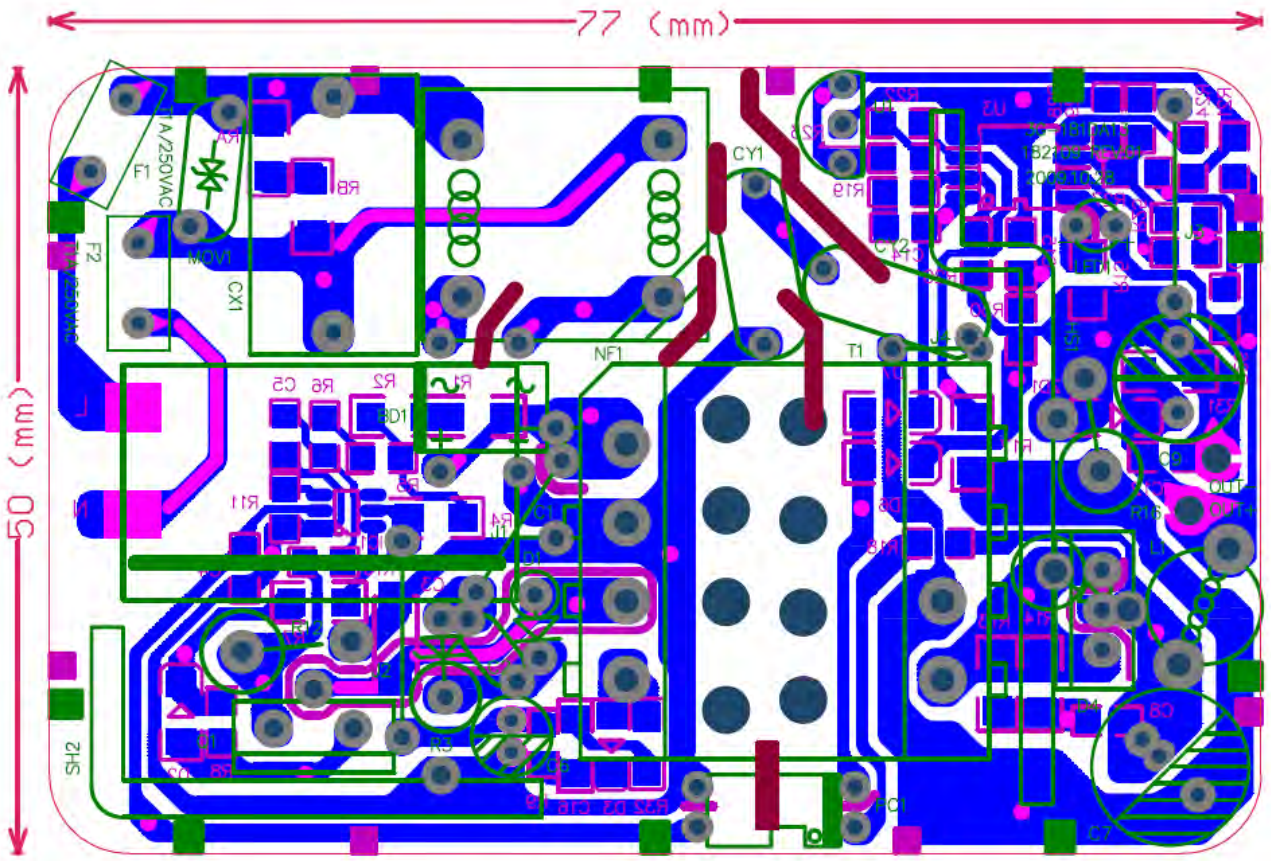
YOUNG-SHANG ELECTRONIC PLANT. TEL:0752—6663113

