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# TEST REPORT
## IEC 60601-1
## Part 1: General requirements for basic safety and essential performance

| | |
|---|---|
| **Report Number. .....:** | **190601528SHA-001** |
| **Date of issue .....:** | 2020-10-26 |
| **Total number of pages.....** | 131 |
| **Name of Testing Laboratory preparing the Report.....:** | Intertek Testing Services Shanghai |
| **Applicant's name.....:** | GlobTek, Inc. |
| **Address .....:** | 186 Veterans Dr. Northvale, NJ 07647 USA |
| **Test specification:** | |
| **Standard.....:** | IEC 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1 (2012 reprint) |
| **Test procedure .....:** | CB Scheme |
| **Non-standard test method .....:** | N/A |
| **Test Report Form No.....:** | IEC60601_1J_PS |
| **Test Report Form(s) Originator ....:** | UL(US) |
| **Master TRF.....:** | 2014-09 |

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**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 .....:** | Medical Power Supply | | |
| **Trade Mark .....:** | GlobTek, Inc. | | |
| **Manufacturer.....:** | Same as applicant | | |
| **Model/Type reference.....:** | GT*41061-*** (Refer to general product information for details.) | | |
| **Ratings.....:** | Input：100-240V~, 50-60Hz or 50/60Hz, 0.6A;<br>Output: 5.0-30.0Vdc, Max.3.6A, Max.18W | | |
| | | | |
| **Testing procedure and testing location:** | | | |
| ☒ **CB Testing Laboratory:** | Intertek Testing Services Shanghai | | |
| **Testing location/ address ..... :** | Building No.86, 1198 Qinzhou Road (North), 200233 Shanghai, China | | |
| ☐ **Associated CB Testing Laboratory:** | | | |
| **Testing location/ address ..... :** | | | |
| **Tested by (name + signature)..... :** | Albert Zhou<br>(Engineer) | Albert Zhou | |
| **Approved by (name + signature) ..... :** | Jack Cheng<br>(Mandated Reviewer) | Jack Cheng | |
| | | | |
| ☐ **Testing procedure: CTF Stage 1:** | | | |
| **Testing location/ address ..... :** | | | |
| **Tested by (name + signature)..... :** | | | |
| **Approved by (name + signature) ..... :** | | | |
| | | | |
| ☐ **Testing procedure: CTF Stage 2:** | | | |
| **Testing location/ address ..... :** | | | |
| **Tested by (name + signature)..... :** | | | |
| **Witnessed by (name + signature) ..... :** | | | |
| **Approved by (name + signature) ..... :** | | | |
| | | | |
| ☐ **Testing procedure: CTF Stage 3 or 4:** | | | |
| **Testing location/ address ..... :** | | | |
| **Tested by (name + signature)..... :** | | | |
| **Witnessed by (name + signature) ..... :** | | | |
| **Approved by (name + signature) ..... :** | | | |
| **Supervised by (name + signature)..... :** | | | |
| | | | |

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

Attachment 1: Photo of EUT (6 pages)

Attachment 2: Circuit diagram/ layout (2 pages)

Attachment 3: USA national differences (4 pages)

Attachment 4: Canada national differences (8 pages)

Attachment 5: Switzerland national differences (1 page)

Attachment 6: Korea national differences (1 page)

Attachment 7: Japan national differences (14 pages)

**Summary of testing**

| **Tests performed (name of test and test clause):** | **Testing location:** |
|---|---|
| 4.11 Power input | Intertek Testing Services Shanghai |
| 5.7 Humidity preconditioning treatment | Building No. 86, 1198 Qinzhou Road (North), 200233 Shanghai, China |
| 7.1.2 Legibility of marking | |
| 7.1.3 Durability of marking test | |
| 8.4.3 Plug discharge test | |
| 8.5.4 Working voltage measurement | |
| 8.7 Leakage current test | |
| 8.8.3 Dielectric strength test | |
| 8.8.4.1 Ball pressure test | |
| 8.9.4 Creepage and clearance measurements | |
| 11.1 Excessive temperatures in ME EQUIPMENT | |
| 13.2 Single fault conditions | |
| 15.3.2 Push Test | |
| 15.3.3 Impact Test | |
| 15.3.4 Drop Test | |
| 15.3.6 Moulding Stress Relief | |
| 15.5.1.2 Transformer short-circuit test | |
| 15.5.1.3 Transformer overload test | |

**Summary of compliance with National Differences**

List of countries addressed:

Canada, USA, Switzerland, Korea, Japan

Group- and national differences for the CENELEC countries according to EN 60601-1:2006 + A11:2011 + A1:2013. The text of the International Standard IEC 60601-1:2005/A1:2012 was approved by CENELEC as a European Standard without any modification.

National differences for Switzerland according to SN EN 60601-1:2006.

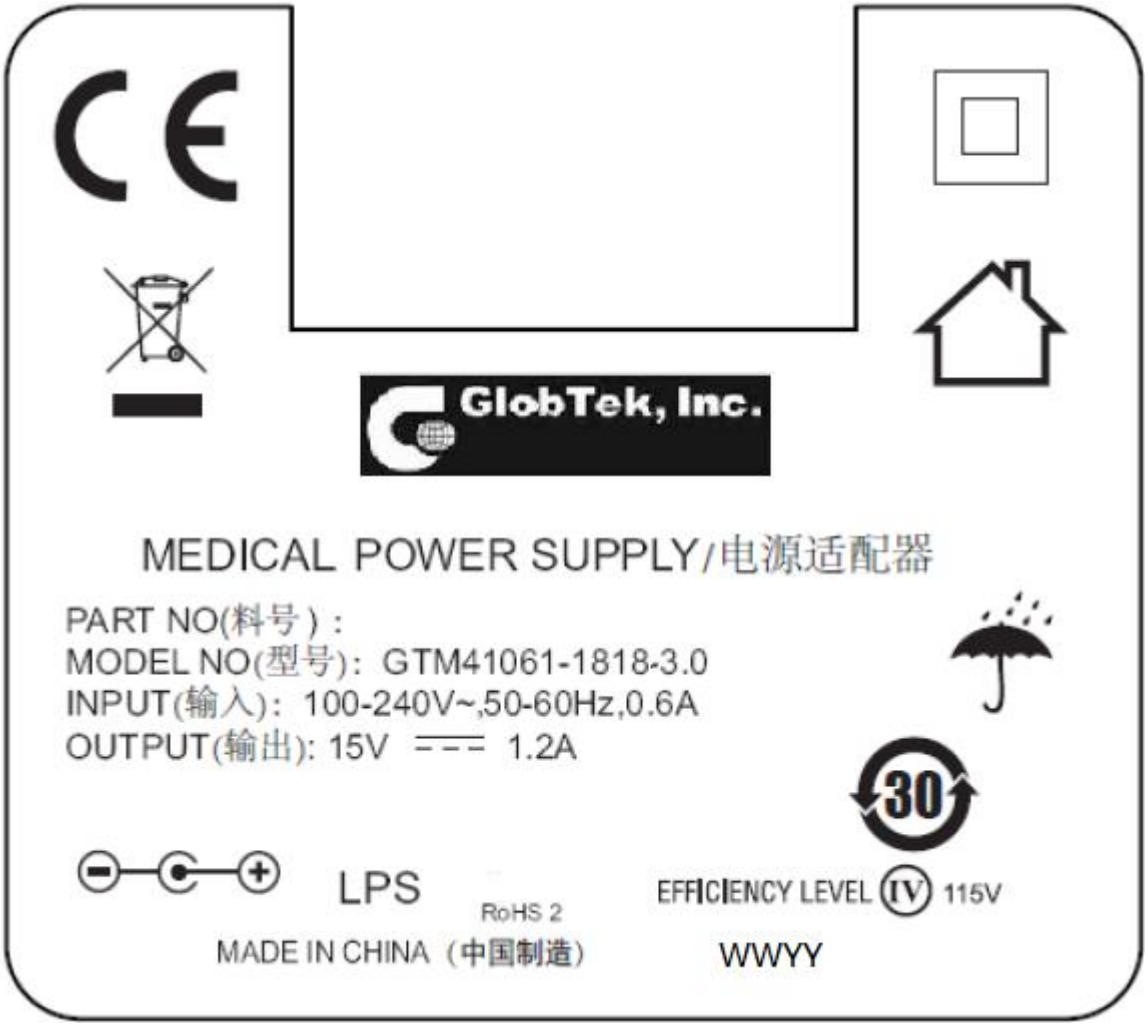
National differences for Korea according to Notification of MFDS No. 2020-12, Annex 1.

National differences for Japan according to JIS T 0601-1:2017.

☒ The product fulfils the requirements of IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012.

**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.**




Note: Other models are with similar label as corresponding above models except different model name and ratings.
The above markings are the minimum requirements required by the safety standard. For the final production samples, the additional markings which do not give rise to misunderstanding may be added.

| GENERAL INFORMATION | |
|---|---|
| **Test item particulars (see also Clause 6):** | |
| Classification of installation and use ..... : | Direct plug-in type: final determination in end product evaluation. |
| Device type (component/sub-assembly/ equipment/ system) : | Component |
| Intended use (Including type of patient, application location) : | PSU (external power adapter or internal power supply board) |
| Mode of operation ..... : | Continuous |
| Supply connection..... | Direct plug-in for power adapter model. |
| Accessories and detachable parts included ..... : | Plug (Evaluated as component) |
| Other options include ..... : | None |
| **Testing** | |
| Date of receipt of test item(s)..... : | 2020-06-18 |
| Dates tests performed..... : | 2020-06-18 to 2020-10-22 |
| **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:**

"(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.**

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

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

| | |
|---|---|
| **The application for obtaining a CB Test Certificate 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 Dr. Northvale, NJ 07647 USA<br>2. GlobTek (Suzhou) Co., Ltd<br>Building 4, No. 76, JinLing East Road, Suzhou Industrial Park, Suzhou, JiangSu 215021, China |

**General product information:**

Product covered by this report is medical power supply module.

The device is direct plug-in power adapter with interchangeable plug portion, which is Class II apparatus. It can be used with different plug types. The evaluation sheets of the different plug types are also attached within this report. Two pieces of outer enclosure are enclosed by ultrasonic welding without screw.
All the types are designed for continuous operation.
The maximum operating temperature of models with output current greater than 3A is 30°C.
The maximum operating temperature of models with output current not greater than 3A is 40°C.

All models have the same circuit diagram, PCB layout and transformer.

All the types are designed for continuous operation and no applied part is defined.

Insulation between mains part and secondary circuits is evaluated as 2MOPP.

**Model similarity:**
GT*41061-***
The 1st "*" part can be 'M' or '-' or 'H' for market identification and not related to safety.
The 2nd "*" part denotes the rated output wattage designation, which can be "01" to "18", in step of 1 denote 1W.
The 3rd "*" part denotes the standard rated output voltage designation, which can be "12", "18", "24" or "30". These standard rated output voltage designations correspond to four isolated transformer models. Each transformer model is identical in insulation construction including clearance and creepage except number of turns per coil.
The 4th "*" part is optional, which can be "-0.1" to "-7.0" in step of 0.1 to denote voltage deviation or blank to indicate no voltage different. The result by subtracting the deviation value from the standard rated output voltage denotes the rated output voltage, with a range of 5 - 30 volts.

**Model list**

| Model | Rated output voltage range | Max. rated output current | Max. rated output power | Transformer designations |
|---|---|---|---|---|
| GT*41061-*12* | 5-12Vdc | 3.6A | 18W | TF001 |
| GT*41061-*18* | 12.1-18Vdc | 1.49A | 18W | TF002 |
| GT*41061-*24* | 18.1-24Vdc | 1.0A | 18W | TF003 |
| GT*41061-*30* | 24.1-30Vdc | 0.75A | 18W | TF004 |

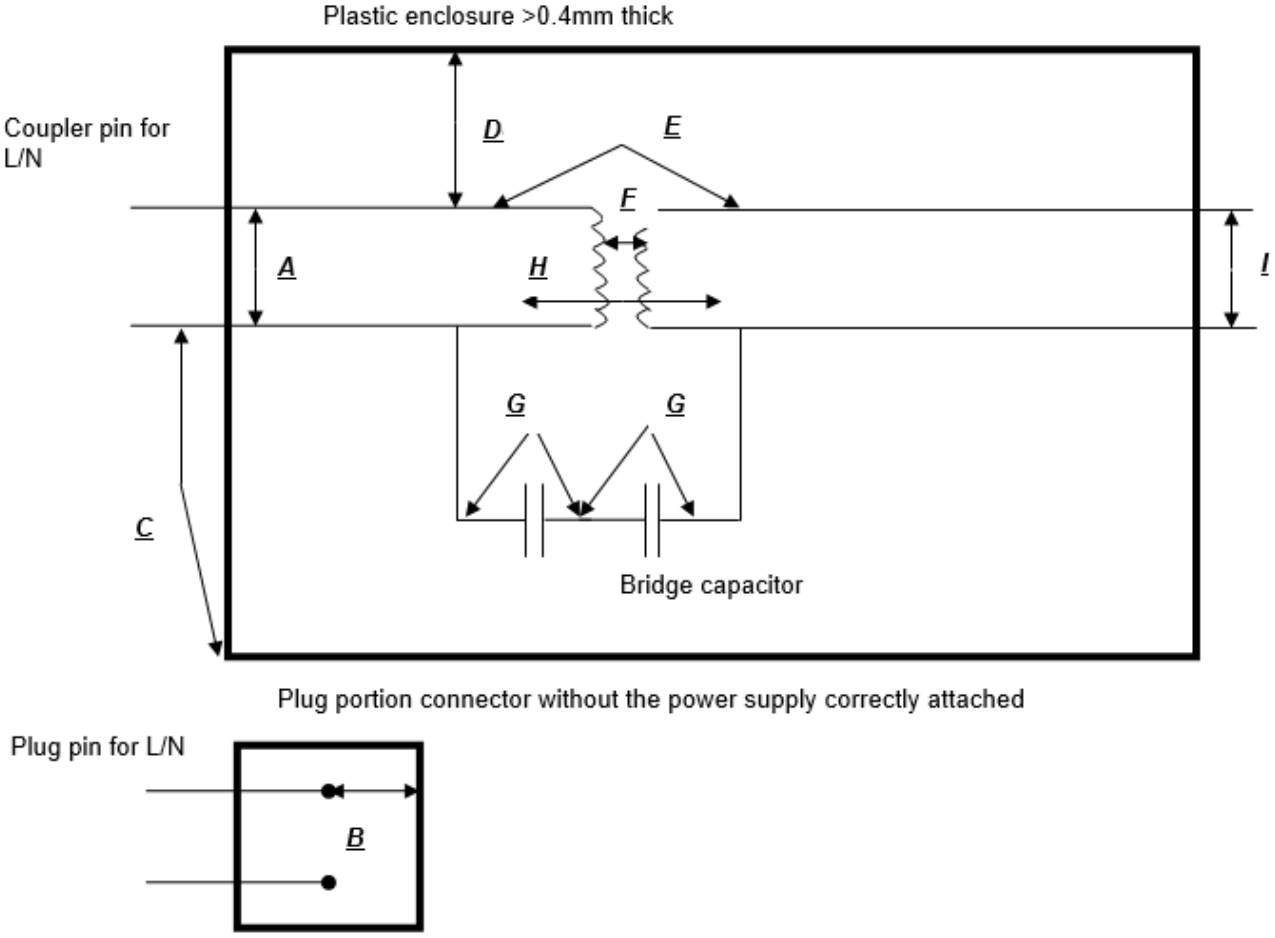
**Technical Considerations:**

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

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

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

**INSULATION DIAGRAM**




| TABLE: INSULATION DIAGRAM | | P |
|---|---|---|
| Pollution degree ..... : | 2 | — |
| Overvoltage category ..... : | II | — |
| Altitude..... : | 3000m | — |
| 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 |
|---|---|---|---|---|---|---|---|---|---|
| | | | $V_{rms}$ | $V_{pk}$ | | | | | |
| A | 1MOOP | IIIb | 240 | 340 | 2.4 | 2.28 | 3.1 | 3.1 | Opposite polarity of mains part |

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **B** | **2MOOP** | **IIIb** | **240** | **340** | **4.8** | **4.56** | **5.6** | **5.6** | **Plug pin-out on the connector side to accessible part when the plug portion is plugged in the socket without the power supply correctly attached.** |
| **C** | **2MOPP** | **IIIb** | **240** | **--** | **7.84** | **5.0** | **9.0** | **9.0** | **Mains part (plug pin) to outer enclosure (accessible position during normal use)** |
| **D** | **2MOPP** | **IIIb** | **240** | **--** | **7.84** | **5.0** | **8.0** | **8.0** | **Internal mains part to accessible outer enclosure** |
| **E** | **2MOPP** | **IIIb** | **240** | **--** | **7.84** | **5.0** | **8.0** | **8.0** | **Mains part to secondary circuits (Optocoupler)** |
| **F** | **2MOPP** | **IIIb** | **276** | **--** | **8.70** | **5.35** | **10.0** | **10.0** | **Mains part to secondary circuits (Transformer)** |
| **G** | **1MOPP (Each) x 2** | **IIIb** | **240** | **--** | **3.92** | **2.43** | **4.1** | **4.1** | **Mains part to secondary circuits (Y capacitor x 2).** |
| **H** | **2MOPP** | **IIIb** | **240** | **--** | **7.84** | **5.0** | **8.7** | **8.7** | **Mains part to secondary circuits (Along PCB trace)** |
| **I** | **2MOOP** | **IIIb** | **--** | **Max. 30Vdc** | **--** | **--** | **--** | **--** | **Accessible part per 8.4.2 c)** |

**Supplementary Information:**

**1) Multiplication factor for MOOP: 1.14; Multiplication factor for MOPP: 1.00.**

**2) Linear interpolation is applied to the determination of required creepage.**

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

**3) The working voltage is highest measured value which acquired by testing all the models listed in the report at the rated input voltage, but not less than the rated input voltage.**

**4) The minimum creepage and clearance is selected from all the types of optocouplers.**

**5) The transformer core regarded as primary conductor is wrapped with 2 layers of insulating tape and the secondary pin-out adopts the jump lead wire soldering.**

**6) There is a slot min. 1 mm wide between two sides of pads of components.**

**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** | See Appended RM Results Table 4.2 | 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.** | No essential performance | N/A |
| **4.4** | **EXPECTED SERVICE LIFE stated in RISK MANAGEMENT FILE .....:** | Risk Management Report 6.1.19 10years | P |
| **4.5** | **Alternative means of addressing particular RISKS considered acceptable based on MANUFACTURER'S justification that RESIDUAL RISKS resulting from application of alternative means are comparable to the RESIDUAL RISKS resulting from requirements of this standard .....:** | No alternative risk control method. | N/A |
| **4.6** | **RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10.....:** | No such parts. | N/A |
| **4.7** | **ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2.....:** | See Appended RM Results Table 4.7 | 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 |
| | **RISK associated with failure of component during EXPECTED SERVICE LIFE of ME EQUIPMENT taken into account to evaluate if a component should be subjected to failure simulation** | | 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 and wiring used according to applicable rating. | P |
| | **Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS** | | P |
| | **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** | | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **b) Requirements of this standard applied in the absence of a relevant IEC or ISO standard** | | P |
| **4.9** | **A COMPONENT WITH HIGH-INTEGRITY CHARACTERISTICS provided because a fault in a particular component can generate an unacceptable RISK .....:** | | N/A |
| | **COMPONENTS WITH HIGH-INTEGRITY CHARACTERISTICS selected and evaluated consistent with their conditions of use and reasonable foreseeable misuse during EXPECTED SERVICE LIFE of ME EQUIPMENT by reviewing RISK MANAGEMENT FILE .....:** | | N/A |
| **4.10** | **Power supply** | | **P** |
| **4.10.1** | **ME EQUIPMENT is suitable for connection to a SUPPLY MAINS, specified to be connected to a separate power supply, can be powered by an INTERNAL ELECTRICAL POWER SOURCE, or a combination of the three .....:** | Suitable for connection to a 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 equipment. | N/A |
| | **– 250 V d.c. or single-phase a.c., or 500 V poly-phase a.c. for ME EQUIPMENT and ME SYSTEMS with a RATED input ≤ 4 kVA (V)..... :** | 100-240Vac, single phase, less than 4KVA | P |
| | **– 500 V for all other ME EQUIPMENT and ME SYSTEMS** | 100-240Vac, single phase, less than 4KVA | N/A |
| **4.11** | **Power input** | | P |
| | **Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10%..... :** | See appended Table 4.11 | P |
| | **– Measurements on ME EQUIPMENT or a ME SYSTEM marked with one or more RATED voltage ranges made at both upper and lower limits of the range.....:** | See appended Table 4.11 | P |
| | **Measurements made at a voltage equal to the mean value of the range when each marking of RATED input was related to the mean value of relevant voltage range** | No such marking. | N/A |
| | **Power input, expressed in volt-amperes, measured with a volt-ampere meter or calculated as the product of steady state current (measured as described above) and supply voltage .....:** | See appended Table 4.11 | P |

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

| | | | |
|---|---|---|---|
| **5** | **GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT** | | **P** |
| **5.1** | **TYPE TESTS determined in consideration of Clause 4, in particular 4.2** | | P |
| | **Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods .....:** | | N/A |
| | **RISK MANAGEMENT FILE identified combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION.** | | N/A |
| **5.2** | **TYPE TESTS conducted on one representative sample under investigation; multiple samples used simultaneously when validity of results was not significantly affected .....:** | Type test on single representative sample. | P |
| **5.3** | **a) Tests conducted within the environmental conditions specified in technical description** | | P |
| | **Temperature (ºC), Relative Humidity (%) .....:** | 0-40ºC, 20%-80%RH | — |
| | **Atmospheric Pressure (kPa) .....:** | 700-1060hPa (3000m altitude) | — |
| | **b) ME EQUIPMENT shielded from other influences that might affect the validity of tests** | | P |
| | **c) Test conditions modified and results adjusted accordingly when ambient temperature could not be maintained .....:** | Considered in temperature test | P |
| **5.4** | **a) ME EQUIPMENT tested under least favourable working conditions specified in instructions for use.....:** | | N/A |
| | **b) ME EQUIPMENT with adjustable or controlled operating values by anyone other than SERVICE PERSONNEL adjusted to values least favourable for the relevant test per instructions for use** | EUT is component power supply, not adjustable. | N/A |
| | **c) When test results influenced by inlet pressure and flow or chemical composition of a cooling liquid, tests performed within the limits in technical description.....:** | No cooling liquid used. | N/A |
| | **d) Potable water used for cooling** | No cooling water used. | N/A |
| **5.5** | **a) Supply voltage during tests was the least favourable of the voltages specified in 4.10.2 or voltages marked on ME EQUIPMENT (V) .....:** | 90/264V considered | P |
| | **b) ME EQUIPMENT marked with a RATED frequency range tested at the least favourable frequency within the range (Hz)..... :** | 50-60Hz or 50/60Hz considered | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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..... :** | 90/264V, 50-60Hz or 50/60Hz considered | P |
| | **d) ME EQUIPMENT intended for only d.c. supply connection tested with d.c. and influence of polarity considered..... :** | No d.c supply connection | N/A |
| | **e)ME EQUIPMENT tested with alternative ACCESSORIES and components specified in ACCOMPANYING DOCUMENTS to result in the least favourable conditions..... :** | No alternative accessory | N/A |
| | **f) ME EQUIPMENT connected to a separate power supply as specified in instructions for use** | No separate power supply used | N/A |
| **5.6** | **When failure occurred or probability of future failure detected during sequence of tests, per agreement with manufacturer, all tests affecting results conducted on a new sample** | No such condition | N/A |
| | **Alternatively, upon repair and modification of the sample, only the relevant tests conducted** | No such condition | 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..... :** | No additional testing should be considered. | P |
| | **Manually detachable parts removed and treated concurrently with major parts and manually removable ACCESS COVERS were opened and detached** | No such part. | N/A |
| | **ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber (relative humidity 93%±3%) and an ambient within 2 °C of T in the range of + 20 °C to + 32 °C for 48 h for units rated IPX0** | Pre-condition performed: 26°C, 93%RH for 48 h | P |
| | **- For units rated higher than IPX0 test time extended to 168 h..... :** | | N/A |
| **5.8** | **Unless stated otherwise, tests in this standard sequenced as in Annex B to prevent influencing results of any subsequent test** | | P |
| **5.9** | **Determination of APPLIED PARTS and ACCESSIBLE PARTS** | | **P** |
| **5.9.1** | **APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS..... :** | See clause 4.6 Remark | N/A |
| **5.9.2** | **ACCESSIBLE PARTS** | | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **5.9.2.1** | **Accessibility, when necessary, determined using standard test finger of Fig 6 applied in a bent or straight position** | See Appended Table 5.9.2 | P |
| | **Openings preventing entry of test finger of Fig. 6 mechanically tested with a straight un-jointed test finger of the same dimensions with a force of 30 N** | | P |
| | **When the straight un-jointed test finger entered, test with the standard test finger (Fig 6) was repeated, if necessary, by pushing the finger through the opening** | Straight un-jointed test finger can't enter opening. | N/A |
| **5.9.2.2** | **Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s** | Test hook can't enter opening | N/A |
| | **All additional parts that became accessible checked using standard test finger and by inspection** | Test hook can't enter opening | N/A |
| **5.9.2.3** | **Conductive parts of actuating mechanisms of electrical controls accessible after removal of handles, knobs, levers and the like regarded as ACCESSIBLE PARTS ..... :** | No such part. | N/A |
| | **Conductive parts of actuating mechanisms not considered ACCESSIBLE PARTS when removal of handles, knobs, etc. required use of a TOOL .:** | No such part. | N/A |

| | | | |
|---|---|---|---|
| **6** | **CLASSIFICATION OF ME EQUIPMENT AND ME SYSTEMS** | | **P** |
| **6.2** | **CLASS I ME EQUIPMENT, externally powered** | | N/A |
| | **CLASS II ME EQUIPMENT, externally powered** | Class II | P |
| | **INTERNALLY POWERED ME EQUIPMENT** | Not internally powered | N/A |
| | **EQUIPMENT with means of connection to a SUPPLY MAINS complied with CLASS I or CLASS II ME EQUIPMENT requirements when so connected, and when not connected to SUPPLY MAINS with INTERNALLY POWERED ME EQUIPMENT requirements** | | N/A |
| | **TYPE B APPLIED PART** | No applied part | N/A |
| | **TYPE BF APPLIED PART** | No applied part | N/A |
| | **TYPE CF APPLIED PART** | No applied part | N/A |
| | **DEFIBRILLATION-PROOF APPLIED PARTS** | No applied part | N/A |
| **6.3** | **ENCLOSURES classified according to degree of protection against ingress of water and particulate matter (IPN$_1$N$_2$) as per IEC 60529 ..... :** | IP20 for adapter model. | N/A |

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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 sterilization required | N/A |
| **6.5** | **ME EQUIPMENT and ME SYSTEMS intended for use in an OXYGEN RICH ENVIRONMENT classified for such use and complied with 11.2.2** | Power supply not investigated for OXYGEN RICH ENVIRONMENT | N/A |
| **6.6** | **CONTINUOUS or Non-CONTINUOUS OPERATION..... :** | 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** | | P |
| | **a) After tests, adhesive labels didn't loosen up or curl up at edges and markings complied with requirements in Clause 7.1.2..... :** | See appended Tables 7.1.3 and 8.10 | P |
| | **b) Markings required by 7.2-7.6 remained CLEARLY LEGIBLE after marking durability test ... :** | See appended Tables 7.1.3 and 8.10 | 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 (not for PERMANENTLY INSTALLED ME EQUIPMENT), 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ..... :** | See attached copy of Marking Plate | P |
| | **Remaining markings fully recorded in ACCOMPANYING DOCUMENTS ..... :** | All required marking provided on name plate. | N/A |
| | **Markings applied to individual packaging when impractical to apply to ME EQUIPMENT** | No such condition | N/A |
| | **A material, component, ACCESSORY, or ME EQUIPMENT intended for a single use, or its packaging marked "Single Use Only", "Do Not Reuse" or with symbol 28 of Table D.1 (ISO 7000-1051, DB:2004-01)..... :** | No part intended for a single use. | N/A |
| **7.2.2** | **ME EQUIPMENT marked with:** | | **P** |
| | **– the name or trademark and contact information of the MANUFACTURER** | See marking plate | P |
| | **– a MODEL OR TYPE REFERENCE** | See attached copy of Marking Plate | P |
| | **– a serial number or lot or batch identifier; and** | See marking plate | P |
| | **– the date of manufacture or use by date** | See marking plate | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or** | | N/A |
| | **Detachable components of the ME EQUIPMENT are marked with the name or trademark of the MANUFACTURER, and** | See marking plate | P |
| | **– a MODEL OR TYPE REFERENCE** | See marking plate | P |
| | **Software forming part of a PEMS identified with a unique identifier, such as revision level or date of release/issue, and identification are available to designated persons .....:** | No software | N/A |
| **7.2.3** | **Symbol 11 on Table D.1 (ISO 7000-1641, DB: 2004-01) used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS** | See the marking label. | P |
| | **Safety sign 10 on Table D.2 (safety sign IEC 60878 Safety 01) used, advising OPERATOR that ACCOMPANYING DOCUMENTS must be consulted** | No such safety sign used. | N/A |
| **7.2.4** | **ACCESSORIES marked with name or trademark and contact information of their MANUFACTURER, and .....:** | No accessory. | N/A |
| | **- with a MODEL or TYPE REFERENCE** | | N/A |
| | **– a serial number or lot or batch identifier** | | N/A |
| | **– the date of manufacture or use by date** | | N/A |
| | **Markings applied to individual packaging when not practical to apply to ACCESSORIES** | | N/A |
| **7.2.5** | **ME EQUIPMENT intended to receive power from other electrical equipment in an ME SYSTEM and compliance with the requirements of this standard is dependent on that other equipment, one of the following is provided:** | Component; final determination to be performed in the end-product | N/A |
| **7.2.6** | **Connection to the Supply Mains** | | **P** |
| | **Except for PERMANENTLY INSTALLED ME EQUIPMENT, marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point** | | P |
| | **For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT, preferably, adjacent to SUPPLY MAINS connection** | Not for permanently installed. | N/A |
| | **– RATED supply voltage(s) or RATED voltage range(s) with a hyphen (-) between minimum and maximum voltages (V, V-V).....:** | 100-240V | P |
| | **Multiple RATED supply voltages or multiple RATED supply voltage ranges are separated by (V/V)...:** | Not so marked. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– Nature of supply (e.g., No. of phases, except single-phase) and type of current .....:** | Single phase, AC. | P |
| | **Symbols 1-5, Table D.1 (symbols of IEC 60417-5032, 5032-1, 5032-2, 5031, and 5033, all 2002-10) used, optionally, for same parameters .....:** | '~' is used. | P |
| | **– RATED supply frequency or RATED frequency range in hertz.....:** | 50-60Hz or 50/60Hz | P |
| | **– Symbol 9 of Table D.1 (symbol IEC 60417-5172, 2003-02) used for CLASS II ME EQUIPMENT....:** | Symbol 9 is used for Class II adapter model. | P |
| **7.2.7** | **RATED input in amps or volt-amps, (A, VA) .....:** | 0.6A | P |
| | **RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A, VA, W) .....:** | | N/A |
| | **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).....:** | 100-240V~ | P |
| | **Input at mean value of range marked when range limits do not differ by more than 10 % from mean value (A, VA, W) .....:** | No such range provided. | N/A |
| | **Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA).....:** | No such rating provided. | N/A |
| | **Marked input of ME EQUIPMENT provided with means for connection of supply conductors of other electrical equipment includes RATED and marked output of such means (A, VA, W).....:** | No such rating provided. | N/A |
| **7.2.8** | **Output connectors** | | **P** |
| **7.2.8.1** | **See 16.9.2.1 b) for MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT** | No MSO | N/A |
| **7.2.8.2** | **Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment** | | P |
| | **Rated Voltage (V), Rated Current (A).....:** | See model similarity | — |
| | **Rated Power (W), Output Frequency (Hz) .....:** | See model similarity | — |
| **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....:** | IP20 | N/A |
| **7.2.10** | **Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols as follows (not applied to parts identified according to 4.6).....:** | No Applied Parts in power supply | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **7.2.11** | **ME EQUIPMENT not marked to the contrary assumed to be suitable for CONTINUOUS OPERATION** | | P |
| | **DUTY CYCLE for ME EQUIPMENT intended for non-CONTINUOUS OPERATION appropriately marked to provide maximum "on" and "off" time .....:** | Continuous operation. | N/A |
| **7.2.12** | **Type and full rating of a fuse marked adjacent to ACCESSIBLE fuse-holder** | No accessible fuse-holder | N/A |
| | **Fuse type.....:** | | **—** |
| | **Voltage (V) and Current (A) rating .....:** | | **—** |
| | **Operating speed (s) and Breaking capacity.....:** | | **—** |
| **7.2.13** | **A safety sign CLEARLY LEGIBLE and visible after INSTALLATION in NORMAL USE applied to a prominent location of EQUIPMENT that produce physiological effects capable of causing HARM to PATIENT or OPERATOR not obvious to OPERATOR ..:** | EUT is component power supply only, no physiological effect | N/A |
| | **Nature of HAZARD and precautions for avoiding or minimizing the associated RISK described in instructions for use .....:** | Component, to be determined as part of end product. | N/A |
| **7.2.14** | **HIGH VOLTAGE TERMINAL DEVICES on the outside of ME EQUIPMENT accessible without the use of a TOOL marked with symbol 24 of Table D.1 (symbol IEC 60417-5036, 2002-10)** | No such high voltage terminal device. | N/A |
| **7.2.15** | **Requirements for cooling provisions marked (e.g., supply of water or air).....:** | Component, to be determined as part of end product. | N/A |
| **7.2.16** | **ME EQUIPMENT with limited mechanical stability** | Component, to be determined in end-product evaluation. | N/A |
| **7.2.17** | **Packaging marked with special handling instructions for transport and/or storage.....:** | Component, to be determined as part of end product. | N/A |
| **7.2.18** | **RATED maximum supply pressure from an external source marked on ME EQUIPMENT adjacent to each input connector, and .....:** | No external pressure source | N/A |
| **7.2.19** | **Symbol 7 of Table D.1 (IEC 60417-5017, 2002-10) marked on FUNCTIONAL EARTH TERMINAL.....:** | No FE terminal. | N/A |
| **7.2.20** | **Protective means, required to be removed to use a particular function of ME EQUIPMENT with alternate applications, marked to indicate the necessity for replacement when the function is no longer needed .....:** | Component, to be determined as part of end product. | N/A |
| | **No marking applied when an interlock provided** | | N/A |
| **7.3** | **Marking on the inside of ME EQUIPMENT or ME 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 element, no lamp holder. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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** | No heating element, no lamp holder. | N/A |
| **7.3.2** | **Symbol 24 of Table D.1 (symbol IEC 60417-5036, 2002-10), or safety sign 3 of Table D.2 used to mark presence of HIGH VOLTAGE parts.....:** | No such HV part. | N/A |
| **7.3.3** | **Type of battery and mode of insertion when applicable is marked .....:** | No battery. | N/A |
| | **An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL .....:** | No battery. | N/A |
| | **A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement by inadequately trained personnel would result in an unacceptable RISK (e.g., excessive temperatures, fire or explosion).....:** | No battery. | N/A |
| | **An identifying marking also provided referring to instructions in ACCOMPANYING DOCUMENTS.....:** | No battery. | N/A |
| **7.3.4** | **Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL** | Specification adjacent to component. | P |
| | **Identified by specification adjacent to the component, or** | | P |
| | **by reference to ACCOMPANYING DOCUMENTS** | | P |
| | **Voltage (V) and Current (A) rating .....:** | T2A, 250V | — |
| | **Operating speed(s), size & breaking capacity.:** | | — |
| **7.3.5** | **PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 (IEC 60417-5019, 2002-10), except for the PROTECTIVE EARTH TERMINAL in an APPLIANCE INLET according to IEC 60320-1** | No Protective earth terminal. | 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 (IEC 60417-5017, 2002 -10) marked on FUNCTIONAL EARTH TERMINALS** | No FE terminal. | N/A |
| **7.3.7** | **Terminals for supply conductors marked adjacent to terminals,.....:** | No hazard | P |
| | **Terminal markings included in ACCOMPANYING DOCUMENTS when ME EQUIPMENT too small to accommodate markings** | Marked on EUT | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 (Code in IEC 60445)** | Not permanently installed | N/A |
| | **Marking for connection to a 3-phase supply, if necessary, complies with IEC 60445** | Not 3-phase | N/A |
| | **Markings on or adjacent to electrical connection points not applied to parts requiring removal to make connection, and remained visible after connection made** | | P |
| **7.3.8** | **"For supply connections, use wiring materials suitable for at least X °C" (where X > than max temperature measured in terminal box or wiring compartment under NORMAL USE), or equivalent, marked at the point of supply connections** | No such high temperature | N/A |
| | **Statement not applied to parts requiring removal to make the connection, and CLEARLY LEGIBLE after connections made** | | N/A |
| **7.4** | **Marking of controls and instruments** | | **N/A** |
| **7.4.1** | **The "on" & "off" positions of switch to control power to ME EQUIPMENT or its parts, including mains switch, marked with symbols 12 and 13 of Table D.1 (IEC 60417-5007, 2002-10, and IEC 60417-5008, 2002-10), or** | No power switch | N/A |
| | **– indicated by an adjacent indicator light, or** | | N/A |
| | **– indicated by other unambiguous means** | | N/A |
| | **The "on/off" positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1 (IEC 60417-5010 2002-10), and** | | 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 (symbol 60417-5011 2002-10), or** | | N/A |
| | **– status indicated by adjacent indicator light** | | N/A |
| | **– status indicated by other unambiguous means** | | N/A |
| **7.4.2** | **Different positions of control devices/switches indicated by figures, letters, or other visual means** | No such device. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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 .....:** | No such device. | N/A |
| | **– or an indication of direction in which magnitude of the function changes** | No such device. | N/A |
| | **Control device or switch that brings the ME EQUIPMENT into the "stand-by" condition marked with symbol IEC 60417-5009 (2002-10) (Table D.1, Symbol 29).** | No stand-by switch | 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** | No numeric indications of parameters. | 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 safety sign used. | N/A |
| | **Markings used to convey a warning, prohibition or mandatory action mitigating a RISK not obvious to OPERATOR are safety signs from ISO 7010.....:** | | N/A |
| | **Affirmative statement together with safety sign placed in instructions for use if insufficient space on ME EQUIPMENT** | | N/A |
| | **Specified colours in ISO 3864-1 used for safety signs.....:** | | N/A |
| **7.6** | **Symbols** | | **P** |
| **7.6.1** | **Meanings of symbols used for marking described in instructions for use.....:** | Accompanying documents have been checked. | P |
| **7.6.2** | **Symbols required by this standard conform to IEC or ISO publication referenced** | IEC 60417-5172: "CLASS II equipment" symbol is used. IEC 60417-5957: "For indoor use only" symbol is used. | P |
| **7.6.3** | **Symbols used for controls and performance conform to the IEC or ISO publication where symbols are defined, as applicable** | No such symbol is used. | N/A |
| **7.7** | **Colours of the insulation of conductors** | | N/A |
| **7.7.1** | **PROTECTIVE EARTH CONDUCTOR identified by green and yellow insulation** | No PE conductor is provided. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **7.7.2** | **Insulation on conductors inside ME EQUIPMENT forming PROTECTIVE EARTH CONNECTIONS identified by green and yellow at least at terminations** | | N/A |
| **7.7.3** | **Green and yellow insulation identify only following conductors:** | | N/A |
| | **– PROTECTIVE EARTH CONDUCTORS** | | N/A |
| | **– conductors specified in 7.7.2** | | N/A |
| | **– POTENTIAL EQUALIZATION CONDUCTORS** | | N/A |
| | **– FUNCTIONAL EARTH CONDUCTORS** | | N/A |
| **7.7.4** | **Neutral conductors of POWER SUPPLY CORDS are "light blue" specified in IEC 60227-1 or IEC 60245-1** | No power supply cord | N/A |
| **7.7.5** | **Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1** | No power supply cord | N/A |
| **7.8** | **Indicator lights and controls** | | N/A |
| **7.8.1** | **Red indicator lights mean: Warning (i.e., immediate response by OPERATOR required)** | No indicator light. | N/A |
| | **Yellow indicator lights mean: Caution (i.e., prompt response by OPERATOR required)** | | N/A |
| | **Green indicator lights mean: Ready for use** | | N/A |
| | **Other colours, if used: Meaning other than red, yellow, or green (colour, meaning).....:** | | N/A |
| **7.8.2** | **Red used only for emergency control** | | N/A |
| **7.9** | **ACCOMPANYING DOCUMENTS** | Accompany documents are provided for some critical issue like technical data, safety warnings, necessary information to set up, but further evaluation is needed on end product level. | P |
| **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** | RM report page 11 EL1 | P |
| | **NORMAL CONDITION considered as simultaneous occurrence of situations identified in 8.1a)** | | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **SINGLE FAULT CONDITION considered to include the occurrences as specified in Clause 8.1b)... :** | The following needs to be considered in the end product:<br>- interruption of any one power-carrying conductor<br>- unintended movement of a component<br>- accidental detachment of conductors and connectors | N/A |
| | **ACCESSIBLE PARTS determined according to 5.9** | | P |
| | **LEAKAGE CURRENTS measured according to 8.7** | | P |
| **8.2** | **Requirements related to power sources** | | N/A |
| **8.2.1** | **Connection to a separate power source** | | N/A |
| | **When ME EQUIPMENT specified for connection to a separate power source other than SUPPLY MAINS, separate power source considered as part of ME EQUIPMENT or combination considered as an ME SYSTEM** | Connection to mains only | N/A |
| | **Tests performed with ME EQUIPMENT connected to separate power supply when one specified** | | N/A |
| | **When a generic separate power supply specified, specification in ACCOMPANYING DOCUMENTS examined** | | N/A |
| **8.2.2** | **No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source** | Component, to be determined in end-product evaluation | N/A |
| | **ME EQUIPMENT connected with correct polarity maintained BASIC SAFETY and ESSENTIAL PERFORMANCE** | Component, to be determined in end-product evaluation | N/A |
| | **Protective devices that can be reset by anyone without a TOOL returns to NORMAL CONDITION on reset** | Component, to be determined in end-product evaluation | N/A |
| **8.3** | **Classification of APPLIED PARTS** | No Applied Parts | N/A |
| **8.4** | **Limitation of voltage, current or energy** | | **P** |
| **8.4.1** | **PATIENT CONNECTIONS intended to deliver Current** | | **P** |
| | **Limits in 8.4.2 not applied to currents intended to flow through body of PATIENT to produce a physiological effect during NORMAL USE** | No such currents. | P |
| **8.4.2** | **ACCESSIBLE PARTS and APPLIED PARTS** | | **P** |
| | **b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT in Cl. 8.7.3 c) when measured per Clause 8.7.4 (mA) ..... :** | See appended Table 8.7 | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed** | The likelihood of the current flowing through body of OPERATOR to be determined in end-product evaluation | P |
| | **– accessible contacts of connectors** | | P |
| | **– contacts of fuseholders accessible during replacement of fuse** | No such part. | N/A |
| | **– contacts of lampholders accessible after removal of lamp** | No such part. | N/A |
| | **– parts inside an ACCESS COVER that can be opened without a TOOL, or where a TOOL is needed but the instructions for use instruct an OPERATOR other than SERVICE PERSONNEL to open the relevant ACCESS COVER** | No such part. | N/A |
| | **Voltage to earth or to other ACCESSIBLE PARTS did not exceed 42.4 V peak a.c. or 60 V d.c. for above parts in NORMAL or single fault condition (V a.c. or d.c.) ..... :** | See appended Table 8.4.2 | P |
| | **Limit of 60 V d.c. applied with no more than 10% peak-to-peak ripple, and when ripple larger than specified value, 42.4 V peak limit applied (V d.c.) ..... :** | See appended Table 8.4.2 | 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) ..... :** | See appended Table 8.4.2 | P |
| | **LEAKAGE CURRENT limits referred to in 8.4.2 b) applied when voltages higher than limits in 8.4.2 c) were present (mA) ..... :** | See appended Table 8.4.2 | P |
| | **d) Voltage and energy limits specified in c) above also applied to the following:** | No such part. | N/A |
| | **– internal parts, other than contacts of plugs, connectors and socket-outlets, touchable by test pin in Fig 8 inserted through an opening in an ENCLOSURE; and** | No internal part is touchable for adapter model. | 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 the RESPONSIBLE ORGANIZATION in NORMAL USE using a TOOL** | | N/A |
| | **Test pin or the test rod inserted through relevant openings with minimal force of no more than 1 N** | No opening for adapter model. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Test rod inserted in every possible position through openings provided for adjustment of pre-set controls that can be adjusted in NORMAL USE, with a force of 10 N** | | N/A |
| | **Test repeated with a TOOL specified in instructions for use** | | N/A |
| | **Test rod freely and vertically suspended through openings on top of ENCLOSURE** | | N/A |
| | **e) Devices used to de-energize parts when an ACCESS COVER opened without a TOOL gives access to parts at voltages above levels permitted by this Clause comply with 8.11.1 for mains isolating switches and remain effective in SINGLE FAULT CONDITION** | No such part for adapter model. | 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 .. :** | See appended Table 8.4.3 | P |
| **8.4.4** | **Residual voltage of conductive parts of capacitive circuits, having become accessible after ME EQUIPMENT was de-energized after removal of ACCESS COVERS, didn't exceed 60V or calculated stored charge didn't exceed 45µC .. :** | No such part. | N/A |
| | **A device manually discharging capacitors used when automatic discharging was not possible and ACCESS COVERS could be removed only with aid of a TOOL** | | N/A |
| | **Capacitor(s) and connected circuitry marked with symbol 24 of Table D.1 (IEC 60417-5036, 2002-10), and manual discharging device specified in technical description..... :** | | N/A |
| **8.5** | **Separation of parts** | | **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 |
| | **Each MEANS OF PROTECTION categorized as a MEANS OF PATIENT PROTECTION or a MEANS OF OPERATOR PROTECTION, taking into account Clause 4.6, and flow chart in Fig A.12** | | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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** | | P |
| | **Components and wiring forming a MEANS OF PROTECTION comply with 8.10** | | P |
| | **Insulation, CREEPAGE, CLEARANCES, components or earth connections not complying with 8.5.1.2 and 8.5.1.3 not considered as MEANS OF PROTECTION, and failure of these parts regarded as NORMAL CONDITION** | | P |
| **8.5.1.2** | **MEANS OF PATIENT PROTECTION (MOPP)** | | P |
| | **Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test of Clause 8.8 at test voltage of Table 6** | | 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** | | N/A |
| | **A Y (Y1 or Y2) capacitor complying with IEC 60384-14 considered one MEANS OF PATIENT PROTECTION .....:** | See Appended Tables 8.8.3 and 8.10 | 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. .....:** | See Appended Tables 8.8.3 and 8.10 | P |
| | **Two capacitors used in series, each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance** | Two identical Y1 used in series | P |
| | **Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (µF) .....:** | 250V, 1000pF | — |
| **8.5.1.3** | **MEANS OF OPERATOR PROTECTION (MOOP)** | | N/A |
| | **Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with:** | The separation between primary and secondary was evaluated by MOPP. | N/A |
| | **– dielectric strength test of 8.8 at test voltage of Table 6; or** | See appended Table 8.8.3 | N/A |
| | **– requirements of IEC 60950-1 for INSULATION CO-ORDINATION** | | N/A |
| | **CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with:** | | N/A |
| | **– limits of Tables 13 to 16 (inclusive); or** | | N/A |
| | **– requirements of IEC 60950-1 for INSULATION CO-ORDINATION** | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6** | | N/A |
| | **– or with requirements and tests of IEC 60950-1 for protective earthing..... :** | | N/A |
| | **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 ..... :** | | N/A |
| | **Two capacitors used in series each RATED for total WORKING VOLTAGE across the pair and have the same NOMINAL capacitance** | | N/A |
| | **Voltage $_{\text{Total Working}}$ (V) and C $_{\text{Nominal}}$ (μF) ..... :** | | **—** |
| | **Points at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION** | | P |
| | **A MEANS OF PROTECTION protecting APPLIED PARTS, or parts identified by 4.6 as parts subject to the same requirements, considered MEANS OF PATIENT PROTECTION..... :** | See the insulation diagram. | P |
| | **A MEANS OF PROTECTION protecting other parts considered MEANS OF OPERATOR PROTECTION .... :** | EUT is evaluated according to requirement of MOPP. | **N/A** |
| **8.5.2** | **Separation of PATIENT CONNECTIONS** | No PATIENT CONNECTIONS | N/A |
| **8.5.3** | **MAXIMUM MAINS VOLTAGE** | | **P** |
| | **– MAXIMUM MAINS VOLTAGE determined to be the highest RATED supply voltage for single-phase or d.c. SUPPLY MAINS powered ME EQUIPMENT, as well as INTERNALLY POWERED ME EQUIPMENT with a means of connection to a SUPPLY MAINS (V)..... :** | 240Vac | P |
| | **When less than 100 V, MAXIMUM MAINS VOLTAGE was 250 V** | No such condition. | N/A |
| | **– MAXIMUM MAINS VOLTAGE was the highest RATED phase to neutral supply voltage for poly-phase ME EQUIPMENT (V)..... :** | No poly-phase supply | N/A |
| | **– for other INTERNALLY POWERED ME EQUIPMENT, maximum mains voltage was 250 V** | Not internally powered | N/A |
| **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) ..... :** | 240Vac | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– 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)..... :** | See Insulation Diagram and Insulation Table | P |
| | **– WORKING VOLTAGE for each MEANS OF PROTECTION forming DOUBLE INSULATION was voltage DOUBLE INSULATION, as a whole, subjected to (V)..... :** | See Insulation Diagram and Insulation Table | P |
| **8.5.5** | **DEFIBRILLATION-PROOF APPLIED PARTS** | No DEFIBRILLATION-PROOF APPLIED PARTS | N/A |
| **8.6** | **Protective and functional earthing and potential equalization of ME EQUIPMENT** | | **N/A** |
| **8.6.1** | **Requirements of 8.6.2 to 8.6.8 applied** | | 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** | No such parts | 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** | No such construction. | N/A |
| | **Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside..... :** | No such construction. | 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** | No such construction. | N/A |
| **8.6.3** | **PROTECTIVE EARTH CONNECTION not used for a moving part** | No such construction. | 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 |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.6.5** | **Surface coatings** | | N/A |
| | **Poorly conducting surface coatings on conductive elements removed at the point of contact** | No such surface coating. | N/A |
| | **Coating not removed when requirements for impedance and current-carrying capacity met** | | N/A |
| **8.6.6** | **Plugs and sockets** | | N/A |
| | **PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections** | No protective connection | N/A |
| | **- applied also where interchangeable parts are PROTECTIVELY EARTHED** | | N/A |
| **8.6.7** | **Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR** | | N/A |
| | **– Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE** | No potential equalization conductor. | 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** | | N/A |
| **8.6.9** | **Class II ME EQUIPMENT** | | P |
| | **Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow** | No earthing connection. | N/A |
| | **ACCOMPANYING DOCUMENTS include a statement that the third conductor in the POWER SUPPLY CORD is only a functional earth.** | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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 |
| | **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)** | Class II equipment. | 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** | | P |
| **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 ..... :** | | N/A |
| | **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 ($I_{ENC}$, $I_{ESFC}$) ..... :** | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Higher values of EARTH LEAKAGE CURRENT permitted for PERMANENTLY INSTALLED ME EQUIPMENT connected to a supply circuit supplying only this ME EQUIPMENT according to local regulations or IEC 60364-7-710 ..... :** | Not permanently installed ME equipment. | N/A |
| | **e) LEAKAGE CURRENTS, regardless of waveform and frequency, did not exceed 10 mA r.m.s. in NORMAL or in SINGLE FAULT CONDITION (measured with a non-frequency-weighted device ..... :** | See appended Table 8.7 | P |
| | **f) LEAKAGE CURRENTS that can flow in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION..... :** | No such condition | 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)** | | P |
| | **Insulation forming MEANS OF OPERATOR PROTECTION and complying with IEC 60950-1 for INSULATION CO-ORDINATION not tested as in 8.8** | No such parts | 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:** | | P |
| | **a) 0.4 mm, min, distance through insulation, or** | Enclosure is 2.0mm thick | 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..... :** | See appended Table 8.8.3 | P |
| | **– or three layers of material, for which all combinations of two layers together passed the appropriate dielectric strength test..... :** | | N/A |
| | **Dielectric strength test for one or two layers was same as for one MEANS OF PROTECTION for SUPPLEMENTARY INSULATION** | | N/A |
| | **Dielectric strength test for one or two layers was same as for two MEANS OF PROTECTION for REINFORCED INSULATION** | See appended Table 8.8.3 | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **BASIC, SUPPLEMENTARY, and REINFORCED INSULATION required between windings of wound components separated by interleaved insulation complying with a) or b), or both, except when** | | N/A |
| | **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** | Certified triple insulated wire is used | P |
| | **– 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** | | P |
| | **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 ..... :** | Additional protection by insulating tape. | P |
| | **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 ..... :** | See Table 8.10 and Material Information Attachment | P |
| **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 ..... :** | | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests..... :** | See also RM clauses in 11 and 15<br>Page 12 EL4 | P |
| | **Satisfactory evidence of compliance provided by manufacturer for resistance to heat..... :** | No evidence provided | N/A |
| | **Tests conducted in absence of satisfactory evidence for resistance to heat..... :** | Ball pressure test performed | P |
| | **a) ENCLOSURE and other external parts of insulating material, except insulation of flexible cords and parts of ceramic material, subjected to ball-pressure test using Fig 21 apparatus... :** | See Table 8.8.4.1 | P |
| | **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) ..... :** | See Table 8.8.4.1 | 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** | No such material | 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 material | N/A |
| | **Insulating material with embedded heating conductors considered as one MEANS OF PROTECTION but not two MEANS OF PROTECTION** | No heating conductor | N/A |
| | **Parts of natural latex rubber aged by suspending samples freely in an oxygen cylinder containing commercial oxygen to a pressure of 2.1 Mpa ± 70 kPa, with an effective capacity of at least 10 times volume of samples** | No such material | 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** | No such material | N/A |
| **8.9** | **CREEPAGE DISTANCES and AIR CLEARANCES** | | **P** |
| **8.9.1.1** | **CREEPAGE DISTANCES and AIR CLEARANCES are ≥ to values in Tables 12 to 16 (inclusive), except as specified in Clauses 8.9.1.2 to 8.9.1.15** | | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **- Insulation between parts of opposite polarity of the MAINS PART on the supply mains side of any mains fuse or OVER-CURRENT RELEASE, one MEANS OF OPERATOR PROTECTION are ≥ to values in Table 13, Table 14 and Table 16** | | P |
| **8.9.1.2** | **Tables 12 to 16 (inclusive) not applied to CREEPAGE and CLEARANCES forming MEANS OF OPERATOR PROTECTION per IEC 60950-1 for INSULATION CO-ORDINATION and used under conditions compliance was tested** | No such part | N/A |
| **8.9.1.3** | **Specified min CLEARANCE applied as min CREEPAGE for CREEPAGE DISTANCES across glass, mica, ceramic and other inorganic insulating materials with similar tracking characteristics** | No such material | N/A |
| **8.9.1.4** | **When min CREEPAGE derived from Tables 12 to 16 (inclusive) was less than min applicable CLEARANCE, value of min CLEARANCE applied as min CREEPAGE DISTANCE** | Noted, but no such condition | N/A |
| **8.9.1.5** | **ME EQUIPMENT RATED to operate at an altitude of 2000 m** | | N/A |
| | **ME EQUIPMENT RATED to operate at an altitude specified by MANUFACTURER (m)..... :** | 3000m | P |
| | **Operating altitude corresponding to actual air pressure for ME EQUIPMENT intended for pressurized environments (e.g., aircraft) used to determine multiplication factor from Table 8, and AIR CLEARANCE was multiplied by this factor** | Multiplication factor for MOOP: 1.14.<br>Multiplication factor for MOPP: 1. | P |
| | **CREEPAGE DISTANCES not subjected to multiplication factors, but were at least as large as the resulting value for AIR CLEARANCE** | | P |
| **8.9.1.6** | **When WORKING VOLTAGE was between those in Tables 12 to 16 (inclusive), CREEPAGE and CLEARANCES calculated as follows:** | | P |
| | **– CREEPAGE DISTANCES determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm)..... :** | See Insulation Diagram and Table | P |
| | **– CLEARANCES for PEAK WORKING VOLTAGES above 2800 V peak or d.c. determined by linear interpolation between the nearest two values, and the calculated spacing rounded off to the next higher 0.1 mm increment (mm)..... :** | No such high voltage. | N/A |
| | **– for AIR CLEARANCES corresponding to PEAK WORKING VOLTAGE up to 2800 V peak or d.c., the higher of the two values applied** | See Insulation Diagram and Table | P |
| **8.9.1.7** | **Material groups classified in accordance with Table 9 (Material Group)..... :** | Material group IIIb was assumed. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Material group evaluated using 50 drops of solution A based on test data for material according to IEC 60112 ..... :** | Material group IIIb was assumed. | N/A |
| | **Material of unknown group considered IIIb** | | P |
| **8.9.1.8** | **– Pollution degree 1: Micro-environment sealed to exclude dust and moisture** | Pollution degree 2 | N/A |
| | **– Pollution degree 2: Micro-environment with non-conductive pollution, except occasional conductivity caused by condensation** | | P |
| | **– Pollution degree 3: Micro-environment subject to conductive pollution, or dry non-conductive pollution that could become conductive due to expected condensation** | Pollution degree 2 | N/A |
| | **– Pollution degree 4: Micro-environment where continuous conductivity occurs due to conductive dust, rain, or other wet conditions** | Pollution degree 2 | N/A |
| | **Pollution degree 4 not used for insulation providing a MEANS OF PROTECTION** | Pollution degree 2 | N/A |
| | **Where insulation between MAINS PART and earth might be compromised, measures such as maintenance ensure that micro-environment is mitigated to a lower pollution degree** | No such construction. | N/A |
| | **Means employed according to Annex M to reduce the pollution degree.....:** | | N/A |
| **8.9.1.9** | **Overvoltage category classification; value of MAINS TRANSIENT VOLTAGE determined from overvoltage category per IEC60664-1 and NOMINAL a.c. MAINS VOLTAGE using Table 10** | | P |
| | **$V_{MT}$ Peak (V) ..... :** | 2500 | — |
| | **$V_{MN}$ r.m.s (V) ..... :** | 300 | — |
| **8.9.1.10** | **AIR CLEARANCE for MAINS PARTS (operating on RATED MAINS VOLTAGES up to 300 V) were values for r.m.s. or d.c. RATED MAINS VOLTAGE in Table 13 plus additional CLEARANCE in Table 14 for PEAK WORKING VOLTAGE** | | P |
| **8.9.1.11** | **SUPPLY MAINS overvoltage category II applied according to IEC 60664-1** | | P |
| | **For ME EQUIPMENT intended for overvoltage category III, Tables 13 to 15 (inclusive) not used for clearance, instead values in the next MAINS TRANSIENT VOLTAGE column upwards used** | No overvoltage category III | N/A |
| | **When PATIENT protection (Table 12) is required for use of ME EQUIPMENT on overvoltage category III SUPPLY MAINS, guidance provided on values required in the rationale for Cl. 8.9 used** | No overvoltage category III | N/A |