**Power supply unit evaluated for Means of Patient Protection (MOPP)**

**(Models additionally marked with 2MOPP near model name)**

**(2 x Y1 capacitors in series provided between primary and secondary circuit)**




77 (mm)
50 (mm)
F1
F2
CX1
CY1
NF1
T1
SH2

# 承 認 書

## SPECIFICATION FOR APPROVAL

| | | |
|---|---|---|
| 客 戶 (CUSTOMER) | 英格爾 | (股) 有限公司 |

| | |
|---|---|
| 品 名 DESCRIPTION | TRANSFORMER |
| 料 號 PART NO. | XF00291 |
| 使 用 機 種 USE MODEL | EF25-05081409-5 |

| | | | | | |
|---|---|---|---|---|---|
| 復核 | 曹志宏 | 檢驗 | 唐 亮 | 制作 | 毛嘉美 |

| 核 準 APPROVED | 校 對 CHECKED | 承 辦 ISSUED |
|---|---|---|
| | | |

揚尚企業有限公司
YOUNG-SHANG ELECTRONIC CO., LTD.
桃園縣中壢市中豐北路 18 號
CHUNG FENG NORTH RD, CHUNG YUAN
CITY TAO YUAN HSIEN TAIWAN . R.O.C
TEL: 886-3-4253830 FAX: 886-3-4256060

揚尚電子廠
YOUNG-SHANG ELECTRONIC PLANT
廣東省惠州博羅縣長寧鎮羅浮路 161 號 NO. 18,
TEL: 00286-752-6662372 6663113 6664994
FAX: 00286-752-6662367

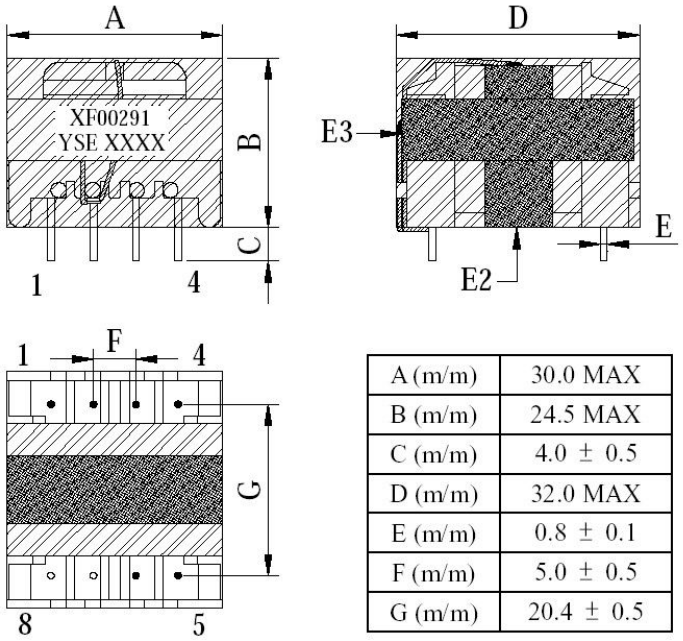
# SPECIFICATION FOR APPROVAL

Y.S.E

PAGE 1 OF 4

| CUSTOMER | 英 格 爾 | Y.S.E. NO | EF25-05081409-5 |
|---|---|---|---|
| PART NO | XF00291 | PART NAME | TRANSFORMER |
| REV NO | E | ISSUE DATE | 2006/6/5 |

1. CONFIGURATION & DIMENSIONS: (UNITE: mm)




| | |
|---|---|
| A (m/m) | 30.0 MAX |
| B (m/m) | 24.5 MAX |
| C (m/m) | 4.0 ± 0.5 |
| D (m/m) | 32.0 MAX |
| E (m/m) | 0.8 ± 0.1 |
| F (m/m) | 5.0 ± 0.5 |
| G (m/m) | 20.4 ± 0.5 |

NOTE:
1. CORE FIXED BY MYLAR TAPE 2Ts.
2. At first wrapped 3Ts 15.5mm tape around the side of x'fmr.
   1). E2: 0.025t*8w+1 layer 3M 1350T-1 tape around the coil and lead wire Ø0.3 (white tube) on top to pin2. then wrapped 1Ts 15.5mm tape again.
   2). E3: Copper film: 0.025t*15w(max)+1 layer 3M 1350T-1 tape) wrapped 1 layer 18mm tape around the E3 copper film.
   3). E3: Around the core and lead Ø0.3 (white tube) to pin2.
   4). Wrapped 1Ts 18mm tape around the side of x'fmr.
   5). PIN7,8 CUT OFF.
3. PIN1-4 朝機臺內繞線.