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.9.1.12** | **A SECONDARY CIRCUIT derived from a SUPPLY MAINS, normally, considered to be overvoltage category I according to IEC 60664-1 when the MAINS PART is overvoltage category II (Table 15)** | No measurement is taken. | N/A |
| | **Table 15 applied to earthed SECONDARY CIRCUIT or INTERNALLY POWERED ME EQUIPMENT** | | N/A |
| | **Requirements for primary circuits in Tables 13 and 14 used for an unearthed SECONDARY CIRCUIT derived from a SUPPLY MAINS** | | N/A |
| | **Table 15 applied when SECONDARY CIRCUIT was separated from MAINS PART by a functionally earthed or PROTECTIVELY EARTHED metal screen or transients in SECONDARY CIRCUIT were below the levels expected for overvoltage category I** | | N/A |
| | **Table 15 column for circuits not subject to transient over-voltages applied to:** | | N/A |
| | **– d.c. SECONDARY CIRCUITS reliably connected to earth and have capacitive filtering limiting peak-to-peak ripple to 10 % of d.c. voltage, and** | | N/A |
| | **– circuits in INTERNALLY POWERED ME EQUIPMENT** | | N/A |
| **8.9.1.13** | **For PEAK WORKING VOLTAGES above 1400 V peak or d.c. Table 15 not applied since all the following conditions were met:** | No such high peak working voltage. | N/A |
| | **– CLEARANCE was at least 5 mm** | | N/A |
| | **– insulation complied with dielectric strength test of 8.8.3 using an a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, or** | | N/A |
| | **– a d.c. test voltage equal to peak value of a.c. test voltage with an r.m.s. value equal to 1.06 times PEAK WORKING VOLTAGE, and** | | N/A |
| | **– CLEARANCE path was partly or entirely through air or along the surface of an insulating material of material group I** | | N/A |
| | **Dielectric strength test conducted only across part(s) of the path that are through air when CLEARANCE path was also partly along surface of a non- group I material** | | N/A |
| **8.9.1.14** | **Minimum CREEPAGE DISTANCES for two MEANS OF OPERATOR PROTECTION obtained by doubling values in Table 16 for one MEANS OF OPERATOR PROTECTION** | | P |
| **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. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.9.2** | **a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION described in 13.1 for insulation in MAINS PART between parts of opposite polarity, therefore, min CREEPAGE and CLEARANCES not applied ..... :** | The spacing between parts of opposite polarity fulfils the values of Table 11. | N/A |
| | **b) Contribution to CREEPAGE DISTANCES of grooves or air gaps less than 1 mm wide limited to widths** | | P |
| | **c) Relative positioning of CLEARANCE providing a MEANS OF PROTECTION is such that the relevant parts are rigid and located by moulding, or there is no reduction of a distance below specified value by deformation or movement of parts** | | P |
| | **Normal or likely limited movements of relevant parts taken into consideration when calculating minimum AIR CLEARANCE** | | 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 were such that CLEARANCES and CREEPAGE DISTANCES don't exist** | Certified optocoupler. | P |
| | **Thermal cycling, humidity preconditioning, and dielectric strength tests in 8.9.3.2 and 8.9.3.4 or 8.9.3.3 and 8.9.3.4 conducted** | Certified optocoupler has conformed to these tests. | P |
| **8.9.3.2** | **For insulating compound forming solid insulation between conductive parts, a single sample subjected to thermal cycling PROCEDURE of 8.9.3.4 followed by humidity preconditioning per 5.7 (for 48 hours), followed by dielectric strength test (clause 8.8.3), test voltage multiplied by 1.6..... :** | Certified optocoupler. | P |
| | **Cracks or voids in insulating compound affecting homogeneity of material didn't occur** | Certified optocoupler has conformed to these tests. | P |
| **8.9.3.3** | **Where insulating compound forms a cemented joint with other insulating parts, three samples tested for reliability of joint** | No such construction. | N/A |
| | **A winding of solvent-based enamelled wire replaced for the test by a metal foil or by a few turns of bare wire placed close to cemented joint, and three samples tested as follows:** | | N/A |
| | **– One sample subjected to thermal cycling PROCEDURE of 8.9.3.4, and immediately after the last period at highest temperature during thermal cycling, it was subjected to dielectric strength test of 8.8.3 except at 1.6 times the test voltage ..... :** | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **– The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of 8.8.3 at 1.6 times the test voltage** | | N/A |
| **8.9.3.4** | **One sample containing the cemented joint subjected to a sequence of temperature cycling tests for 10 times ..... :** | No need. | N/A |
| **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 as indicated in RISK MANAGEMENT FILE..... :** | Risk management report<br>Page 11 EL3 | P |
| **8.10.2** | **Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment in a HAZARDOUS SITUATION ..... :** | Final determination in the end-product | N/A |
| | **Conductors and connectors of ME EQUIPMENT when breaking free at their joint are not capable of touching circuit points resulting in a HAZARDOUS SITUATION described in 13.1** | | N/A |
| | **Breaking free of one means of mechanical restraint considered a SINGLE FAULT CONDITION** | No such construction. | N/A |
| | **Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS described in 13.1 due to poor contact** | No stranded conductor. | N/A |
| **8.10.3** | **Flexible cords detachable without a TOOL used to interconnect different parts of ME EQUIPMENT provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS of 8.4 when a connection is loosened or broken as shown by measurement or test finger ..... :** | No such cord. | 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 control device; no cord connected foot-operated control device. | N/A |
| | **d.c. limit of 60 V applied to d.c. with no more than 10 % peak-to-peak ripple** | | N/A |
| | **42.4 V peak limit applied when ripple exceeded 10 % peak-to-peak limit** | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.10.4.2** | **Connection and anchorage at both ends of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT at both ends of cable to control device complied with 8.11.3 when breaking free or shorting between conductors could result in a HAZARDOUS SITUATION described in 13.1** | No cord connected hand-held control device; no cord connected foot-operated control device. | N/A |
| | **This requirement applied to other HAND-HELD parts when disturbance or breaking of one or more of connections could result in a HAZARDOUS SITUATION described in 13.1** | | N/A |
| **8.10.5** | **Mechanical protection of wiring** | | N/A |
| | **a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges where damage to insulation could result in a HAZARDOUS SITUATION described in 13.1 ..... :** | No internal moving part. | N/A |
| | **b) Wiring, cord forms, or components are not likely to be damaged during assembly or during opening or closing of ACCESS COVERS where such damage could result in a HAZARDOUS SITUATION described in 13.1** | No ACCESS COVERS | N/A |
| **8.10.6** | **Guiding rollers of insulated conductors prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead concerned in NORMAL USE** | No guiding roller. | N/A |
| **8.10.7** | **a) Insulating sleeve that can only be removed by breaking or cutting, or secured at both ends, is used on internal wiring of when needed ..... :** | No insulating sleeve. | N/A |
| | **b) Sheath of a flexible cord not used as a MEANS OF PROTECTION inside ME EQUIPMENT when it is subject to mechanical or thermal stresses beyond its RATED characteristics** | No such condition. | N/A |
| | **c) Insulated conductors subject to temperatures > 70 °C in NORMAL USE provided with insulation of heat-resistant material when compliance is likely to be impaired due to deterioration of insulation ..... :** | No such high temperature is acquired by test indicated in 11.1. | P |
| **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..... :** | Plug | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c)** | Not permanently installed. | N/A |
| | **PERMANENTLY INSTALLED ME EQUIPMENT provided with means to isolate its circuits electrically from the SUPPLY MAINS are capable of being locked in the off position if reconnection would result in a HAZARDOUS SITUATION or** | | N/A |
| | **– any OPERATOR including SERVICE PERSONNEL is unable to view the means of isolation from their intended position** | | N/A |
| | **The locking mechanism by the RESPONSIBLE ORGANIZATION, and** | | N/A |
| | **- the isolation device specified in the ACCOMPANYING DOCUMENTS** | Final determination in the end-product | N/A |
| | **b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ..... :** | Plug is incorporated in EUT. | P |
| | **c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE and CLEARANCES in IEC 61058-1 for a MAINS TRANSIENT VOLTAGE of 4 kV ..... :** | No mains switch | N/A |
| | **d) A SUPPLY MAINS switch not incorporated in a POWER SUPPLY CORD or external flexible lead** | No mains switch | N/A |
| | **e) Actuator of a SUPPLY MAINS switch used to comply with 8.11.1 a) complies with IEC 60447** | No mains switch | N/A |
| | **f) A suitable plug device such as an APPLIANCE COUPLER or a flexible cord with a MAINS PLUG used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS switch to isolate it from SUPPLY MAINS considered to comply with 8.11.1 a) ..... :** | See appended Table 8.10 | P |
| | **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** | | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering** | No such part | N/A |
| | **A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage (symbol 10 of Table D.1 is insufficient)** | | N/A |
| | **For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause** | | N/A |
| | **Standard test finger of Fig 6 applied** | | N/A |
| **8.11.2** | **MULTIPLE SOCKET-OUTLETS integral with ME EQUIPMENT complied with 16.2 d), second dash; and 16.9.2** | No multiple socket-outlets. | 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. | 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).. :** | No power supply cord. | 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 ($mm^2$ Cu)..... :** | No power supply cord. | 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 ..... :** | No power supply cord. | N/A |
| **8.11.3.5** | **Cord anchorage (for APPLIANCE COUPLERS not complying with IEC 60320-1)** | | N/A |
| | **a) Conductors of POWER SUPPLY CORD provided with strain relieve and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage** | No power supply cord. | N/A |
| | **b) Cord anchorage of POWER SUPPLY CORD is made of and arranged as follows when a total insulation failure of POWER SUPPLY CORD caused conductive non-PROTECTIVELY EARTHED ACCESSIBLE PARTS to exceed limits of 8.4:** | No power supply cord. | N/A |