| REPORTED BY | CHECKED BY | APPROVED BY | 3. | |
|---|---|---|---|---|
| | | | 2. | |
| 毛嘉美 | 唐 亮 | 曹志宏 | RECV 1. | |

YOUNG-SHANG ELECTRONIC PLANT. TEL:0752—6663113

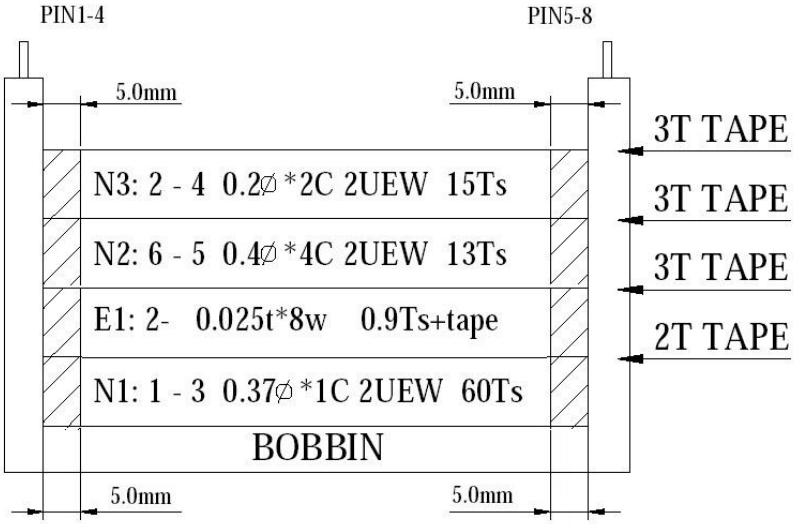
# SPECIFICATION FOR APPROVAL

Y.S.E

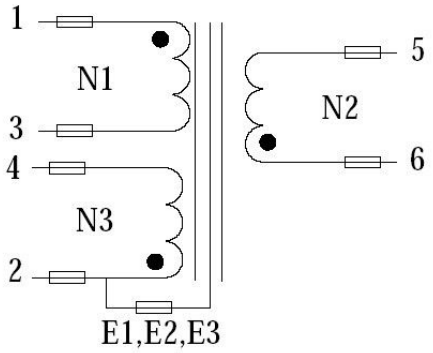
PAGE 2 OF 4

| CUSTOMER | 英 格 爾 | Y.S.E. NO | EF25-05081409-5 |
|---|---|---|---|
| PART NO | XF00291 | PART NAME | TRANSFORMER |
| REV NO | E | ISSUE DATE | 2006/6/5 |

2. WINDING SEQUENCE:




3. SCHEMATIC:




| REPORTED BY | CHECKED BY | APPROVED BY | 3. | |
|---|---|---|---|---|
| | | | 2. | |
| 毛嘉美 | 唐 亮 | 曹志宏 | REV 1. | |

YOUNG-SHANG ELECTRONIC PLANT. TEL:0752—6663113

# SPECIFICATION FOR APPROVAL

Y.S.E

PAGE 3 OF 4

| CUSTOMER | 英 格 爾 | Y.S.E. NO | EF25-05081409-5 |
|---|---|---|---|
| PART NO | XF00291 | PART NAME | TRANSFORMER |
| REV NO | E | ISSUE DATE | 2006/6/5 |

4. ELECTRONICAL CHARACTER:

| TEST INSTRUMENT | INDUCTANCE(L) @ 1KHZ 0.25VRMS CH-1061 | DCR 502AC |
|---|---|---|
| 1-3 | 1.0mH ± 5%<br>LK: 65uH MAX (PIN2,4,5,6 Short) | 0.6Ω MAX |
| 6-5 | | 45mΩ MAX |
| 2-4 | | 0.3Ω MAX |

5. HI-POT : (CH9071)

APPLY AC 4000V 5mA BETWEEN PRI. TO SEC. FOR 60 SEC.

APPLY AC 1800V 5mA BETWEEN PRI. TO CORE FOR 60 SEC.

APPLY AC 1800V 5mA BETWEEN SEC. TO CORE FOR 60 SEC.