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

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or** | | N/A |
| | **ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x $D^2$ gram attached to the free end of cord (g) ..... :** | | N/A |
| | **Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance** | | N/A |
| | **Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D ..... :** | | N/A |
| **8.11.4** | **MAINS TERMINAL DEVICES** | | N/A |
| **8.11.4.1** | **PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD replaceable by SERVICE PERSONNEL provided with MAINS TERMINAL DEVICES ensuring reliable connection** | No mains terminal device. | N/A |
| | **Terminals alone are not used to keep conductors in position, except when barriers are provided such that CREEPAGE and CLEARANCES cannot be reduced below 8.9 if any conductor breaks away** | | N/A |
| | **Terminals of components other than terminal blocks complying with requirements of this Clause and marked according to 7.3.7 used as terminals intended for external conductors** | | N/A |
| | **Screws and nuts clamping external conductors do not serve to secure any other component, except they also clamp internal conductors when unlikely to be displaced when fitting the supply conductors** | | N/A |
| **8.11.4.2** | **Arrangement of MAINS TERMINAL DEVICES** | | N/A |
| | **a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection** | No mains terminal device. | N/A |
| | **b) PROTECTIVE EARTH CONDUCTOR connections complied with 8.6** | | N/A |
| | **c) Marking of MAINS TERMINAL DEVICES complied with 7.3** | | N/A |
| | **d) MAINS TERMINAL DEVICES not accessible without use of a TOOL** | | N/A |
| | **e) A MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction** | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.11.4.3** | **Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced below 8.9 after fastening and loosening a conductor of largest cross-sectional area 10 times** | No mains terminal device. | N/A |
| **8.11.4.4** | **Terminals with clamping means for a rewireable flexible cord did not require special preparation of conductors and conductors were not damaged and did not slip out when clamping means tightened as verified by test of 8.11.3.4** | No mains terminal device. | N/A |
| **8.11.4.5** | **Adequate space provided inside ME EQUIPMENT designed for FIXED wiring or a rewireable POWER SUPPLY CORD to allow for connection of conductors, and covers fitted without damage to conductors or their insulation** | No mains terminal device. | N/A |
| | **Correct connection and positioning of conductors before ACCESS COVER was fitted verified by an installation test** | | N/A |
| **8.11.5** | **Mains fuses and OVER-CURRENT RELEASES** | | **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 per clause 8.6.9, and in at least one supply lead for other single-phase CLASS II ME EQUIPMENT.... :** | See appended Table 8.10. | P |
| | **– neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT** | Not permanently installed. | N/A |
| | **Effect of short-circuit fault conditions in other circuits VERIFIED before eliminating fuses or OVER-CURRENT RELEASES** | | N/A |
| | **Protective devices have adequate breaking capacity to interrupt the maximum fault current including the available short-circuit ..... :** | See appended Table 8.10 | P |
| | **A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR** | | P |
| | **Fuses complying with IEC 60127 have high breaking capacity (1 500 A) and prospective short-circuit current > 35 A or 10 times current rating of the fuse, whichever is greater** | EUT is only component, high breaking capacity fuse not used<br>To be evaluated on end product | 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 is not less than minimum required for POWER SUPPLY CORD as in clause 8.11.3.3 ($mm^2$ Cu) ..... :** | No such internal wire. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits sufficient to prevent fire in case of fault currents..... :** | See appended Table 13.2. | P |
| | **When necessary, ME EQUIPMENT connected to a SUPPLY MAINS with max available short-circuit fault, and subsequent simulation of a fault in a single insulation in MAINS PART did not result in any of the HAZARDOUS SITUATIONS in 13.1.2** | | P |
| **9** | **PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS** | | **P** |
| **9.1** | **ME EQUIPMENT complies with Clause 4 for design and manufacture, and mechanical strength (15.3)** | | P |
| **9.2** | **HAZARDS associated with moving parts** | Final determination in the end product. | N/A |
| **9.3** | **Rough surfaces, sharp corners and edges of ME EQUIPMENT that could result in injury or damage avoided or covered .....:** | No rough surface / sharp edge. | P |
| **9.4** | **Instability HAZARDS** | Component, to be determined as part of end product | N/A |
| **9.5** | **Expelled parts HAZARD** | No such parts | N/A |
| **9.6** | **Acoustic energy (including infra- and ultrasound) and vibration** | Component, to be determined as part of end product | N/A |
| **9.7** | **Pressure vessels and parts subject to pneumatic and hydraulic pressure** | No such parts | N/A |
| **9.8** | **HAZARDS associated with support systems** | Component, to be determined in the end product. | N/A |
| **10** | **PROTECTION AGAINST UNWANTED AND EXCESSIVE RADIATION HAZARDS** | | N/A |
| | **X-Radiation** | Not applicable to component power supply | N/A |
| **11** | **PROTECTION AGAINST EXCESSIVE 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 23 operating in worst-case NORMAL USE at maximum rated ambient operating temperature T ..... :** | See appended 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-out | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **11.1.2** | **Temperature of APPLIED PARTS** | No such parts | N/A |
| **11.1.3** | **Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE ..... :** | See appended Table 11.1.3 Acceptability of obtained values to be determined in the end product. | N/A |
| | **Test corner not used where engineering judgment and rationale by MANUFACTURER indicated test corner will not impact measurements, as documented in RISK MANAGEMENT FILE** | Test corner used | N/A |
| **11.1.4** | **GUARDS preventing contact with hot or cold accessible surfaces removable only with a TOOL** | No such guards | N/A |
| **11.2** | **Fire prevention** | | **P** |
| **11.2.1** | **ENCLOSURE has strength and rigidity necessary to prevent a fire caused by reasonably foreseeable misuse and met mechanical strength tests for ENCLOSURES in 15.3** | | P |
| **11.2.2** | **Me equipment and me systems used in conjunction with OXYGEN RICH ENVIRONMENTS** | Component, not evaluated for use with Oxygen Rich Environment | N/A |
| **11.2.3** | **SINGLE FAULT CONDITIONS related to OXYGEN RICH ENVIRONMENTS ME EQUIPMENT and ME SYSTEMS considered** | Component, not evaluated for use with Oxygen Rich Environment | N/A |
| **11.3** | **Constructional requirements for fire ENCLOSURES 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 ..... :** | Risk Management Report page 11 H2<br>See Appended RM Results Table 11.3 | P |
| | **Constructional requirements were met, or** | | P |
| | **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 ..... :** | 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** | UL 94 approved | N/A |
| | **b) Fire ENCLOSURE met following:** | | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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** | No openings on the enclosure. | P |
| | **2) No openings on the sides within the area included within the inclined line C in Fig 39** | | P |
| | **3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials, except constructions based on Table 25 and a mesh; FV-2 or better for TRANSPORTABLE ME EQUIPMENT, FV-1 or better for fixed EQUIPMENT, or STATIONARY EQUIPMENT per IEC 60695-11-10, determined by ENCLOSURE examination or flammability classification based on 11.3a)..... :** | See appended Table 8.10 | P |
| **11.4** | **ME EQUIPMENT and ME SYSTEMS intended for use with flammable anaesthetics** | Not evaluated for use in the presence of flammable anaesthetics. | N/A |
| **11.5** | **ME EQUIPMENT and ME SYSTEMS intended for use in conjunction with flammable agents** | Not evaluated for use in the presence of flammable agent. | N/A |
| **11.6** | **Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the ME EQUIPMENT** | Final determination to be competed in the end product | N/A |
| **11.6.5** | **Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS** | | **P** |
| | **ME EQUIPMENT with IP Code placed in least favourable position of NORMAL USE and subjected to tests of IEC 60529 (IP Code)..... :** | IP20 | P |
| | **ME EQUIPMENT met dielectric strength and LEAKAGE CURRENT tests and there were no bridging of insulation or electrical components that could result in the loss of BASIC SAFETY or ESSENTIAL PERFORMANCE in NORMAL CONDITION or in combination with a SINGLE FAULT CONDITION.. :** | See appended Tables 8.7 8.8.3 | P |
| **11.7** | **ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented per ISO 10993** | Component, to be determined in end-product evaluation. | N/A |
| **11.8** | **Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE** | Component, to be determined in end-product evaluation. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **12** | **ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS** | | N/A |
| **12.1** | **RISKS associated with accuracy of controls and instruments stated in RISK MANAGEMENT PROCESS confirmed by RISK MANAGEMENT FILE review ..... :** | Not applicable to component power supply | N/A |
| | **PROTECTION AGAINST HAZARDOUS OUTPUT..... :** | Not applicable to component power supply | N/A |
| **13** | **HAZARDOUS SITUATIONS AND FAULT CONDITIONS** | | **P** |
| **13.1** | **Specific HAZARDOUS SITUATIONS** | | **P** |
| **13.1.1** | **None of HAZARDOUS SITUATIONS in 13.1.2-13.1.4, inclusive, occurred when SINGLE FAULT CONDITIONS applied, one at a time, as in 4.7 and 13.2** | | 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** | | P |
| | **– Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur** | | P |
| | **– Temperatures of ME EQUIPMENT parts that are not APPLIED PARTS likely to be touched did not exceed values in Table 23 when measured and adjusted as in 11.1.3..... :** | See appended Tables 11.1.1, 11.1.2.1, and 11.1.2.2 | P |
| | **–Allowable values for "other components and materials" in Table 22 times 1.5 minus 12.5 °C were not exceeded** | | P |
| | **Limits for windings in Tables 26, 27, and 31 not exceeded** | | P |
| | **Table 22 not exceeded in all other cases** | | P |
| | **Temperatures measured according to 11.1.3** | | P |
| | **SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances, not applied to parts and components where:** | Test wasn't exempted. | N/A |
| | **– Supply circuit was unable to supply 15 W one minute after 15 W drawn from supply circuit in SINGLE FAULT CONDITION ..... :** | | N/A |
| | **- or secondary circuits mounted on materials with a minimum flame rating of FV1, and** | | N/A |
| | **- Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and** | | N/A |
| | **- Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and** | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **- Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide** | | N/A |
| | **- or components in the circuit have HIGH INTEGRITY CHARACTERISTICS ..... :** | | N/A |
| | **– or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation** | | N/A |
| | **After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function** | Fuse only | P |
| **13.1.3** | **– limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION based on 8.7.3 did not exceed..... :** | See appended Table 8.7 | P |
| | **– voltage limits for ACCESSIBLE PARTS including APPLIED PARTS in 8.4.2 did not exceed ..... :** | See appended Table 8.7 | P |
| **13.1.4** | **ME EQUIPMENT complied with the requirements of 9.1 to 9.8 for specific MECHANICAL HAZARDS** | Component, to be determined in end product evaluation. | N/A |
| **13. 2** | **SINGLE FAULT CONDITIONS** | | **P** |
| **13.2.1** | **During application of SINGLE FAULT CONDITIONS in 13.2.2 -13.2.13, inclusive, NORMAL CONDITIONS in 8.1 a) applied in least favourable combination :** | See appended Table 13.2 | P |
| **13.2.2 – 13.2.12** | **ME EQUIPMENT complied with 13.2.2 -13.2.12..... :** | See appended Table 13.2<br>Final determination to be competed in the end product | P |
| **13.2.13** | **ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4 (inclusive), and cooling down to within 3 °C of the temperature in the test environment** | | P |
| | **ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted** | | P |
| | **For insulation of thermoplastic materials relied upon as a MEANS OF PROTECTION (see 8.8), the ball-pressure test specified in 8.8.4.1 a) performed at a temperature 25 °C higher than temperature of insulation measured during tests of 13.2.13.2 to 13.2.13.4 (inclusive).** | | P |
| **13.2.13.2** | **ME EQUIPMENT with heating elements** | No Heating Elements provided | N/A |
| **13.2.13.3** | **ME EQUIPMENT with motors** | No motors provided in power supply | N/A |
| **13.2.13.4** | **ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION** | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **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** | Continuous operation. | N/A |
| | **When a load-reducing device operated in NORMAL USE, test continued with ME EQUIPMENT running idle** | | N/A |
| | **Motor winding temperatures did not exceed values in 13.2.10 ..... :** | | N/A |
| | **Insulation Class ..... :** | | — |
| | **Maximum temperature measured (°C)..... :** | | — |
| **14** | **PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS)** | | N/A |
| | **Requirements of this clause not applied to power supply** | No Such Parts/ PESS not relied upon for Basic Safety or Essential Performance | 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 in accordance with IEC 60601-1-6, when applicable ..... :** | No controls and indicators. | N/A |
| **15.2** | **Parts of ME EQUIPMENT subject to mechanical wear, electrical, environmental degradation or ageing resulting in unacceptable RISK when unchecked for a long period, are accessible for inspection, replacement, and maintenance** | No such parts. | N/A |
| | **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 by subjecting external parts of ENCLOSURE to a steady force of 250 N ± 10 N for 5 s applied to a circular (30mm) plane surface, except bottom of ENCLOSURE of an ME EQUIPMENT >18 kg, using a suitable test tool ... :** | See Appended Table 15.3. Final determination to be competed in the end product | P |
| | **No damage resulting in an unacceptable RISK sustained** | See Appended Table 15.3. | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **15.3.3** | **Impact test conducted by subjecting a complete ENCLOSURE or its largest non-reinforced area, except for HAND-HELD ME EQUIPMENT and parts, to a free falling 500 g ± 25 g solid smooth steel ball, pprox.. 50 mm in diameter from a height of 1.3 m ..... :** | See Appended Table 15.3. Final determination to be competed in the end product | P |
| | **No damage resulting in an unacceptable RISK sustained** | See Appended Table 15.3. | 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 allowed to fall freely once from each of 3 different positions as in NORMAL USE from height specified in ACCOMPANYING DOCUMENTS, or from 1 m onto a 50 mm ± 5 mm thick hardwood board lying flat on a concrete or rigid base ..... :** | No HAND-HELD ME EQUIPMENT. | N/A |
| | **No unacceptable RISK resulted** | | N/A |
| **15.3.4.2** | **Sample of PORTABLE ME EQUIPMENT, ACCESSORIES and PORTABLE part with SAFE WORKING LOAD lifted to a height as in Table 29 above a 50 ± 5 mm thick hardwood board lying flat on a concrete floor or rigid base, dropped 3 times from each orientation in NORMAL USE (cm) .....:** | See Appended Table 15.3. Final determination to be competed in the end product | P |
| | **No damage resulting in an unacceptable RISK sustained** | No damage | N/A |
| **15.3.5** | **Rough handling tests for MOBILE ME EQUIPMENT** | Not mobile ME equipment. | N/A |
| **15.3.6** | **Examination of ENCLOSURE made from moulded or formed thermoplastic material indicated that material distortion due to release of internal stresses by moulding or forming operations will not result in an unacceptable RISK** | | 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 ..... :** | 70 °C | P |
| | **No damage resulting in an unacceptable RISK** | No damage. | 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** | No such environmental influences. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Based on review of EQUIPMENT, ACCOMPANYING DOCUMENTS, specifications and processing of materials, and MANUFACTURER'S relevant tests or calculations, corrosion, ageing, mechanical wear, degradation of biological materials due to bacteria, plants, animals and the like, will not result in an unacceptable RISK** | Component, to be determined in end product evaluation. | N/A |
| **15.4** | **ME EQUIPMENT components and general assembly** | | N/A |
| **15.4.1** | **Incorrect connection of accessible connectors, removable without a TOOL, prevented where an unacceptable RISK exists, in particular ..... :** | No such connections | N/A |
| **15.4.2** | **Temperature and overload control devices** | | N/A |
| **15.4.2.1** | **a) THERMAL CUT-OUTS and OVER-CURRENT RELEASES with automatic resetting not used in ME EQUIPMENT when their use could lead to a HAZARDOUS SITUATION described in 13.1by resetting action as verified by review of the design documentation and RISK MANAGEMENT FILE ..... :** | No such part. | N/A |
| | **b) THERMAL CUT-OUTS with a safety function that are reset by a soldering not fitted in ME EQUIPMENT** | No such part. | N/A |
| | **c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided where a failure of a THERMOSTAT could in a HAZARDOUS SITUATION described in 13.1; the temperature of operation of the additional device is outside that attainable at the extreme setting of the normal control device, but within the temperature limit for the ME EQUIPMENT ..... :** | No such part. | N/A |
| | **d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION described in 13.1 or the loss of ESSENTIAL PERFORMANCE ..... :** | No such part. | N/A |
| | **e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS** | No such part. | N/A |
| | **f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety of ME EQUIPMENT as verified by following tests:** | | N/A |
| | **Positive temperature coefficient devices (PTC's) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17 as applicable** | | N/A |
| | **ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13 ..... :** | See appended Table 13.2 | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) Certified according to appropriate standards ..** | | N/A |
| | **In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions (other than PTC's) operated 200 times** | | N/A |
| | **Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards** | | N/A |
| | **When certification based on IEC standards, or data from MANUFACTURER demonstrating reliability of component to perform its safety-related function is not available, manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times** | | N/A |
| | **Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted** | | N/A |
| | **g) Protective device, provided on ME EQUIPMENT incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating** | No such part. | N/A |
| | **h) ME EQUIPMENT with tubular heating elements provided with protection against overheating in both leads where a conductive connection to earth could result in overheating as verified by review of design and RISK MANAGEMENT FILE ..... :** | No such part. | N/A |
| **15.4.2.2** | **Temperature settings clearly indicated when means provided to vary setting of THERMOSTATS** | Not applicable to component power supply | N/A |
| **15.4.3** | **Batteries** | | N/A |
| **15.4.3.1** | **Battery housings from which gases can escape during charging or discharging are ventilated to prevent unacceptable RISK from accumulation of gasses and possible ignition :** | No batteries. | N/A |
| | **Battery compartments designed to prevent accidental short circuiting of battery when this could result in a HAZARDOUS SITUATION as described in clause 13.1** | | N/A |
| **15.4.3.2** | **Means provided to prevent incorrect connection of polarity when a HAZARDOUS SITUATION may develop by incorrect connection or replacement of a battery..... :** | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **15.4.3.3** | **Overcharging of battery prevented by virtue of design when it could result in an unacceptable RISK as verified by review of design ..... :** | | N/A |
| **15.4.3.4** | **Primary lithium batteries comply with IEC 80086-4** | | N/A |
| | **Secondary lithium batteries comply with IEC 62133** | | N/A |
| **15.4.3.5** | **A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire caused by excessive currents when (in case of a short circuit) layout of internal wiring, cross-sectional area, rating of connected components can result in a fire :** | | N/A |
| | **Protective device has adequate breaking capacity to interrupt the maximum fault current** | | N/A |
| | **Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented** | | N/A |
| | **Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPS provided, or** | | N/A |
| | **Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION described in clause 13.1** | | N/A |
| **15.4.4** | **Indicator lights provided to indicate ME EQUIPMENT is ready for NORMAL USE, except when apparent to OPERATOR from normal operating position, and marking of 7.4.1 are insufficient for this purpose ..... :** | No such indicator. | N/A |
| | **An additional indicator light provided on ME EQUIPMENT with a stand-by state or a warm-up state exceeding 15 s, except when apparent to OPERATOR from normal operating position** | | N/A |
| | **Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational when a HAZARDOUS SITUATION could exist, except when apparent to OPERATOR from normal operating position** | | N/A |
| | **Requirement not applied to heated stylus-pens for recording purposes** | | N/A |
| | **Indicator lights provided on ME EQUIPMENT to indicate an output exists where an accidental or prolonged operation of output circuit could constitute a HAZARDOUS SITUATION** | | N/A |
| | **Colours of indicator lights complied with 7.8.1** | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Charging mode visibly indicated in ME EQUIPMENT incorporating a means for charging an INTERNAL ELECTRICAL POWER SOURCE** | | N/A |
| **15.4.5** | **Pre-set controls** | No such parts in power supply | N/A |
| **15.4.6** | **Actuating parts of controls of ME EQUIPMENT** | No such parts in power supply | N/A |
| **15.4.7** | **Cord-connected HAND-HELD and foot-operated control devices** | No such parts in power supply | N/A |
| **15.4.8** | **Aluminium wires less than 16 $mm^2$ in cross-sectional area are not used** | No such wire. | N/A |
| **15.4.9** | **Oil container in PORTABLE ME EQUIPMENT** | No such parts in power supply | N/A |
| **15.5** | **MAINS SUPPLY TRANSFORMERS OF ME EQUIPMENT and 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 in the event of short circuit or overload of output windings and comply with this Clause and tests of 15.5.1.2 – 3 ..... :** | See appended Tables 15.5.1.2 and 15.5.1.3 | 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 of 8.8.3 conducted on transformer after short circuit and overload tests ..... :** | See appended Table 15.5.2 | 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 for transformers not tested according to 5X frequency and 5X voltage test of 15.5.2 a) or 2x frequency and 2x voltage test of 15.5.2 b)** | | N/A |
| **15.5.1.3** | **Multiple overload tests conducted on windings with more than one protective device to evaluate worst-case NORMAL USE loading and protection ..... :** | No more than one protective device | N/A |
| **15.5.2** | **Transformers operating at a frequency above 1 kHz tested in accordance with clause 8.8.3 ..... :** | | N/A |
| | **Transformer windings provided with adequate insulation to prevent internal short-circuits that could cause overheating which could result in a HAZARDOUS SITUATION** | | P |
| | **Dielectric strength tests were conducted in accordance with requirements of this clause with no breakdown of insulation system and no detectable deterioration of transformer ..... :** | See appended Table 15.5.2 | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **15.5.3** | **Transformers forming MEANS OF PROTECTION as required by 8.5 comply with ..... :** | Transformer evaluated according to the requirements of this standard. | P |
| | **- Means provided to prevent displacement of end turns beyond the inter-winding insulation** | | P |
| | **- protective earth screens with a single turn have insulated overlap not less than 3mm and the width of the screen is at least equal to the axial winding length of the primary side** | | P |
| | **- Exit of wires form internal windings of toroid transformers protected with double sleeving providing 2 MOPs and a total wall thickness of 0.3mm extending 20mm from the windings** | | P |
| | **- insulation between primary and secondary windings complies with 8.8.2** | | P |
| | **- CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4 and the exceptions of this sub-clause** | | P |
| **16** | **ME SYSTEMS** | | N/A |
| | **Evaluation of ME SYSTEMS ..... :** | Component power supply; compliance determined in the end product | N/A |
| **17** | **ELECTROMAGNETIC COMPATIBILITY OF ME EQUIPMENT AND ME SYSTEMS** | | P |
| | **RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review . :** | | P |
| **ANNEX G** | **PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES** | | N/A |
| | **Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANESTHETIC MIXTURE WITH AIR occurs** | Not evaluated for use with Flammable Anesthetic Mixture | N/A |
| **ANNEX L** | **INSULATED WINDING WIRES FOR USE WITHOUT INTERLEAVED INSULATION** | | N/A |
| **L.1** | **BASIC, SUPPLEMENTARY, DOUBLE, and REINFORCED INSULATION in wound components without interleaved insulation complied with this Annex covering round winding wires between 0.05 mm and 5.00 mm diameters** | Approved TIW is used in mains 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** | Approved TIW is used in mains transformer. | 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** | Approved TIW is used in mains transformer. | N/A |
| | **Temperature (°C)..... :** | | **—** |
| | **Humidity (%)..... :** | | **—** |
| **L.3.1** | **Dielectric strength** | | N/A |
| | **Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted by preparing the sample according to IEC 60851-5:1996, Clause 4.4.1 for a twisted pair with test voltages at least twice Tables 6 & 7, but not less than below with no breakdown:** | Approved TIW is used in mains transformer. | N/A |
| | **– 3000 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :** | | N/A |
| | **– 6000 V for REINFORCED INSULATION (V) ..... :** | | N/A |
| **L.3.2** | **Flexibility and adherence** | | N/A |
| | **Sample subjected to flexibility and adherence test 8 of IEC 60851-3:1996, clause 5.1.1, using mandrel diameters of Table L.1** | Approved TIW is used in mains transformer. | N/A |
| | **Sample examined according to IEC 60851-3: 1997, clause 5.1.1.4, followed by dielectric test of clause 8.8.3, except test voltage applied between wire and mandrel with no breakdown** | | N/A |
| | **Test voltage was at least the voltage in Tables 6 and 7but not less than the following:** | | N/A |
| | **– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :** | | N/A |
| | **– 3000 V for REINFORCED INSULATION (V) ..... :** | | N/A |
| | **Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 Mpa ± 11.8 Mpa ..... :** | | N/A |
| **L.3.3** | **Heat Shock** | | N/A |
| | **Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3, except test voltage applied between the wire and mandrel** | Approved TIW is used in mains transformer. | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:** | | N/A |
| | **– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :** | | N/A |
| | **– 3000 V for REINFORCED INSULATION (V) ..... :** | | N/A |
| | **Oven temperature based on Table L.2 (°C)..... :** | | — |
| | **Mandrel diameter and tension applied as in clause L.3.2, (Mpa; N/mm$^2$) ..... :** | | N/A |
| | **Dielectric strength test conducted at room temperature after removal from the oven** | | N/A |
| **L.3.4** | **Retention of electric strength after bending** | | |
| | **Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests** | Approved TIW is used in mains transformer. | N/A |
| | **Test voltage was at least the voltage in Tables 6 and 7, but not less than the following:** | | N/A |
| | **– 1500 V for BASIC and SUPPLEMENTARY INSULATION (V)..... :** | | N/A |
| | **– 3000 V for REINFORCED INSULATION (V) ..... :** | | N/A |
| | **Test voltage applied between the shot and conductor.** | | N/A |
| | **Mandrel diameter and tension applied as in L.3.2, (Mpa; N/mm$^2$) ..... :** | | N/A |
| **L.4** | **Tests during manufacture** | | N/A |
| **L.4.1** | **Production line dielectric strength tests conducted by the manufacture according to L.4.2 and L.4.3 .....:** | Approved TIW is used in mains transformer. | N/A |
| **L.4.2** | **Test voltage for routine testing (100 % testing) is at least the voltage in Tables 6 and 7 but not less than the following:** | Approved TIW is used in mains transformer. | 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) .....:** | Approved TIW is used in mains transformer. | 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 |

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|---|---|---|---|
| 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** | Risk management procedure GTQPR05000 A2. 5.0 | — | Risk Management Process (excluding production and post-production) | P |
| **3.2** | Risk management procedure GTQPR05000 A2. 5.0 | — | Adequate Resources | P |
| **3.2** | Risk management procedure GTQPR05000 A2. 5.0 | — | Assignment of qualified personnel | P |
| **3.2** | Risk management procedure GTQPR05000 A2. 5.0 | — | Policy for determining criteria for risk acceptability | P |
| **3.3** | — | Risk Management Report 2.0 | Qualification of personnel | P |
| **3.4a** | — | Risk management plan | Scope of risk management activities/identification and description of device/ applicable life-cycles | P |
| **3.4b** | — | Risk management plan | Assignment of responsibilities and authorities | P |
| **3.4c** | — | Risk management plan | Requirement for review of risk management activities | P |
| **3.4d** | — | Risk management plan | Criteria for risk acceptability | P |
| **3.4e** | — | Risk management plan | verification activities | P |
| **3.5** | — | Risk management plan | RMF | P |
| **4.1** | — | Risk management procedure GTQPR05000 A 2 6.0 | Documents produced during clause 4.2 and 4.4 shall include: -Identification/description of the device -Identification of the persons involved in the risk analysis -Scope and date of the risk analysis | P |
| **4.2** | — | Risk Management Report 6.1 | Identification of characteristics | P |
| **4.3** | — | Risk Management Report 6.2 | Hazards identification | P |
| **4.4** | — | Risk Management Report 6.4 | Risk estimation | P |
| **5** | — | Risk Management Report 7 | Risk evaluation | P |
| **6.2** | — | Risk Management Report 8.1 | Risk control options | P |