6. MATERIAL LIST:

| # | ITEM | MATERIAL | SUPPLIER |
|---|---|---|---|
| 1. | CORE | EF25 PC40<br>PL-7 | TDK<br>SAM WHA CO., LTD |
| 2. | BOBBIN | PHENOLIC T375J 94V-0<br>150℃ | CHANG CHUN PLASTICS CO.,LTD.<br>E59481(S) |
| 3. | WIRE | POLYURETHANE ENAMELD<br>COPPER WIRE 130℃ | PACIFIC ELECTRIC WIRE & CABLE<br>CO.,LTD E201757 |
| 4. | INSULATION TAPE | POLYESTER #1350T-1 130℃ | MINNESO TAMINING& MFG 3M<br>CENTER E17385(N) |
| | | TAPE CT 130℃ | YAHUA PRESSURE SENSITIVE GLUE<br>Co.,LTD E165111 |
| 5. | VARNISH | V-1630FS 130℃ | VIKING PRODUCTS E73071 |
| 6. | TUBE | TEFLON TUBE 150V 200℃ | GREAT HOLDING INDUSTRIES CO.,LTD<br>E156256 |
| 7. | MARGIN TAPE | COMPOSITE FILM<br>NO.44 130℃ | MINNESOTAMINING& MFG 3M CENTER<br>E17385(N) |
| | | TAPE CT 130℃ | YAHUA PRESSURE SENSITIVE GLUE<br>Co.,LTD E165111 |
| 8. | SHIELD | COPPER FOIL | OPTION |

| REPORTED BY | CHECKED BY | APPROVED BY | 3. | |
|---|---|---|---|---|
| | | | 2. | |
| 毛嘉美 | 唐 亮 | 曹志宏 | REV 1. | |

YOUNG-SHANG ELECTRONIC PLANT. TEL:0752—6663113

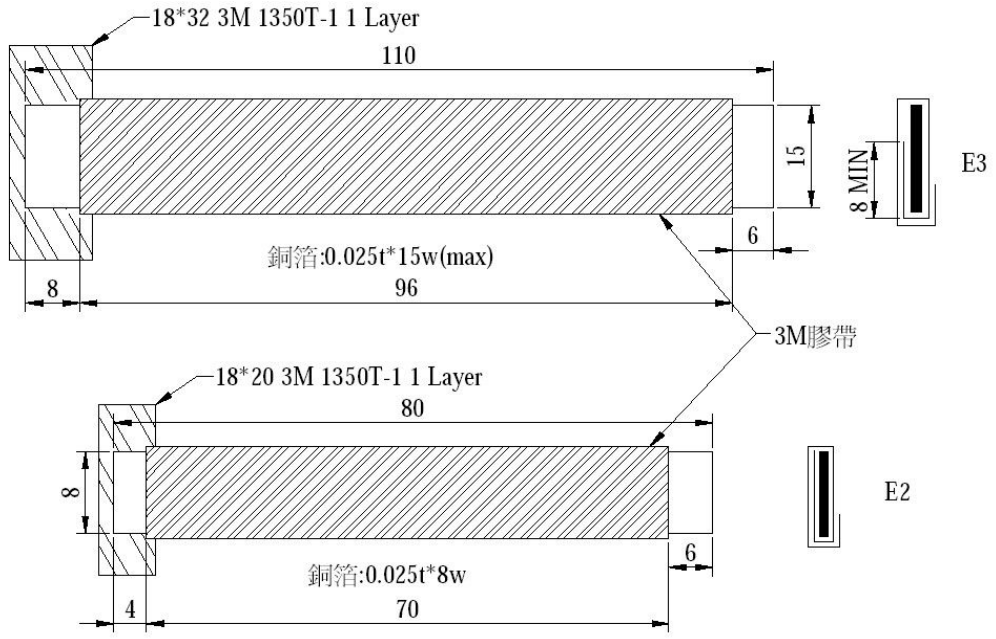
# SPECIFICATION FOR APPROVAL

Y.S.E

PAGE 4 OF 4

| CUSTOMER | 英 格 爾 | Y.S.E. NO | EF25-05081409-5 |
|---|---|---|---|
| PART NO | XF00291 | PART NAME | TRANSFORMER |
| REV NO | E | ISSUE DATE | 2006/6/5 |

7. 銅箔圖: (UNITE: mm)




公差:±0.5mm

| REPORTED BY | CHECKED BY | APPROVED BY | 3. | |
|---|---|---|---|---|
| | | | 2. | |
| 毛嘉美 | 唐 亮 | 曹志宏 | RECV 1.0 | |

YOUNG-SHANG ELECTRONIC PLANT. TEL:0752—6663113