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|---|---|---|---|
| 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** | | |
| **6.3** | — | Risk Management Report 8.1 | Implementation/effectiveness of risk control | P |
| **6.4** | — | Risk Management Report 8.2 | Residual risk evaluation | P |
| **6.5** | — | Risk Management Report 8.3 | Risk/benefit analysis | P |
| **6.6a** | — | Risk Management Report 8.1 | Introduction of new risks due to risk control | P |
| **6.6b** | — | Risk Management Report 8.2 | Estimation of previously risk due to risk control | P |
| **6.7** | — | Risk Management Report 8.1 | Completeness of risk control | P |
| **7** | — | Risk Management Report 10 | Overall residual risk evaluation | P |
| **8** | — | Risk Management Report | Risk Management Report | P |
| **Supplementary Information:**<br>**Document Ref should be with regards to the policy/procedure documents and documents containing device specific output.** | | | | |

| 4.3 | **TABLE: ESSENTIAL PERFORMANCE** | N/A |
|---|---|---|

| 4.5 | **RM RESULTS TABLE: Equivalent Safety for ME Equipment of ME System** | N/A |
|---|---|---|

| 4.6 | **RM RESULTS TABLE: ME Equipment or system parts contacting the patient** | N/A |
|---|---|---|

| 4.7 | **RM RESULTS TABLE: Single Fault Condition for ME Equipment** | N/A |
|---|---|---|

| 4.8 | **RM RESULTS TABLE: Components of ME Equipment** | N/A |
|---|---|---|

| 4.9 | **RM RESULTS TABLE: Use of components with high-integrity characteristics** | N/A |
|---|---|---|

| 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: GTM41061-1512-7.0, with 5Vdc/3A output | | | | | | |
| Normal condition | | 90 | 50/60 | 0.377 | 19.6 | 0.578 |
| Normal condition | | 100 | 50/60 | 0.343 | 19.6 | 0.571 |
| Normal condition | | 240 | 50/60 | 0.159 | 20.5 | 0.537 |
| Normal condition | | 264 | 50/60 | 0.153 | 20.9 | 0.518 |
| Model: GTM41061-1812-7.0, with 5Vdc/3.6A output | | | | | | |
| Normal condition | | 90 | 50/60 | 0.472 | 24.0 | 0.565 |
| Normal condition | | 100 | 50/60 | 0.433 | 23.7 | 0.547 |
| Normal condition | | 240 | 50/60 | 0.191 | 23.2 | 0.506 |
| Normal condition | | 264 | 50/60 | 0.180 | 23.6 | 0.497 |
| Model: GTM41061-1818-3.0, with 15Vdc/1.2A output | | | | | | |
| Normal condition | | 90 | 50/60 | 0.405 | 21.1 | 0.579 |
| Normal condition | | 100 | 50/60 | 0.368 | 21.0 | 0.571 |
| Normal condition | | 240 | 50/60 | 0.171 | 21.9 | 0.534 |
| Normal condition | | 264 | 50/60 | 0.164 | 22.1 | 0.511 |
| Model: GTM41061-1824 | | | | | | |
| Normal condition | | 90 | 50/60 | 0.425 | 21.0 | 0.550 |
| Normal condition | | 100 | 50/60 | 0.397 | 20.8 | 0.525 |
| Normal condition | | 240 | 50/60 | 0.177 | 21.1 | 0.497 |
| Normal condition | | 264 | 50/60 | 0.169 | 21.7 | 0.486 |
| Model: GTM41061-1830 | | | | | | |
| Normal condition | | 90 | 50/60 | 0.418 | 21.4 | 0.569 |
| Normal condition | | 100 | 50/60 | 0.388 | 21.3 | 0.549 |
| Normal condition | | 240 | 50/60 | 0.215 | 22.4 | 0.434 |
| Normal condition | | 264 | 50/60 | 0.206 | 22.8 | 0.419 |
| **Supplementary Information:** | | | | | | |

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

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

| 5.9.2 | TABLE: Determination of ACCESSIBLE parts | P |
|---|---|---|
| **Location** | **Determination method (NOTE1)** | **Comments** |
| Enclosure | Test finger, test hook | Can't insert |
| **Supplementary information:**<br>NOTE 1 - The determination methods are: visual; rigid test finger; jointed test finger; test hook. | | |

| 7.1.2 | TABLE: Legibility of Marking | | P |
|---|---|---|---|
| **Markings tested** | | **Ambient Illuminance (lx)** | **Remarks** |
| **Outside Markings (Clause 7.2) .....:** | | 100-1500 lx | Clearly legible |
| **Inside Markings (Clause 7.3) .....:** | | -- | -- |
| **Controls & Instruments (Clause 7.4) .....:** | | -- | -- |
| **Safety Signs (Clause 7.5).....:** | | -- | -- |
| **Symbols (Clause 7.6) .....:** | | 100-1500 lx | Clearly legible |
| **Supplementary information:**<br>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 ..... :** | **PET** | Pass |
| **Ink/other printing material or process..... :** | **Heat transfer print** | Pass |
| **Material (composition) of Warning Label ..... :** | -- | N/A |
| **Ink/other printing material or process..... :** | -- | N/A |
| **Other..... :** | -- | N/A |
| **Supplementary information:**<br>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 |

| | | |
|---|---|---|
| **7.2.2** | **RM RESULTS TABLE: Identification** | **N/A** |

| | | |
|---|---|---|
| **7.2.13** | **RM RESULTS TABLE: Physiological effects (safety signs and warning)** | **N/A** |

| | | |
|---|---|---|
| **7.2.17** | **RM RESULTS TABLE: Protective packaging** | **N/A** |

| | | |
|---|---|---|
| **7.3.3** | **RM RESULTS TABLE: Batteries** | **N/A** |

| | | |
|---|---|---|
| **7.3.7** | **RM RESULTS TABLE: Supply terminals** | **N/A** |

| | | |
|---|---|---|
| **7.4.2** | **RM RESULTS TABLE: Control devices** | **N/A** |

| | | |
|---|---|---|
| **7.5** | **RM RESULTS TABLE: Safety signs** | **N/A** |

| | | |
|---|---|---|
| **7.9.2.4** | **RM RESULTS TABLE: Electrical power source** | **N/A** |

| | | |
|---|---|---|
| **7.9.3.2** | **RM RESULTS TABLE: Replacement of fuses, power supply cords, other parts** | **N/A** |

| | | |
|---|---|---|
| **8.1 b** | **RM RESULTS TABLE: Fundamental rule of protection against electric shock - accidental detachment of conductors and connectors** | **N/A** |

| **8.4.2** | **TABLE: TABLE: Working Voltage / Power Measurement** | | | | | **P** |
|---|---|---|---|---|---|---|
| **Test supply voltage/frequency (V/Hz)[1] ..... :** | | | | | | 264V / 60Hz |
| **Location From/To** | **Measured values** | | | | | **Remarks** |
| | **Vrms** | **Vpk or Vdc** | **Peak-to-peak ripple[2]** | **Power W/VA** | **Energy (J)** | |
| **Transformer, primary to secondary** | Max. 276Vrms | -- | -- | -- | -- | For all models |
| **Optocoupler primary to secondary** | Max. 240Vrms | -- | -- | -- | -- | For all models |

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

| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | | | | | P |
|---|---|---|---|---|---|---|
| **Y capacitor primary to secondary** | Max. 240Vrms | -- | -- | -- | -- | For all models |
| **Secondary output connector** | -- | <60Vdc | <10% | -- | -- | For all models |

**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

| 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** | | | | | | | | | | |
| **Model GTM41061-1830** | **35** | **33** | **34** | **33** | **36** | **35** | **33** | **35** | **31** | **33** |
| **Model GTM41061-1818-3.0** | **33** | **34** | **34** | **35** | **33** | **32** | **34** | **36** | **32** | **34** |
| **Model GTM41061-1812-7.0** | **34** | **31** | **33** | **36** | **36** | **34** | **33** | **32** | **34** | **33** |
| **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:**

| 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:**

| | | |
|---|---|---|
| **8.5.2.2** | **RM RESULTS TABLE: Type B applied parts** | **N/A** |

| | | |
|---|---|---|
| **8.5.2.3** | **RM RESULTS TABLE: PATIENT Leads** | **N/A** |

| | | |
|---|---|---|
| **8.5.5.1a** | **TABLE: defibrillation-proof applied parts – measurement of hazardous electrical energies** | **N/A** |

| | | |
|---|---|---|
| **8.5.5.1b** | **TABLE: defibrillation-proof applied parts – verification of recovery time** | **N/A** |

| | | |
|---|---|---|
| **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** |

| | | |
|---|---|---|
| **8.6.3** | **RM RESULTS TABLE: Protective earthing of moving parts** | **N/A** |

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

| 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**

| 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** |
| 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 uA NC; 500 uA SFC |
| NC | | 264 | 60 | 10.7 | For all models, from L/N to accessible enclosure |
| SFC, interrupt one conductor | | 264 | 60 | 21.3 | |
| SFC, one Y1 capacitor is short circuited. | | 264 | 60 | 24.3 | |
| NC | | 264 | 60 | 59.2 | For all models, from L/N to output terminal (+) |
| SFC, interrupt one conductor | | 264 | 60 | 61.3 | |
| SFC, one Y1 capacitor is short circuited. | | 264 | 60 | 85.2 | |
| NC | | 264 | 60 | 28.4 | For all models, from L/N to output terminal (-) |
| SFC, interrupt one conductor | | 264 | 60 | 43.7 | |
| SFC, one Y1 capacitor is short circuited. | | 264 | 60 | 61.6 | |

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

| | | | | |
|---|---|---|---|---|
| Fig. 15 - Patient Leakage Current (P) | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current);<br>100 uA NC; 500 uA SFC (a.c.)<br>Type CF AP: 10 uA NC; 50 uA 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 uA<br>Type CF AP: 50 uA |
| -- | -- | -- | -- | -- |
| 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 uA NC; 50 uA SFC(d.c. current);<br>100 uA NC; 500 uA SFC (a.c.) ;<br>Type CF AP: 10 uA NC; 50 uA 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 uA<br>Type CF: N/A |
| -- | -- | -- | -- | -- |
| Fig. 19 – Patient Auxiliary Current | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 uA NC; 50 uA SFC (d.c. current);<br>100 uA NC; 500 uA SFC (a.c.) ;<br>Type CF AP: 10 uA NC;50 uA 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 uA NC; 100uA SFC (d.c. current);<br>500 uA NC; 1000 uA SFC (a.c.);<br>Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current) |
| -- | -- | -- | -- | -- |
| Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP | — | — | — | Maximum allowed values:<br>Type B or BF AP: 50 uA NC; 100uA SFC (d.c. current);<br>500 uA NC;1000 uA SFC (a.c.);<br>Type CF AP: 50 uA NC; 100 uA SFC (d.c. or a.c. current) |
| -- | -- | -- | -- | -- |
| Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP | — | — | — | Maximum allowed values:<br>Type B: NA<br>Type BF: 5000uA<br>Type CF: 100 uA |
| -- | -- | -- | -- | -- |
| Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed | — | — | — | Maximum allowed values:<br>Type B & BF: 1000 uA<br>Type CF: N/A |

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

| | | | | |
|---|---|---|---|---|
| -- | -- | -- | -- | -- |

**Supplementary information:**

Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5;
Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;

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

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

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

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

| 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. | | |
| **A** | **1MOOP** | **340** | **--** | **1500** | No breakdown |
| **B** | **2MOOP** | **340** | **--** | **3000** | No breakdown |
| **C** | **2MOPP** | **340** | **--** | **4000** | No breakdown |
| **D** | **2MOPP** | **340** | **--** | **4000** | No breakdown |
| **E** | **2MOPP** | **340** | **--** | **4000** | No breakdown |
| **F** | **2MOPP** | **340** | **--** | **4000** | No breakdown |
| **G** | **2MOPP** | **340** | **--** | **4000** | No breakdown |
| **H** | **2MOPP** | **340** | **--** | **4000** | No breakdown |

**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).

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

| | | | |
|---|---|---|---|
| **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)** |
|---|---|---|
| **Enclosure & Blade holder** | | |
| SE1X (pass 125°C ball pressure test by UL) | -- | -- |
| C2950 | 125 | 1.4 |
| CX7211 | 125 | 1.4 |
| EXCY0098 | 125 | 1.3 |
| LN-1250P | 125 | 1.3 |
| LN-1250G | 125 | 1.4 |
| PA-765A | 125 | 1.3 |
| PC-540 | 125 | 1.3 |
| **Bobbin of Mains transformer** | | |
| T375J | 125 | 1.3 |
| T375HF | 125 | 1.2 |
| PM-9820 | 125 | 1.3 |
| CP-J-8800 | 125 | 1.4 |
| **Supplementary information:** | | |

| | | |
|---|---|---|
| **8.8.4.1** | **RM RESULTS TABLE: Mechanical strength and resistance to heat** | **P** |

| **8.9.2** | **TABLE: Short circuiting of each single one of the CREEPAGE DISTANCES and AIR CLEARANCES for insulation in the MAINS PART between parts of opposite polarity in lieu of complying with the required measurements in 8.9.4** | **N/A** |
|---|---|---|

| **Specific areas of circuits short-circuited and test conditions** | **Test in lieu of CREEPAGE DISTANCE or AIR CLEARANCE[1]** | **HAZARDOUS SITUATION observed (i.e., fire hazard, shock hazard, explosion, discharge of parts, etc.)? Yes/No** | **Remarks** |
|---|---|---|---|
| **--** | **--** | **--** | **--** |

**Supplementary information:**
Note 1: AC - AIR CLEARANCE CD - CREEPAGE DISTANCE

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

| 8.9.3.2 | Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts | | N/A |
|---|---|---|---|
| **Test Sequence No.** | **Each test duration and temperature** | **Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)** | **Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No** |
| **1** | **68 h at T1 ± 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** | | |
| **2** | **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** | | |
| **3** | **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** | | |
| **4** | **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** | | |
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**Supplementary information:**

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

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

| 8.9.3.4 | Table: Thermal cycling tests on one sample of cemented joint (see 8.9.3.3) | | N/A |
|---|---|---|---|
| **Test Sequence No.** | **Each test duration and temperature** | **Dielectric test voltage (V = Test voltage in 8.8.3 times 1.6)** | **Dielectric strength test after humidity preconditioning per cl. 5.7 except for 48 h only, Breakdown: Yes/No** |
| **1** | **68 h at T1 ± 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** | | |
| **2** | **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** | | |
| **3** | **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** | | |
| **4** | **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** | | |
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**Supplementary information:**

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

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

| 8.10 | TABLE: List of critical components | | | | P |
|---|---|---|---|---|---|
| Object/part No. | Manufacturer/ trademark | Type/model | Technical data | Standard (Edition / year) | Mark(s) of conformity[1]) |
| PCB | WALEX ELECTRONIC (WUXI) CO LTD | T2A,<br>T2B,<br>T4,<br>T2 | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E154355<br>Tested with appliance |
| Alt. | PACIFIC WIN INDUSTRIAL LTD | PW-02,<br>PW-03 | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E228070<br>Tested with appliance |
| Alt. | DONGGUAN HE TONG ELECTRONICS CO LTD | CEM1 | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E243157<br>Tested with appliance |
| Alt. | CHEERFUL ELECTRONIC | 03,<br>03A | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E199724<br>Tested with appliance |
| Alt. | DONGGUAN DAYSUN ELECTRONIC CO LTD | DS2 | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E251754<br>Tested with appliance |
| Alt. | SUZHOU CITY YILIHUA ELECTRONICS | YLH-1 | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E251781<br>Tested with appliance |
| Alt. | DAFENG AREX ELECTRONICS TECHNOLOGY CO LTD | 02V0,<br>04V0,<br>03V0 | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E186016<br>Tested with appliance |
| Alt. | BRITE PLUS ELECTRONICS (SUZHOU) CO LTD | DKV0-3A,<br>DGV0-3A | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E177671<br>Tested with appliance |
| Alt. | SHANGHAI H-FAST ELECTRONICS CO LTD | 411001,<br>211001 | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E337862<br>Tested with appliance |

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

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|---|---|---|---|---|---|
| Alt. | SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD | TCX | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E250336<br>Tested with appliance |
| Alt. | Jiangxi ZHONG XIN HUA Electronics Industry Co Ltd | ZXH-2<br>ZXH-3 | Min. V-0, min 1.6 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E331298<br>Tested with appliance |
| Insulating tape wrapping around the PCB edge | 3M COMPANY ELECTRICAL MARKETS DIV (EMD) | 1350F-1,<br>1350T-1 | 130°C | IEC/EN 60601-1<br>UL 510 | UL E17385<br>Tested with appliance |
| Alt. | BONDTEC PACIFIC CO LTD | 370S | 130°C | IEC/EN 60601-1<br>UL 510 | UL E175868<br>Tested with appliance |
| Alt. | JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD | PZ,<br>CT,<br>WF | 130°C | IEC/EN 60601-1<br>UL 510 | UL E165111<br>Tested with appliance |
| Alt. | JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD | JY25-A | 130°C | IEC/EN 60601-1<br>UL 510 | UL E246950<br>Tested with appliance |
| Alt. | CHANG SHU LIANG YI TAPE INDUSTRY CO LTD | LY-XX | 130°C | IEC/EN 60601-1<br>UL 510 | UL E246820<br>Tested with appliance |
| Fuse (F1, F2)<br>(F2 is optional.) | Conquer Electronics Co., Ltd. | MST | T2A, 250V | IEC/EN 60127-2<br>UL 248-1<br>UL 248-14 | VDE 40017118<br>UL E82636 |
| Alt. | Ever Island Electric Co., Ltd. and Walter Electric | 2010 | T2A, 250V | IEC/EN 60127-2<br>UL 248-1<br>UL 248-14 | VDE 40018781<br>UL E220181 |
| Alt. | Bel Fuse Ltd. | RST | T2A, 250V | IEC/EN 60127-2<br>UL 248-1<br>UL 248-14 | VDE 40011144<br>UL E20624 |
| Alt. | Cooper Bussmann LLC | SS-5 | T2A, 250V | IEC/EN 60127-2<br>UL 248-1<br>UL 248-14 | VDE 40015513<br>UL E19180 |

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

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|---|---|---|---|---|---|
| Alt. | Das & Sons International Ltd. | 385T series | T2A, 250V | IEC/EN 60127-2<br>UL 248-1<br>UL 248-14 | VDE 40008524<br>UL E205718 |
| Alt. | Shenzhen Lanson Electronics Co. | SMT | T2A, 250V | IEC/EN 60127-2<br>UL 248-1<br>UL 248-14 | VDE 40012592<br>UL E221465 |
| Alt. | Walter Electronic Co. Ltd. | ICP series | T2A, 250V | IEC/EN 60127-2<br>UL 248-1<br>UL 248-14 | VDE 40012824<br>UL E56092 |
| Insulation tube used on the fuse (Only for fuse ICP | SHENZHEN WOER HEAT-SHRINKABLE MATERIAL CO LTD | RSFR, RSFR-H, RSFR-HPF | 600V, 125°C | IEC/EN 60601-1<br>UL 224 | UL E203950<br>Tested with appliance |
| Alt. | QIFURUI ELECTRONICS CO | QFR-h | 600V, 125°C | IEC/EN 60601-1<br>UL 224 | UL E225897<br>Tested with appliance |
| Alt. | DONGGUAN SALIPT CO LTD | SALIPT S-901-300, SALIPT S-901-600 | Min. 300V, 125°C | IEC/EN 60601-1<br>UL 224 | UL E209436<br>Tested with appliance |
| Alt. | GUANGZHOU KAIHENG ENTERPRISE GROUP | K-2 (+), K-2 (CB) | Min. 300V, 125°C | IEC/EN 60601-1<br>UL 224 | UL E214175<br>Tested with appliance |
| Alt. | CHANGYUAN ELECTRONICS (SHENZHEN) CO LTD | CB-HFT | Min. 300V, 125°C | IEC/EN 60601-1<br>UL 224 | UL E180908<br>Tested with appliance |
| X capacitor (CX1) (optional) | Cheng Tung Industrial Co., Ltd. | CTX | X2, AC310V, Max.0,47µF, 40/110/21/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40022642<br>UL E193049 |
| Alt. | Tenta Electric Industrial Co. Ltd. | MEX | X2, AC275V, Max. 0,47µF, 40/100/21/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 119119<br>UL E222911 |
| Alt. | Ultra Tech Xiphi Enterprise Co. Ltd. | HQX | X2, AC275V, Max. 0,47µF, 40/100/21/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40015608<br>UL E183780 |

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| Alt. | Okaya Electric Industries | RE series | X2, AC275V, Max. 0,47µF, 55/100/56/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40028657<br>UL E47474 |
| Alt. | VISHAY Capacitors Belgium NV | F1772 series | X2, AC310V, Max. 0,47µF, 40/100/56/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40005079<br>UL E354331 |
| Alt. | Winday Electronic Industries Co., Ltd. | MPX | X2, AC275V, Max. 0,47µF, 40/100/21/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40018071<br>UL E302125 |
| Alt. | Dain Electronics Co., Ltd. | MPX,<br>MEX,<br>NPX | X2, AC275V, Max. 0,47µF, 40/100/21/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40018798<br>UL E147776 |
| Alt. | Sinhua Electronics (Huzhou) Co., Ltd. | MPX | X2, AC300V, Max. 0,47µF, 40/100/21/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40014686<br>UL E237560 |
| Alt. | Shunde Da Hua Electric Co., Ltd. | HD-MKP series | X2, AC275V, Max. 0,47µF, 40/105/21/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40001126<br>UL E227157 |
| Alt. | Foshan Shunde Chuang Ge | MKP-X2 | X2, AC275V, Max. 0,47µF, 40/105/21/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40008922<br>UL E308832 |
| Alt. | Hongzhi Enterprises Ltd. | MPX | X2, AC275V, Max. 0,47µF, 40/100/56/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40023936<br>UL E192572 |
| Alt. | Jiangsu Xinghua Huayu Co., Ltd. | MPX | X2, AC275V, Max. 0.47µF, 40/100/21/C | IEC/EN 60384-14 | VDE 40022417 |
| Y-Capacitor (CY1, CY2) (optional) | TDK Corporation | CD | Type Y1, max. 1000pF, min. 250V, 25/125/21/B | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40029780<br>UL E37861 |
| Alt. | SUCCESS ELECTRONICS CO LTD | SE, SB | Type Y1, max. 1000pF, min. 250V, 30/125/56/C | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40008996<br>UL E114280 |
| Alt. | MURATA MFG CO LTD | KX | Type Y1, max. 1000pF, min. 250V, 25/125/21/B | IEC/EN 60384-14<br>UL 60384-14<br>UL 1414 | VDE 40002831<br>UL E37921 |

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| Alt. | WALSIN TECHNOLOGY CORP | AH | Type Y1, max. 1000pF, min. 250V, 25/125/21/C | IEC/EN 60384-14 UL 60384-14 UL 1414 | VDE 40001804 UL E146544 |
| Alt. | JYA-NAY CO LTD | JN | Type Y1, max. 1000pF, min. 250V, 25/125/21/C | IEC/EN 60384-14 UL 60384-14 UL 1414 | VDE 40001831 UL E201384 |
| Alt. | HAOHUA ELECTRONIC CO | CT7 | Type Y1, max. 1000pF, min. 250V, 30/125/56/C | IEC/EN 60384-14 UL 60384-14 UL 1414 | VDE 40003902 UL E233106 |
| Alt. | HONGZHI ENTERPRISES LTD | Y Series | Type Y1, max. 1000pF, min. 400V, 25/125/21/B | IEC/EN 60384-14 UL 60384-14 UL 1414 | VDE 40038760 UL E192572 |
| Alt. | JERRO ELECTRONICS CORP | JX-series | Type Y1, max. 1000pF, min. 250V, 40/125/21/C | IEC/EN 60384-14 UL 60384-14 UL 1414 | VDE 40032158 UL E333001 |
| Varistor (MOV1) (optional) | JOYIN CO LTD | 10N471K, 14N471K | 300VAC, 6kV/3kA, 40/85/56 V-1 | IEC 61051-2 UL 1449 | VDE 005937 UL E325508 |
| Alt. | CENTRA SCIENCE CORP | 10D471K, 14D471K | 300VAC, 6kV/3kA, 40/85/56 V-1 | IEC 61051-2 UL 1449 | VDE 40008220 UL E316325 |
| Alt. | THINKING ELECTRONIC INDUSTRIAL CO LTD | TVR10471K, TVR14471K | 300VAC, 6kV/3kA, 40/85/56 V-1 | IEC 61051-2 UL 1449 | VDE 005944 UL E314979 |
| Alt. | SUCCESS ELECTRONICS CO LTD | SVR10D471K, SVR14D471K | 300VAC, 6kV/3kA, 40/85/56 V-1 | IEC 61051-2 UL 1449 | VDE 40030401 UL E330256 |
| Alt. | CERAMATE TECHNICAL CO LTD | GNR10D471K, GNR14D471K | 300VAC, 6kV/3kA, 40/85/56 V-1 | IEC 61051-2 UL 1449 | VDE 40031745 UL E315429 |
| Alt. | BRIGHTKING (SHENZHEN) CO LTD | 10D471K, 14D471K | 300VAC, 6kV/3kA, 40/85/56 V-1 | IEC 61051-2 UL 1449 | VDE 40027827 UL E327997 |
| Alt. | LIEN SHUN ELECTRONICS CO LTD | 10D471K, 14D471K | 300VAC, 6kV/3kA, 40/85/56 V-1 | IEC 61051-2 UL 1449 | VDE 40005858 UL E315524 |

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

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| Alt. | GUANGXI NEW FUTURE INFORMATION INDUSTRY CO LTD | 10D471K, 14D471K | 300VAC, 6kV/3kA, 40/85/56 V-1 | IEC 61051-2 UL 1449 | VDE 40030322 UL E323753 |
| Optocoupler (U1) | LITE-ON Technology Corporation | LTV-817 | Ext. Cr: min. 8.01 mm; DTI: min. 0.6 mm; Thermal cycling test. Max. operating temp.: 115°C | IEC/EN 60747-5-2 IEC/EN 60950-1 UL 1577 | VDE 40015248 Semko No. 1119078 UL E113898 |
| Alt. | Everlight Electronics Co., Ltd. | EL817 | Ext. Cr: min. 7.7 mm; DTI: min. 0.5 mm; Thermal cycling test. Max. operating temp.: 110°C | IEC/EN 60747-5-2 IEC/EN 60950-1 UL 1577 | VDE 132249 Nemko No. P11214765/A1 UL E214129 |
| Alt. | Bright Led Electronics Corp. | BPC-817, BPC-817 M, BPC-817 S | Ext. Cr: min. 7.0 mm; DTI: min. 0.4 mm; Thermal cycling test. Max. operating temp.: 100°C | IEC/EN 60747-5-2 IEC/EN 60950-1 UL 1577 | VDE 40007240 Semko No. 813247 UL E236324 |
| Alt. | Fairchild Semiconductor Pte. Ltd. | FOD817B | Ext. Cr: min. 7.8 mm; DTI: min. 0.6 mm; Thermal cycling test. Max. operating temp.: 115°C | IEC/EN 60747-5-2 IEC/EN 60950-1 UL 1577 | VDE 40026857 Semko No. 1024922 UL E90700 |
| Transformer (T1) | GlobTek BOAM Haopuwei ENG | TF001, TF002, TF003, TF004 | Class E, with critical component listed below | IEC/EN 60601-1 | Tested with appliance |
| -Magnet wire | PACIFIC ELECTRIC WIRE & CABLE (SHENZHEN) CO LTD | UEWN/U | 130°C | IEC/EN 60601-1 UL 1446 | UL E201757 Tested with appliance |
| -Alt. | JUNG SHING WIRE CO LTD | UEW-4, UEY-2 | 130°C | IEC/EN 60601-1 UL 1446 | UL E174837 Tested with appliance |

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

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| -Alt. | JIANGSU HONGLIU MAGNET WIRE TECHNOLOGY CO LTD | 2UEW/130 | 130°C | IEC/EN 60601-1 UL 1446 | UL E335065 Tested with appliance |
| -Alt. | CHANGZHOU DAYANG WIRE & CABLE CO LTD | 2UEW/130 | 130°C | IEC/EN 60601-1 UL 1446 | UL E158909 Tested with appliance |
| -Alt. | WUXI JUFENG COMPOUND LINE CO LTD | 2UEWB | 130°C | IEC/EN 60601-1 UL 1446 | UL E206882 Tested with appliance |
| -Alt. | JIANGSU DARTONG M & E CO LTD | UEW | 130°C | IEC/EN 60601-1 UL 1446 | UL E237377 Tested with appliance |
| -Alt. | SHANDONG SAINT ELECTRIC CO LTD | UEW/130 | 130°C | IEC/EN 60601-1 UL 1446 | UL E194410 Tested with appliance |
| -Alt. | ZHEJIANG LANGLI ELECTRIC EQUIPMENTS CO LTD | UEW | 130°C | IEC/EN 60601-1 UL 1446 | UL E222214 Tested with appliance |
| -Alt. | NINGBO JINTIAN NEW MATERIAL CO LTD | 2UEW/130 | 130°C | IEC/EN 60601-1 UL 1446 | UL E227047 Tested with appliance |
| -Triple-insulated wire (Secondary) | GREAT LEOFLON INDUSTRIAL CO LTD | TRW(B) | Min.130°C | IEC/EN 60601-1 UL 2353 | UL E211989 Tested with appliance |
| -Alt. | COSMOLINK CO LTD | TIW-M | Min.130°C | IEC/EN 60601-1 UL 2353 | UL E213764 Tested with appliance |
| -Alt. | FURUKAWA ELECTRIC CO LTD | TEX-E | Min.130°C | IEC/EN 60601-1 UL 2353 | UL E206440 Tested with appliance |
| -Alt. | TOTOKU ELECTRIC CO LTD | TIW-2 | Min.130°C | IEC/EN 60601-1 UL 2353 | UL E166483 Tested with appliance |
| -Bobbin | CHANG CHUN PLASTICS CO LTD | T375J, T375HF | V-0, 150°C, Min. thickness 0.45 mm | IEC/EN 60601-1 UL 94 UL 746 A/B/C/D | UL E59481 Tested with appliance |

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

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|---|---|---|---|---|---|
| -Alt. | SUMITOMO BAKELITE CO LTD | PM-9820 | V-0, 150°C, Min. thickness 0.45 mm | IEC/EN 60601-1<br>UL 94<br>UL 746 A/B/C/D | UL E41429<br>Tested with appliance |
| -Alt. | HITACHI CHEMICAL CO LTD | CP-J-8800 | V-0, 150°C, Min. thickness 0.45 mm | IEC/EN 60601-1<br>UL 94<br>UL 746 A/B/C/D | UL E42956<br>Tested with appliance |
| -Insulating tape | 3M COMPANY ELECTRICAL MARKETS DIV (EMD) | 1350F-1, 1350T-1 | Min.130°C | IEC/EN 60601-1<br>UL 510 | UL E17385<br>Tested with appliance |
| -Alt. | BONDTEC PACIFIC CO LTD | 370S | Min.130°C | IEC/EN 60601-1<br>UL 510 | UL E175868<br>Tested with appliance |
| -Alt. | JINGJIANG YAHUA PRESSURE SENSITIVE GLUE CO LTD | PZ, CT, WF | Min.130°C | IEC/EN 60601-1<br>UL 510 | UL E165111<br>Tested with appliance |
| -Alt. | JINGJIANG JINGYI ADHESIVE PRODUCT CO LTD | JY25-A | Min.130°C | IEC/EN 60601-1<br>UL 510 | UL E246950<br>Tested with appliance |
| -Alt. | CHANG SHU LIANG YI TAPE INDUSTRY CO LTD | LY-XX | Min.130°C | IEC/EN 60601-1<br>UL 510 | UL E246820<br>Tested with appliance |
| -Pin-out support (PCB material) | DONGGUAN DAYSUN ELECTRONIC CO LTD | DS2 | Min. V-0, min 1.0 mm thickness, 130°C | IEC/EN 60601-1<br>UL 796 | UL E251754<br>Tested with appliance |
| -Alt | Interchangeable | Interchangeable | Min. V-1, min 1.0 mm thickness, min. 130°C | UL 796: 2016 | UL approved |
| Line filter (LF1) (Optional) | GlobTek<br>BOAM<br>haopuwei<br>HEJIA | NF00030 | Class A | IEC/EN 60601-1 | Tested with appliance |
| Enclosure & Blade holder | SABIC INNOVATIVE PLASTICS B V | SE1X | Min. V-1 at 1.5 mm thickness, 105°C | IEC/EN 60601-1<br>UL 94<br>UL 746 A/B/C/D | UL E45329<br>Tested with appliance |
| Alt. | | C2950 | Min. V-0 at 1.5 mm thickness, 75°C | | |

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

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|---|---|---|---|---|---|
| Alt. | | CX7211 | Min. V-1 at 1.25 mm thickness, 85°C | | |
| Alt. | | 945 (GG) | Min. V-0 at 1.5 mm thickness, 120°C | | |
| Alt. | COVESTRO DEUTSCHLAND AG [PC RESINS] | 6485 | Min. V-0 at 1.5 mm thickness, 115°C | IEC/EN 60601-1<br>UL 94<br>UL 746 A/B/C/D | UL E41613<br>Tested with appliance |
| Alt. | TEIJIN CHEMICALS LTD | LN-1250P, LN-1250G | Min. V-0 at 1.5 mm thickness, 115°C | IEC/EN 60601-1<br>UL 94<br>UL 746 A/B/C/D | UL E50075<br>Tested with appliance |
| Alt. | SABIC JAPAN L L C | SE1X | Min. V-1 at 1.5 mm thickness, 105°C | IEC/EN 60601-1<br>UL 94<br>UL 746 A/B/C/D | UL E207780<br>Tested with appliance |
| Alt. | | C2950 | Min. V-0 at 1.5 mm thickness, 75°C | | |
| Alt. | | CX7211 | Min. V-1 at 1.25 mm thickness, 85°C | | |
| Alt. | | 945 (GG) | Min. V-0 at 1.5 mm thickness, 120°C | | |
| Alt. | CHI MEI Corporation | PA-765A | Min. V-1 at 1.5 mm thickness, 80°C | IEC/EN 60601-1<br>UL 94<br>UL 746 A/B/C/D | UL E56070<br>Tested with appliance |
| Alt. | CHI MEI Corporation | PC-540 | Min. V-0 at 1.5 mm thickness, 80°C | IEC/EN 60601-1<br>UL 94<br>UL 746 A/B/C/D | UL E56070<br>Tested with appliance |
| Label | DONGGUAN XIANGQUAN PRINTING CO LTD | XQ03 | Rated min 80°C<br>Suitable for use on the plastic enclosure | IEC/EN 60601-1<br>UL 969 | Tested with appliance<br>UL MH27594 |
| Alt. | FAN JA PAPER PRINTING CO LTD | FJ-03-3 | Rated min 80°C<br>Suitable for use on the plastic enclosure | IEC/EN 60601-1<br>UL 969 | Tested with appliance<br>UL MH19546 |

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

| | | | | | |
|---|---|---|---|---|---|
| Alt. | FAN JA PAPER PRINTING CO LTD | FJ07 | Rated min 80°C Suitable for use on the plastic enclosure (PC or ABS) | IEC/EN 60601-1 UL 969 | Tested with appliance UL MH19546 |
| Alt. | DONGGUAN XIANGQUAN PRINTING CO LTD | XQ004-B | Rated min 80°C Suitable for use on the plastic enclosure | IEC/EN 60601-1 UL 969 | Tested with appliance UL MH47303 |
| Alt. | E-LIN ADHESIVE LABEL CO LTD | EL-15 | Rated min 80°C Suitable for use on the plastic enclosure | IEC/EN 60601-1 UL 969 | Tested with appliance UL MH45549 |
| Alt. | SHENZHEN CORWIN PRINTING CO LTD | CW-01 | Rated min 80°C Suitable for use on the plastic enclosure | IEC/EN 60601-1 UL 969 | Tested with appliance UL MH47077 |
| Alt. | YUEN CHANG SPECIAL PRINTING (SHENZHEN) CO LTD | JL-08 JL-02 | Rated min 80°C Suitable for use on the plastic enclosure (PC or ABS) | IEC/EN 60601-1 UL 969 | Tested with appliance UL MH29752 |
| Alt. | SUZHOU HAIRONG PACKING PRODUCTION CO LTD | HR-01 HR-02 | Rated min 80°C Suitable for use on the plastic enclosure | IEC/EN 60601-1 UL 969 | Tested with appliance UL MH48692 |
| Alt. | GlobTek | -- | Engraving or Silkscreen or laser printing | IEC/EN 60601-1 | Tested with appliance |

**Supplementary information:**

1) Provided evidence ensures the agreed level of compliance. See OD-CB2039.

For all transformers and all filters under all manufacturers.

| 8.10.1 | RM RESULTS TABLE: Fixing of components | P |
|---|---|---|

| 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:** | | | | |

| 9.2.1 | RM RESULTS TABLE: HAZARDS associated with moving parts - General | N/A |
|---|---|---|

| 9.2.2.2 | TABLE: Measurement of gap “a” according to Table 20 (ISO 13852: 1996) | N/A |
|---|---|---|

| 9.2.3.2 | TABLE: Over-travel End Stop Test | N/A |
|---|---|---|

| 9.2.4 | RM RESULTS TABLE: Emergency stopping devices | N/A |
|---|---|---|

| 9.2.5 | RM RESULTS TABLE: Release of patient | N/A |
|---|---|---|

| 9.4.2.1 | TABLE: Instability—overbalance in transport position | N/A |
|---|---|---|

| 9.4.2.2 | TABLE: Instability—overbalance excluding transport position | N/A |
|---|---|---|

| 9.4.2.3 | TABLE: Instability—overbalance from horizontal and vertical forces | N/A |
|---|---|---|

| 9.4.2.4.2 | TABLE: Castors and wheels – Force for propulsion | N/A |
|---|---|---|

| 9.4.2.4.3 | TABLE: Castors and wheels – Movement over a threshold | N/A |
|---|---|---|

| 9.4.3.1 | TABLE: Instability from unwanted lateral movement (including sliding) in transport position | N/A |
|---|---|---|

| 9.4.3.2 | TABLE: Instability from unwanted lateral movement (including sliding) excluding transport position | N/A |
|---|---|---|

| 9.4.4 | TABLE: Grips and other handling devices | N/A |
|---|---|---|

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **9.5.1** | **RM RESULTS TABLE: Protective means** | | **N/A** |
| **9.6.1** | **RM RESULTS TABLE: Acoustic energy - General** | | **N/A** |
| **9.6.2.2** | **RM RESULTS TABLE: Infrasound and ultrasound energy** | | **N/A** |
| **9.7.2** | **RM RESULTS TABLE: Pneumatic and hydraulic parts** | | **N/A** |
| **9.7.5** | **TABLE: Pressure vessels** | | **N/A** |
| **9.7.7** | **RM RESULTS TABLE: Pressure-relief device** | | **N/A** |
| **9.8.1** | **RM RESULTS TABLE: Hazards associated with support systems - General** | | **N/A** |
| **9.8.2** | **RM RESULTS TABLE: Tensile safety factor** | | **N/A** |
| **9.8.3.1** | **RM RESULTS TABLE: Strength of patient or operator support or suspension systems - General** | | **N/A** |
| **9.8.3.2** | **TABLE: PATIENT support/suspension system - Static forces** | | **N/A** |
| **9.8.3.3** | **TABLE: Support/Suspension System – Dynamic forces due to loading from persons** | | **N/A** |
| **9.8.5** | **RM RESULTS TABLE: Systems without mechanical protective devices** | | **N/A** |
| **10.1.1** | **TABLE: Measurement of X - radiation** | | **N/A** |
| **10.1.2** | **RM RESULTS TABLE: ME equipment intended to produce diagnostic or therapeutic X-radiation** | | **N/A** |
| **10.2** | **RM RESULTS TABLE: Alpha, beta, gamma, neutron & other particle radiation** | | **N/A** |
| **10.5** | **RM RESULTS TABLE: Other visible electromagnetic radiation** | | **N/A** |
| **10.6** | **RM RESULTS TABLE: RISK associated with infrared radiation other than emitted by lasers and LEDS** | | **N/A** |
| **10.7** | **RM RESULTS TABLE: RISK associated with ultraviolet radiation other than emitted by lasers and LEDS** | | **N/A** |

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

| 11.1.1 | TABLE: Excessive temperatures in ME EQUIPMENT | | | | | P |
|---|---|---|---|---|---|---|
| Model No. ..... : | 1 | -- | -- | -- | -- | -- |
| Test ambient (°C) ..... : | 40.0 | -- | -- | -- | -- | -- |
| Test supply voltage/frequency (V/Hz)[4] .. : | See below | -- | -- | -- | -- | -- |

| 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 |
|---|---|---|---|---|---|
| Input: 90V~/60Hz | | | | | |
| 1 | 1 | CX1 body | 100 | 68.6 | See table 8.10 |
| 1 | 2 | LF1 | 105 | 86.2 | -- |
| 1 | 3 | C1 body | 105 | 83.5 | T marking on capacitor body |
| 1 | 4 | CY1 body | 85 | 79.3 | -- |
| 1 | 5 | U1 body | 100 | 78.2 | See table 8.10 |
| 1 | 6 | T1 winding | 110 | 89.5 | Thermocouples are used, so the limit is to be reduced by 10°C. |
| 1 | 7 | T1 core | 120 | 86.1 | -- |
| 1 | 8 | PCB near D7 | 130 | 83.3 | See table 8.10 |
| 1 | 9 | PCB near primary heatsink | 130 | 72.4 | See table 8.10 |
| 1 | 10 | Plastic enclosure | 60 | 55.3 | Table 23 used, enclosure is likely to be touched for 10s to 1min. |
| 1 | 11 | Output cord inside enclosure | 70 | 45.2 | 8.10.7 c) |
| Input: 264V~/60Hz | | | | | |
| 1 | 1 | CX1 body | 100 | 69.7 | See table 8.10 |
| 1 | 2 | LF1 | 105 | 71.7 | -- |
| 1 | 3 | C1 body | 105 | 82.9 | T marking on capacitor body |
| 1 | 4 | CY1 body | 85 | 77.6 | -- |
| 1 | 5 | U1 body | 100 | 83.8 | See table 8.10 |

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

| | | | | | |
|---|---|---|---|---|---|
| 1 | 6 | T1 winding | 110 | 94.8 | Thermocouples are used, so the limit is to be reduced by 10°C. |
| 1 | 7 | T1 core | 120 | 91.4 | -- |
| 1 | 8 | PCB near D7 | 130 | 88.6 | See table 8.10 |
| 1 | 9 | PCB near primary heatsink | 130 | 82.4 | See table 8.10 |
| 1 | 10 | Plastic enclosure | 60 | 55.8 | Table 23 used, enclosure is likely to be touched for 10s to 1min. |
| 1 | 11 | Output cord inside enclosure | 70 | 45.5 | 8.10.7 c) |

**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.

[6] Model No.1 represents Model GTM41061-1830 which is chosen as the worst case for evaluation.

| | | |
|---|---|---|
| **11.1.1** | **RM RESULTS TABLE: Maximum temperature during normal use (Table 23 or 24)** | **N/A** |

| | | |
|---|---|---|
| **11.1.2.1** | **RM RESULTS TABLE: Applied parts intended to supply heat to patient** | **N/A** |

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

| **11.1.3** | **TABLE: Temperature of windings by change-of-resistance method** | | | | | | **N/A** |
|---|---|---|---|---|---|---|---|
| **Temperature T of winding:** | **$t_1$ (°C)** | **$R_1$ (Ω)** | **$t_2$ (°C)** | **$R_2$ (Ω)** | **T (°C)** | **Allowed $T_{max}$ (°C)** | **Insulation class** |
| -- | -- | -- | -- | -- | -- | -- | -- |
| **Supplementary information:** | | | | | | | |

| | | |
|---|---|---|
| **11.1.3** | **RM RESULTS TABLE: Measurements** | **N/A** |

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **11.2.2.1** | **RM RESULTS TABLE: Risk of fire in an oxygen rich environment** | | **N/A** |
| **11.2.2.1** | **TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source** | | **N/A** |
| **11.3** | **RM RESULTS TABLE: Constructional requirements for fire enclosures of ME equipment** | | **N/A** |
| **11.5** | **RM RESULTS TABLE: ME equipment and ME systems intended for use in conjunction with flammable agents** | | **N/A** |
| **11.6.1** | **TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances** | | **N/A** |
| **11.6.3** | **RM RESULTS TABLE: Spillage on ME equipment and ME system** | | **N/A** |
| **11.6.5** | **RM RESULTS TABLE: Ingress of water or particulate matter into ME EQUIPMENT and ME SYSTEMS** | | **N/A** |
| **11.6.7** | **RM RESULTS TABLE: Sterilization of ME equipment and ME systems** | | **N/A** |
| **11.6.8** | **RM RESULTS TABLE: Compatibility with substances used** | | **N/A** |
| **12.1** | **RM RESULTS TABLE: Accuracy of controls and equipment** | | **N/A** |
| **12.4.1** | **RM RESULTS TABLE: Intentional exceeding of safety limits** | | **N/A** |
| **12.4.2** | **RM RESULTS TABLE: Indication of parameters relevant to safety** | | **N/A** |
| **12.4.3** | **RM RESULTS TABLE: Accidental selection of excessive output values** | | **N/A** |
| **12.4.4** | **RM RESULTS TABLE: Incorrect output** | | **N/A** |
| **12.4.5.3** | **RM RESULTS TABLE: Radiotherapy equipment** | | **N/A** |
| **12.4.5.4** | **RM RESULTS TABLE: Other ME equipment producing diagnostic or therapeutic radiation** | | **N/A** |
| **12.4.6** | **RM RESULTS TABLE: Diagnostic or therapeutic acoustic pressure** | | **N/A** |

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

| | | |
|---|---|---|
| **13.1.2** | **TABLE: measurement of power or energy dissipation in parts & components to waive SINGLE FAULT CONDITIONS in 4.7, 8.1 b), 8.7.2, and 13.2.2 relative to emission of flames, molten metal, or ignitable substances** | **N/A** |

| | |
|---|---|
| **Power dissipated less than (W).....:** | **15** |
| **Energy dissipated less than (J).....:** | **900** |

| Part or component tested | Measured power dissipated (W) | Calculated energy dissipated (J) | SINGLE FAULT CONDITIONS waived (Yes/No) | Remarks |
|---|---|---|---|---|
| -- | -- | -- | -- | -- |

**Supplementary information:**

| | | |
|---|---|---|
| **13.2** | **TABLE: SINGLE FAULT CONDITIONS in accordance with 13.2.2 to 13.2.13, inclusive** | P |

| Clause No. | Description of SINGLE FAULT CONDITION | Results observed | HAZARDOUS SITUATION (Yes/No) |
|---|---|---|---|
| **13.2.2** | **Electrical SINGLE FAULT CONDITIONS per Clause 8.1:** | **—** | **—** |
| | D8 short-circuited | No output, circuit protected. | No |
| | T1 sec. short-circuited | No output, circuit protected. | No |
| | R14 short-circuited | No output, circuit protected. | No |
| | D5 short-circuited | No output, circuit protected. | No |
| | D1 short-circuited | Fuse open immediately. | No |
| | C1 short-circuited | No output, circuit protected. | No |
| | U1 sec. short-circuited | No output, circuit protected. | No |
| | U1 pri. short-circuited | No output, circuit protected. | No |
| | D6 short-circuitedd | No output, circuit protected. | No |
| **13.2.3** | **Overheating of transformers per Clause 15.5:** | **—** | **—** |
| | | See 15.5 | 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 thermostat used | N/A |
| **13.2.5** | **Failure of temperature limiting devices according to 13.2.13 & 15.4.2, overloading, THERMOSTATS short circuited or interrupted, the less favourable of the two:** | **—** | **—** |
| | | No temperature limiting device | N/A |

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

| Clause No. | Description of SINGLE FAULT CONDITION | Results observed | HAZARDOUS SITUATION (Yes/No) |
|---|---|---|---|
| **13.2.6** | **Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted)** | **—** | **—** |
| | | No Leakage of liquid | N/A |
| **13.2.7** | **Impairment of cooling that could result in a HAZARD using test method of 11.1:** | **—** | **—** |
| | **Single ventilation fans locked consecutively** | No fan used | N/A |
| | **Ventilation openings on top and sides impaired by covering openings on top of ENCLOSURE or positioning of ME EQUIPMENT against walls** | No ventilation opening | N/A |
| | **Simulated blocking of filters** | No filter | N/A |
| | **Flow of a cooling agent interrupted** | No cooling agent used | N/A |
| **13.2.8** | **Locking of moving parts – Only one part locked at a time – Also see 13.2.10 below:** | **—** | **—** |
| | | No moving part | N/A |
| **13.2.9** | **Interruption and short circuiting of motor capacitors – Motor capacitors short & open circuited [1] – Also see 13.10** | **—** | **—** |
| | | No such motor | N/A |
| | | No such motor | N/A |
| **13.2.10** | **Additional test criteria for motor operated ME EQUIPMENT in 13.2.8 &13.2.9:** | **—** | **—** |
| | **For every test in SINGLE FAULT CONDITION of 13.2.8 and 13.2.9, motor-operated EQUIPMENT stared from COLD CONDITION at RATED voltage or at the upper limit of RATED voltage range for specified time:** | No motor | N/A |
| | **Temperatures of windings determined at the end of specified test periods or at the instant of operation of fuses, THERMAL CUT-OUTS, motor protective devices** | No motor | N/A |
| | **Temperatures measured as specified in 11.1.3 d)** | No motor | N/A |
| | **Temperatures did not exceed limits of Table 26** | No motor | N/A |
| **13.2.11** | **Failures of components in ME EQUIPMENT used in conjunction with OXYGEN RICH ENVIRONMENTS:** | **—** | **—** |
| | | Not used in conjunction with OXYGEN RICH ENVIRONMENTS: | N/A |
| **13.2.12** | **Failure of parts that might result in a MECHANICAL HAZARD (See 9 & 15.3):** | **—** | **—** |

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

| Clause No. | Description of SINGLE FAULT CONDITION | Results observed | HAZARDOUS SITUATION (Yes/No) |
|---|---|---|---|
| | See clause 9 and clause 15.3 | To be checked on end product | N/A |
| **Supplementary information:**<br>[1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10. | | | |

| | | |
|---|---|---|
| **13.2.6** | **RM RESULTS TABLE: Leakage of liquid** | **N/A** |

| | | |
|---|---|---|
| **14.1** | **RM RESULTS TABLE: Programmable electrical medical systems - General** | **N/A** |

| | | |
|---|---|---|
| **14.6.1** | **RM RESULTS TABLE: Identification of known and foreseeable hazards** | **N/A** |

| | | |
|---|---|---|
| **14.6.2** | **RM RESULTS TABLE: Risk control** | **N/A** |

| | | |
|---|---|---|
| **14.7** | **RM RESULTS TABLE: Requirement specification** | **N/A** |

| | | |
|---|---|---|
| **14.8** | **RM RESULTS TABLE: Architecture** | **N/A** |

| | | |
|---|---|---|
| **14.10** | **RM RESULTS TABLE: Verification** | **N/A** |

| | | |
|---|---|---|
| **14.11** | **RM RESULTS TABLE: PEMS validation** | **N/A** |

| | | |
|---|---|---|
| **14.13** | **RM RESULTS TABLE: Connection of PEMS by NETWORK/DATA COUPLING to other equipment** | **N/A** |

| **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 |
| **15.3.3** | **Impact Test** | **Steel ball (50 mm in dia., 500 g ± 25 g) falling from a 1.3 m** | No damage |
| **15.3.4.1** | **Drop Test (hand-held)** | **Free fall height (m) = 1** | No damage |
| **15.3.4.2** | **Drop Test (portable)** | **Drop height (cm) =** | N/A |
| **15.3.5** | **Rough handling test** | **Travel speed (m/s) =** | N/A |
| **15.3.6** | **Mould Stress Relief** | **7 h in oven at temperature (°C) = 70** | No damage |

| 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).**

**[2] Although ME equipment installation and use type are not specified, mechanical strength tests including push test, 1 m height drop test and mould stress relief test are performed considering the usage for adapter model.**

| | | |
|---|---|---|
| **15.4.1** | **RM RESULTS TABLE: Construction of connectors** | **N/A** |
| **15.4.2.1 a** | **RM RESULTS TABLE: THERMAL CUT-OUTS and OVER-CURRENT RELEASES** | **N/A** |
| **15.4.2.1 c** | **RM RESULTS TABLE: Independent non-SELF-RESETTING THERMAL CUT-OUT** | **N/A** |
| **15.4.2.1 d** | **RM RESULTS TABLE: Loss of function of ME EQUIPMENT** | **N/A** |
| **15.4.2.1 h** | **RM RESULTS TABLE: ME EQUIPMENT with tubular heating elements** | **N/A** |
| **15.4.3.1** | **RM RESULTS TABLE: Housing** | **N/A** |
| **15.4.3.2** | **RM RESULTS TABLE: Connection** | **N/A** |
| **15.4.3.3** | **RM RESULTS TABLE: Protection against overcharging** | **N/A** |
| **15.4.4** | **RM RESULTS TABLE: Indicators** | **N/A** |
| **15.4.5** | **RM RESULTS TABLE: Pre-set controls** | **N/A** |
| **15.4.6** | **TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests** | **N/A** |

| | | |
|---|---|---|
| **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]:** | 264Vac | **—** |
| **RATED input frequency (Hz):** | 60Hz | **—** |

| 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) |
|---|---|---|---|---|---|---|---|
| TF001 | E | Fuse 2.0A(S.C. current 0.01A) | No | 5min[2] | 165[3] | 32.1 | 25 |
| TF002 | E | Fuse 2.0A(S.C. current 0.01A) | No | 5min[2] | 165[3] | 31.1 | 25 |

| IEC 60601-1 | | | | | | | |
|---|---|---|---|---|---|---|---|
| Clause | Requirement + Test | | | Result - Remark | | | Verdict |
| TF003 | E | Fuse 2.0A(S.C. current 0.01A) | No | 5min[2] | 165[3] | 30.2 | 25 |
| TF004 | E | Fuse 2.0A(S.C. current 0.01A) | No | 5min[2] | 165[3] | 32.2 | 25 |

**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.

[2] SMPS current limiting circuits operated immediately.

[3] Thermocouples are used, so the limit is to be reduced by10 °C.

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

| 15.5.1.3 | TABLE: transformer overload test – conducted only when protective device under short-circuit test operated | P |
|---|---|---|

| | |
|---|---|
| **Primary voltage, most adverse value between 90 % to 110 % of RATED voltage (V)[1]:** | 264V |
| **RATED input frequency (Hz):** | 60Hz |
| **Test current just below minimum current that would activate protective device & achieve thermal stability under method a) (A):** | See below |
| **Test current based on Table 32 when protective device that operated under method a) is external to transformer, and it was shunted (A):** | Not 60127-1 fuse |

| 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) |
|---|---|---|---|---|---|
| TF001 | E | Fuse 2.0A (OL current 0.453A) | 165[2] | 78.6 | 25 |
| TF002 | E | Fuse 2.0A (OL current 0.433A) | 165[2] | 76.8 | 25 |
| TF003 | E | Fuse 2.0A (OL current 0.443A) | 165[2] | 77.2 | 25 |
| TF004 | E | Fuse 2.0A (OL current 0.438A) | 165[2] | 76.1 | 25 |

**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.

[2] Thermocouples are used, so the limit is to be reduced by 10 ° C.

| 15.5.2 | TABLE: Transformer dielectric strength after humidity preconditioning of 5.7 | P |
|---|---|---|

| Transformer Model/Type/ Part No | Test voltage applied between | Test voltage, (V) | Test frequency (Hz) | Breakdown Yes/No | Deterioration Yes/No |
|---|---|---|---|---|---|
| All models | Primary & secondary windings | 4000 | 50 | No | No |
| All models | Secondary winding & core | 4000 | 50 | No | No |
| All models | 1 of 2 layers insulation tape | 4000 | 50 | No | No |
| All models | Primary winding | 1200 | 300 | No | No |

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

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

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

| | | |
|---|---|---|
| **16.6.1** | **TABLE: LEAKAGE CURRENTS in ME SYSTEM _ TOUCH CURRENT MEASUREMENTS** | **N/A** |

| | | |
|---|---|---|
| **16.9.1** | **RM RESULTS TABLE: Connection terminals and connectors** | **N/A** |

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

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

## ATTACHMENT 1: Photo of EUT

**Photo 1: External view of EUT without plug portion attached**



**Photo 2: External view of EUT**



**Photo 3: Component side view of PCB (Mains transformer shall be mounted as shown in the following figures)**

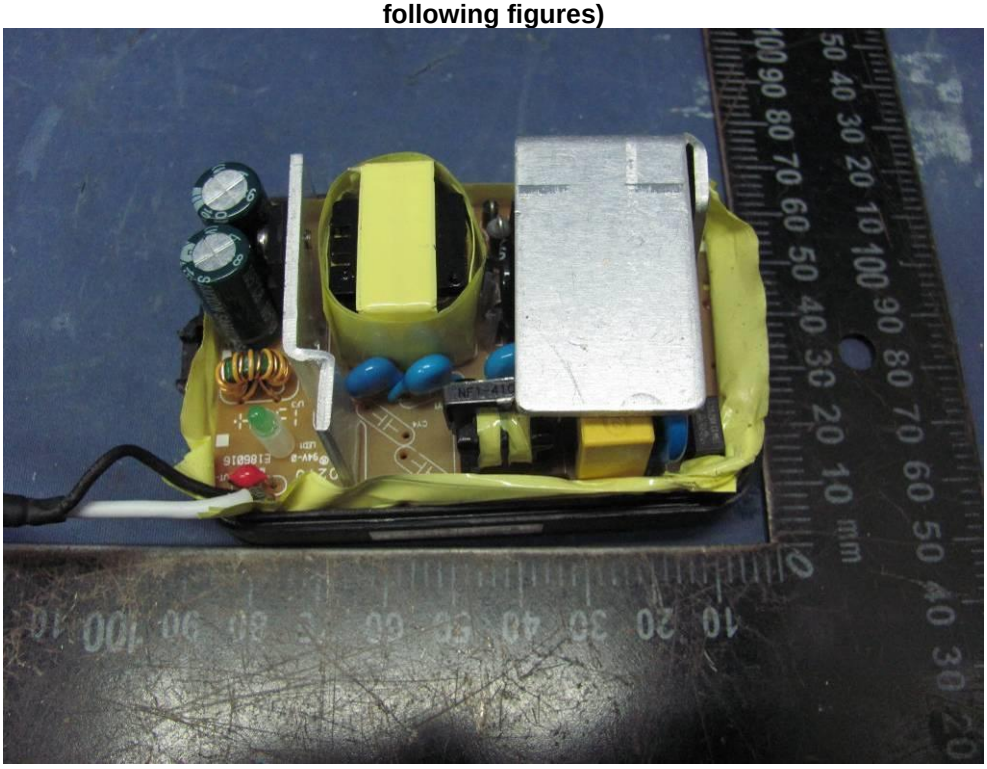


**Photo 4: Secondary wire installation view of mains transformer (Jump lead wire)**

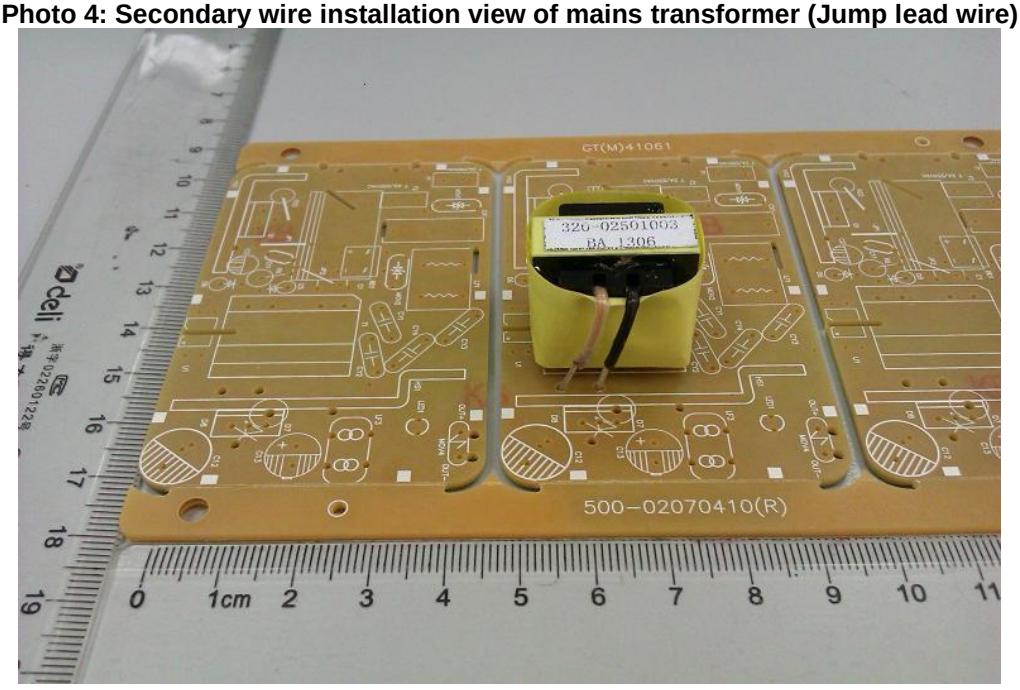


**Photo 5: Installation view of mains transformer (without secondary pin-outs on the bobbin)**

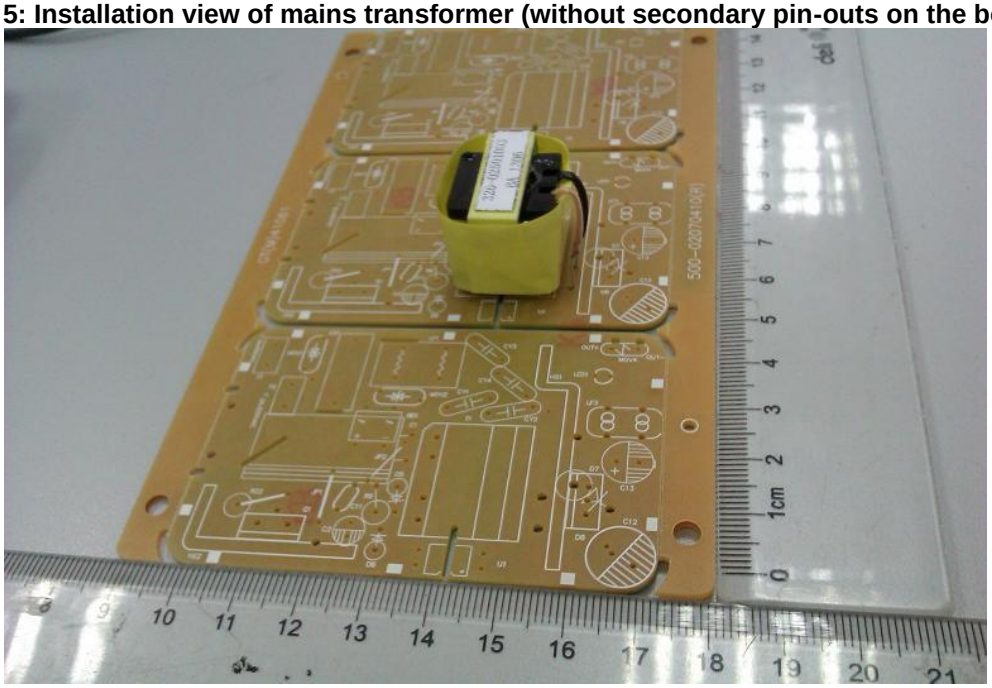


**Photo 6: Soldering side view of PCB**

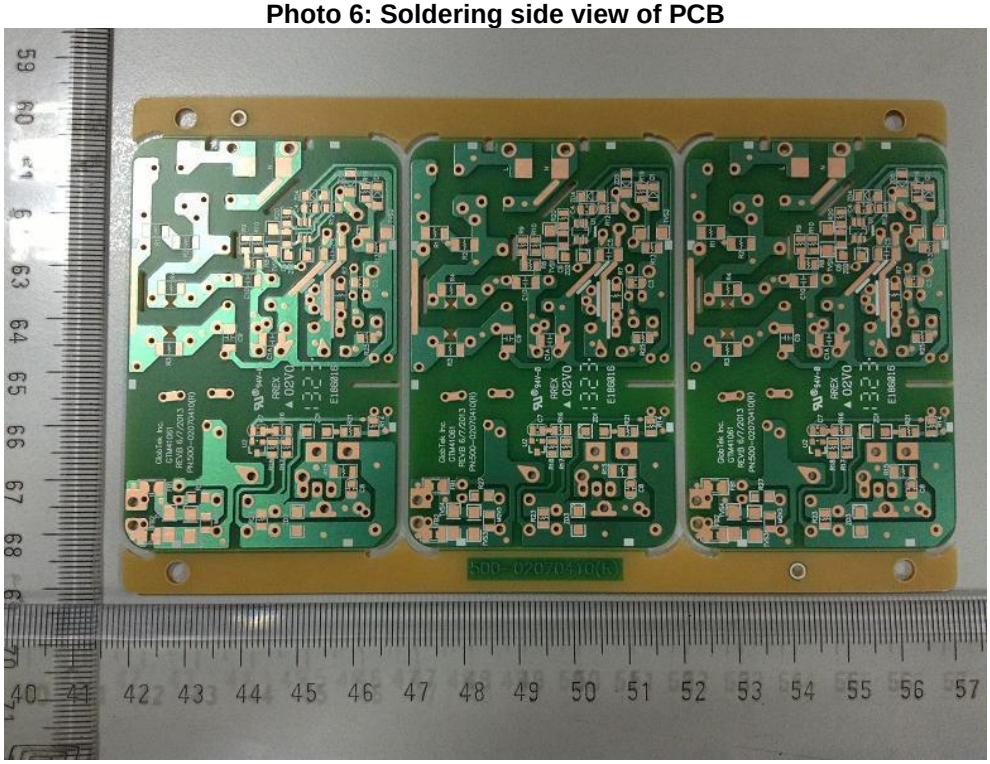


**Photo 7: External view of mains transformer**

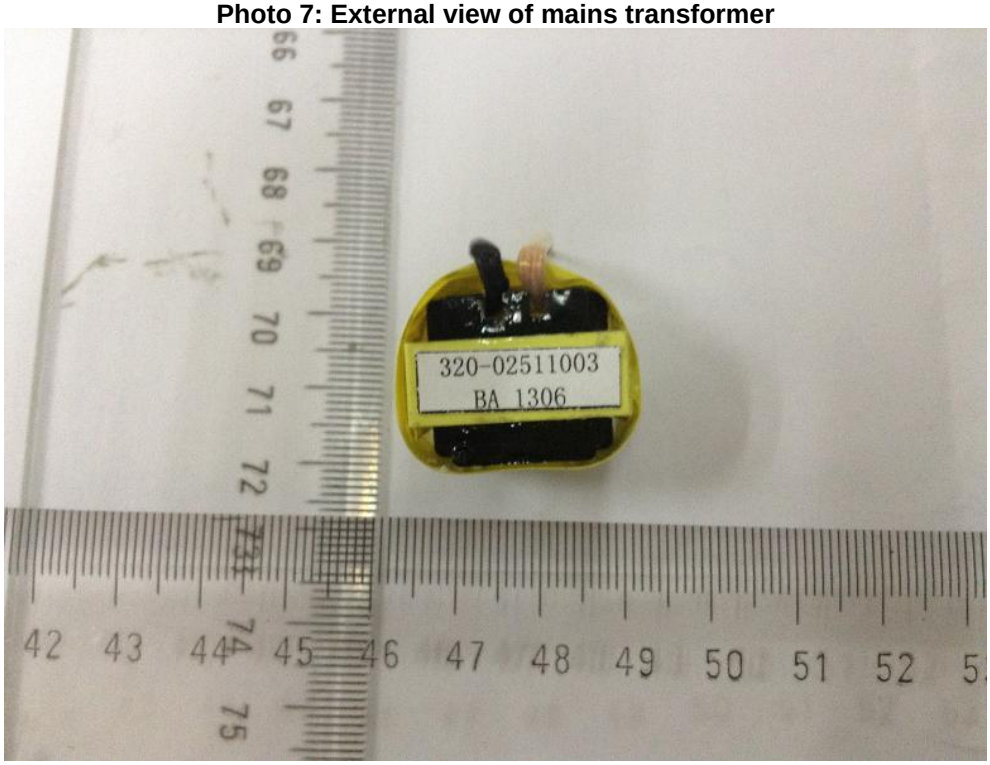



**Photo 8: External view of mains transformer**

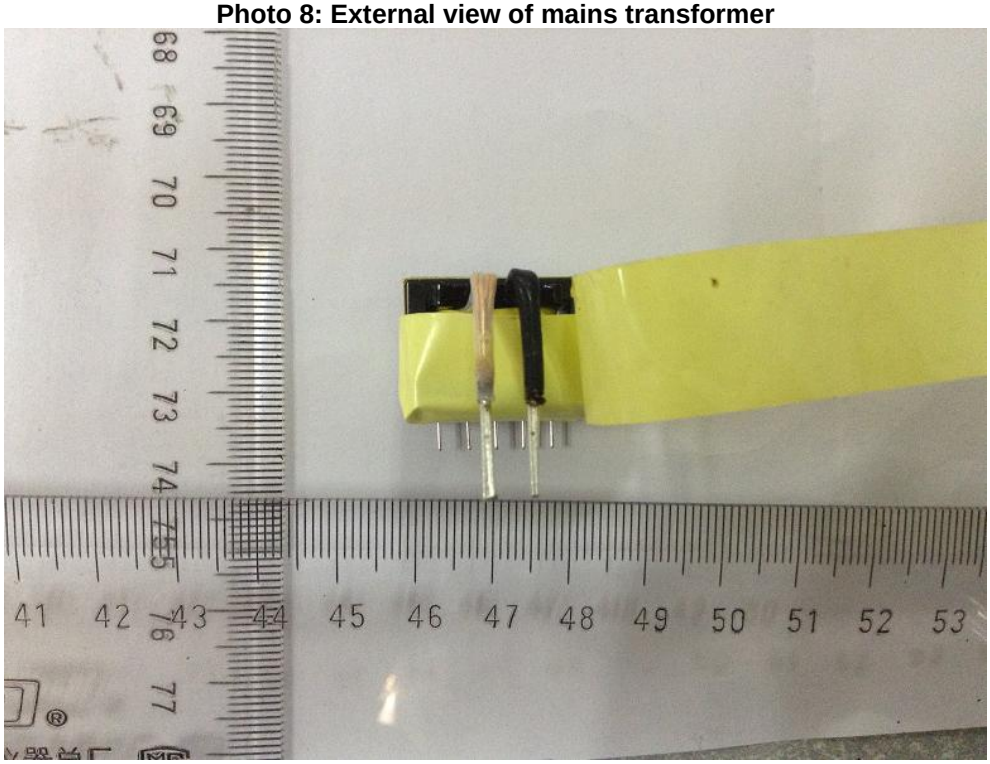


**Photo 9: External view of mains transformer**

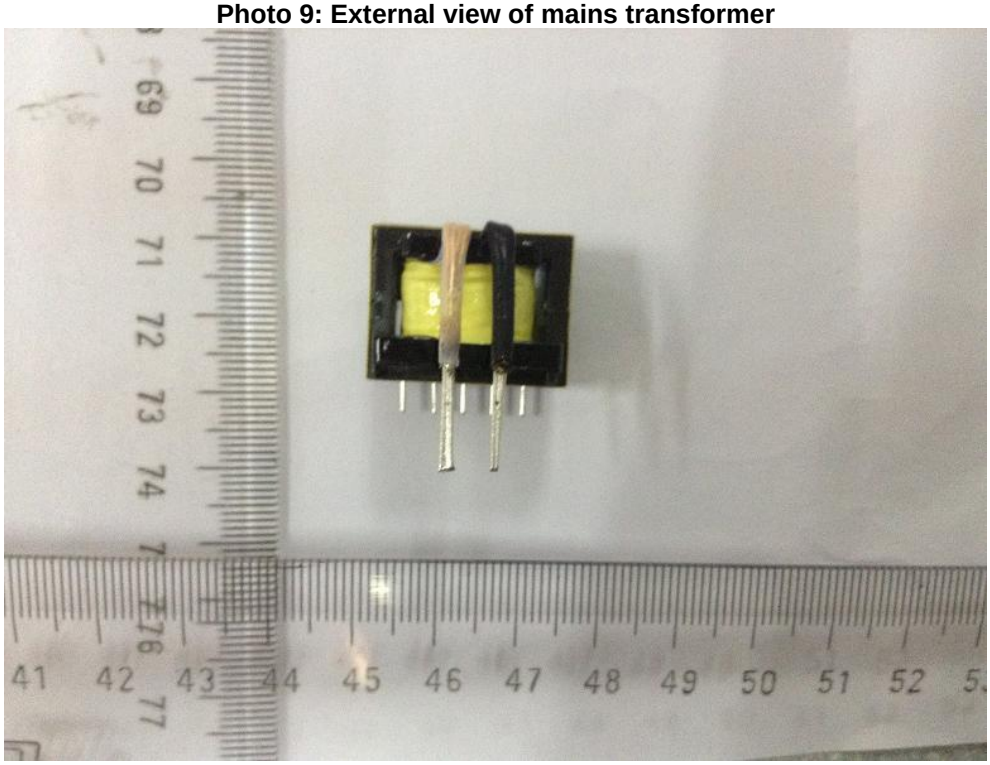


**Photo 10: External view of mains transformer**

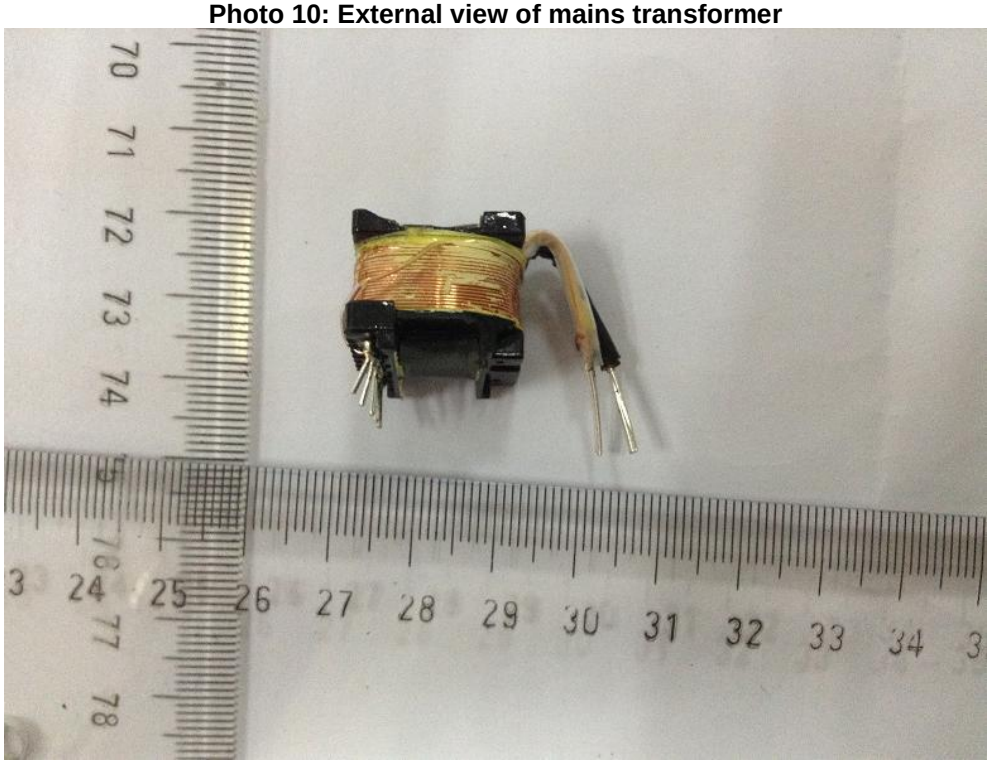
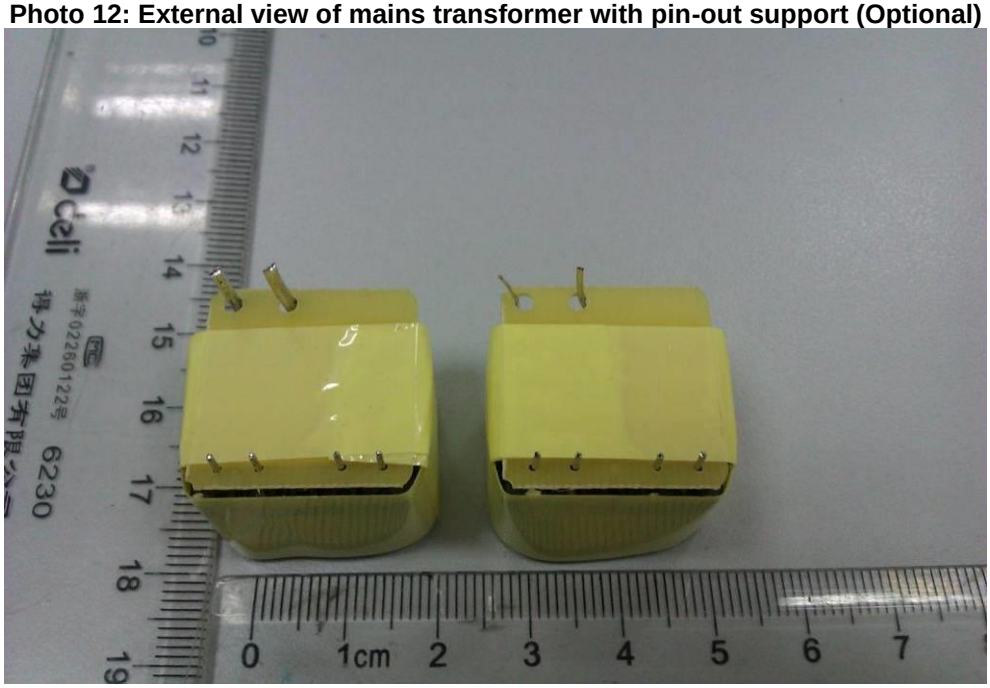


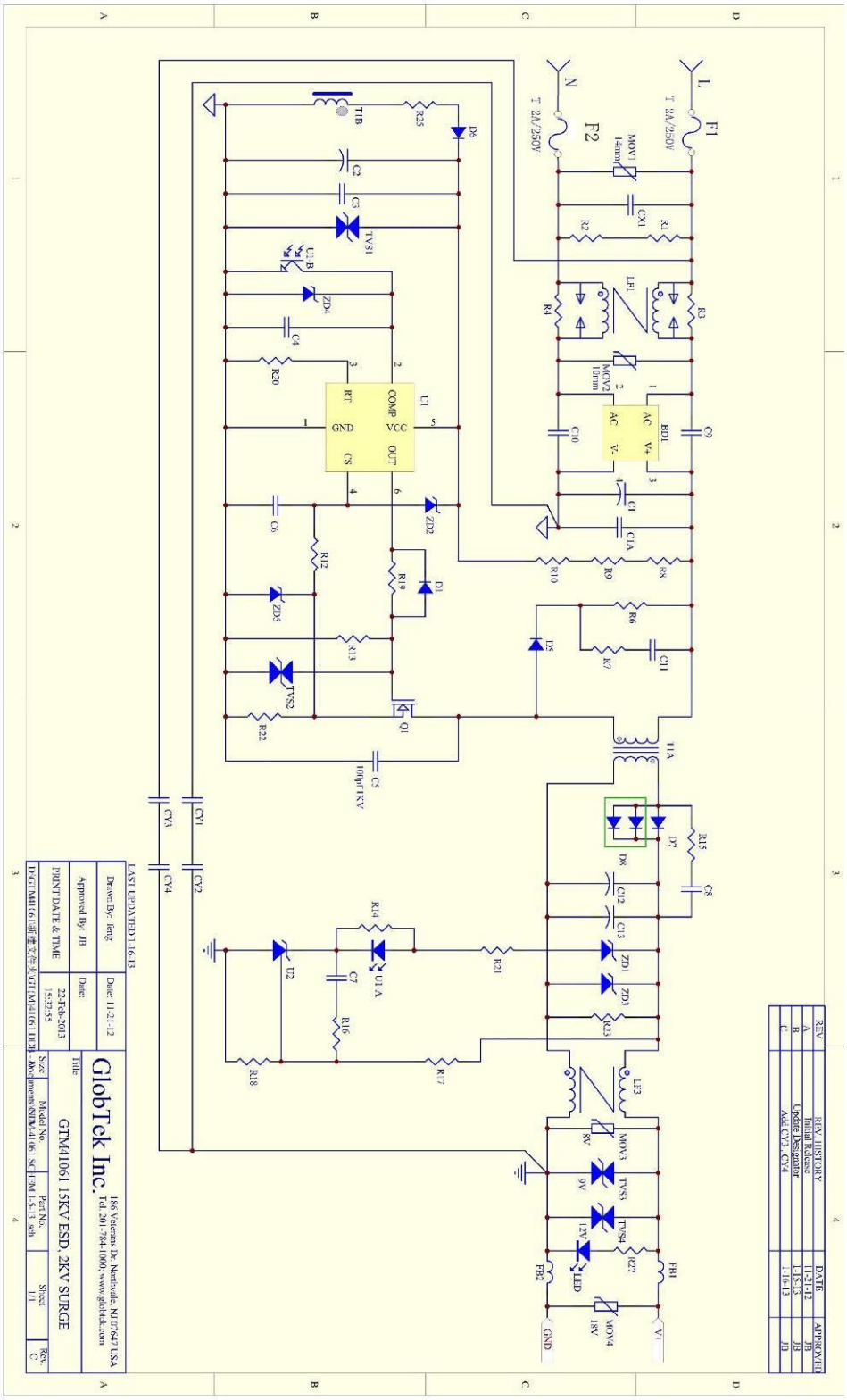
**Photo 11: External view of mains transformer with pin-out support (Optional)**

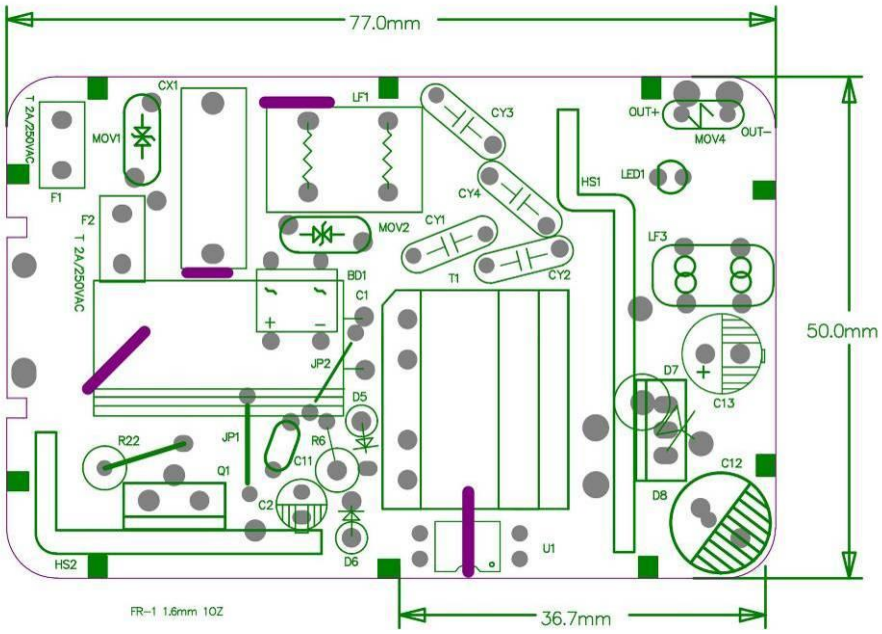


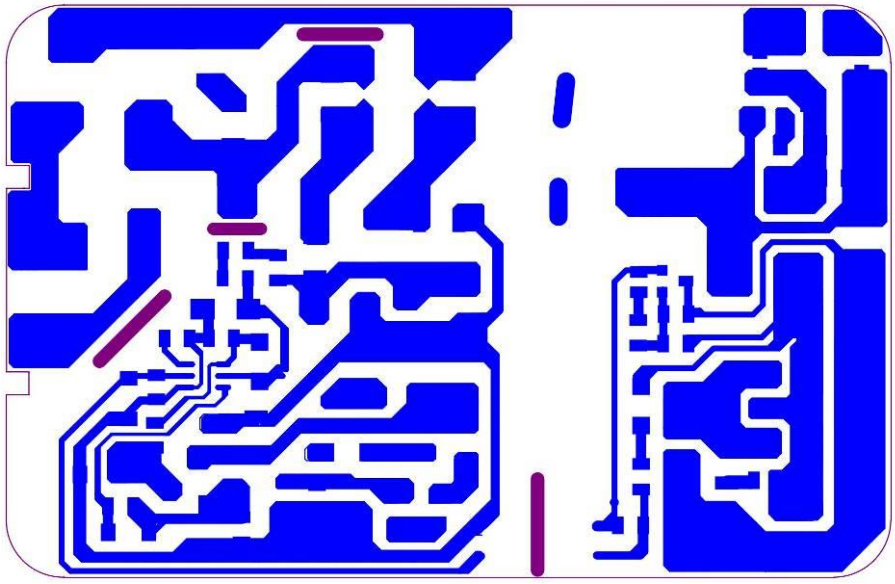

**Photo 12: External view of mains transformer with pin-out support (Optional)**



## ATTACHMENT 2: Circuit Diagram / Layout




77.0mm
50.0mm
36.7mm
CX1
LF1
CY3
OUT+
OUT-
MOV4
MOV1
F1
T 2A/250VAC
LED1
HS1
CY4
F2
MOV2
CY1
LF3
T1
CY2
BD1
C1
JP2
D5
D7
C13
R22
JP1
R6
C11
Q1
C12
C2
D8
U1
HS2
D6
FR-1 1.6mm 1OZ



| IEC60601_ATTACHMENT 3 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

# ATTACHMENT TO TEST REPORT
# IEC 60601-1:2005 + AMD 1:2012
# US NATIONAL DIFFERENCES

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

**Differences according to** ..... : National standard AAMI/IEC 60601-1:2005 + AMD 1:2012

**Attachment Form No**. ..... : US_ND_IEC60601_1P

**Attachment Originator.....** : UL(US)

**Master Attachment**..... : 2019-09-02

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| | | | |
|---|---|---|---|
| | **National Differences** | | P |
| 4.8 | Components of ME EQUIPMENT | | P |
| | b) where there is no relevant IEC/ISO standard, the relevant ANSI standard applied; if no relevant ANSI standard exists, the requirements of this standard were applied.<br>(*Replacement of clause 4.8 b*) | | P |
| 4.10.2 | SUPPLY MAINS FOR ME EQUIPMENT AND ME SYSTEMS | | P |
| | *(Replacement to reflect agreement with the National Electrical Code (NEC):*<br>The reference to "500 V" replaced with "600 V" in the second and third dashes. | | P |
| | *(Addition to reflect agreement with the NEC)*<br>In the text of the second-to-last dash of this sub-clause, "and the NEC" added after reference to "IEC 60364-4-41" | | N/A |
| **6.0** | **Classification of ME EQUIPMENT and ME SYSTEMS** | | N/A |
| 6.6 | Mode of operation | | N/A |
| | *(Addition to reflect agreement with NFPA 70)*<br>X-Ray systems are classified as long time operation (> 5 min) or momentary operation (< 5 sec). | Not X-ray system | N/A |
| **7.0** | **ME EQUIPMENT identification, marking and documents** | | N/A |
| 7.2.11 | Mode of operation | | N/A |
| | *(Addition to reflect agreement with NFPA 70)*<br>X-Ray systems are marked as long time operation or momentary operation. | Not X-ray system | N/A |

| IEC60601_ATTACHMENT 3 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|---|---|---|---|
| 7.2.22 | (*Addition of new item*)<br>Colours of medical gas cylinders | | N/A |
| | To reflect agreement with NFPA 99: Cylinders containing medical gases and their connection points are coloured in accordance with the requirements of NFPA 99. | No medical gas | N/A |
| **8.0** | **Protection against electrical hazards from ME EQUIPMENT** | | P |
| 8.2 | Requirements related to power sources | | N/A |
| | *(Addition to reflect agreement with the NEC)*<br>All FIXED ME EQUIPMENT and PERMANENTLY INSTALLED ME EQUIPMENT are CLASS I ME EQUIPMENT. | Direct plug-in | N/A |
| 8.6.1 | Application of requirements | | N/A |
| | *(Addition to reflect agreement with NFPA 99)*<br>The enclosure of X-ray ME EQUIPMENT operating over 600 Vac, 850 Vdc MAINS VOLTAGE, or containing voltages up to 50 V peak and enclosed in protectively earthed enclosure as well as connections to X-ray tubes and other high voltage components that include high voltage shielded cables are PROTECTIVELY EARTHED. | Not X-ray system | N/A |
| | *(Addition to reflect agreement with NFPA 99)*<br>Non-current carrying conductive parts of X-Ray ME EQUIPMENT likely to become energized are PROTECTIVELY EARTHED | Not X-ray system | N/A |
| 8.7.3 | Allowable values | | P |
| | *(Deletion to reflect agreement with NFPA 99 which does not allow for allowance greater than the stated values)*<br>Delete the second sentence and note to sub-clause 8.7.3 d) so that it reads:<br>d) The allowable values of the EARTH LEAKAGE CURRENT are 5 mA in NORMAL CONDITION and 10 mA in SINGLE FAULT CONDITION | See table 8.7. | P |
| 8.11 | MAINS PARTS, components and layout | | N/A |
| | *(Addition to reflect agreement with the NEC*)<br>Permanently connected ME EQUIPMENT has provision for the connection of one of the wiring systems that is in accordance with the NEC. | Not permanently connected. | N/A |

| IEC60601_ATTACHMENT 3 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Exception:<br>Fixed and stationary X-ray ME EQUIPMENT supplied from a branch circuit rated at 30 A or less, and ME EQUIPMENT that is not strictly portable but obviously is intended to be stationary, may be acceptable if provided with a length of attached hard service flexible cord - such as Type S, or the equivalent, for supply connection. | No such cord is provided. | N/A |
| | The installation of connecting cords between EQUIPMENT parts meets the requirements of the NEC, as applicable. Cable used as external interconnection between units are as follows: | No such cable. | N/A |
| | 1) If exposed to abuse, the cables are Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable | No such cable. | N/A |
| | 2) If not exposed to abuse, the cables are as indicated in item 1) above or are:<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<br>wiring material, or<br>iii) 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. | No such cable. | N/A |
| | Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of paediatric wards, rooms, or areas are listed tamper resistant or employ a listed tamper resistant cover in accordance with the NEC. | No such cable. | N/A |
| | b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked. | No such cable. | N/A |
| 8.11.3.2 | *(Addition to reflect agreement with the NEC)*<br>The flexible cord is of a type that is acceptable for the particular application. It is acceptable for use at a voltage not less than the rated voltage of the appliance and has an ampacity, as given in the NEC, not less than the current rating of the appliance ..... : | No such cord. | N/A |
| 8.11.3.3 | Cross-sectional area of POWER SUPPLY CORDS | | N/A |

| IEC60601_ATTACHMENT 3 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|---|---|---|---|
| | *(Addition to reflect agreement with NFPA 99)*<br>For X-Ray ME EQUIPMENT with an attachment plug, the current rating on a hospital grade plug should be 2X the maximum input current of the equipment. | Not X-ray equipment. | N/A |
| | 1) If exposed to abuse, the cables are Type SJT, SJTO, SJO, ST, SO, STO, or equivalent flexible cord or similar multiple-conductor appliance-wiring material such as computer cable. | | N/A |
| | 2) If not exposed to abuse, the cables are as indicated in item 1) above or are:<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, or<br>iii) 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. | | N/A |
| | Receptacles provided as part of ME EQUIPMENT or ME SYSTEMS for use in the patient care areas of paediatric wards, rooms, or areas are listed tamper resistant or employ a listed tamper resistant cover in accordance with the NEC. | | N/A |
| | b) For ME EQUIPMENT provided with NEMA configuration non-locking plug types 120 V/15 A, 125 V/20 A, 250 V/15 A, 250 V/20 A “Hospital Grade” mains plug is provided and the POWER SUPPLY CORD is marked. | | N/A |
| | | | |

| IEC60601_ATTACHMENT 4 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

# ATTACHMENT TO TEST REPORT
# IEC 60601-1:2005, COR1:2006, COR2:2007, AMD:1:2012.
# CANADIAN NATIONAL DIFFERENCES

**Medical electrical equipment — Part 1: General requirements for basic safety and essential performance**

| | |
|---|---|
| **Differences according to**.....: | CAN/CSA-C22.2 No. 60601-1:14 |
| **Attachment Form No**.....: | CA_ND_IEC60601_1P |
| **Attachment Originator .....**: | CSA Group |
| **Master Attachment**.....: | 2019-06-18 |

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Note *: IEC CANADIAN NATIONAL DIFFERENCES in Canada are called CANADIAN DEVIATIONS.

| | **National Differences** | | |
|---|---|---|---|
| **1** | **Scope, object and related standards** | | **P** |
| 1.1 | Scope | | P |
| | *[Replace the first paragraph with the following]*<br><br>This Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT and MEDICAL ELECTRICAL SYSTEMS designed to be used in accordance with CSA C22.1 (Canadian Electrical Code, Part I) and CSA Z32. | | P |
| | *[Add the following note]*<br><br>Note 1A: In the IEC 60601 Standards series adopted for use in Canada, the Canadian standards may modify, replace, or delete requirements contained in the IEC standard as appropriate to the ME EQUIPMENT and ME SYSTEMS under evaluation, and they may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements. | | — |
| 1.3 | Collateral standards | | P |
| | *[Replace this clause with the following]*<br><br>Applicable Canadian 60601 collateral standards become normative at the date of their publication and apply together with this Standard. | | P |
| 1.4 | Particular standards | | P |
| | *[Replace this clause with the following]*<br><br>Applicable Canadian 60601/80601 particular standards may modify, replace, or delete requirements contained in this Standard. The requirement of a Canadian 60601/80601 particular safety standard takes priority over this Standard. | | P |

| | | | |
|---|---|---|---|
| **2** | **Normative references** | | **P** |
| | *[Add the following]*<br><br>Where reference is made to CSA Group Standards, such reference are considered to refer | | P |

| IEC60601_ATTACHMENT 4 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | to the latest edition and all amendments published to that edition. This Standard refers to the following Standards, and the years shown indicate the latest editions available at the time of printing:<br><br>**CSA Group**<br>B51-09<br>Boiler, pressure vessel, and pressure piping code<br>C22.1-12<br>Canadian Electrical Code, Part I<br>CAN/CSA-C22.2 No. 0-10<br>General requirements — Canadian Electrical Code, Part II<br>C22.2 No. 21-95 (R2009)<br>Cord sets and power supply cords<br>C22.2 No. 42-10<br>General use receptacles, attachment plugs, and similar wiring devices<br>C22.2 No. 49-10<br>Flexible cords and cables<br>CAN/CSA-E61558-2-1-03 (R2012)<br>Safety of power transformers, power supply units and similar — Part 2: Particular requirements for separating transformers for general use<br>Z32-09<br>Electrical safety and essential electrical systems in health care facilities<br>CAN/CSA-Z305.8-03 (R2013)<br>Medical supply units<br>Z305.12-06 (R2012)<br>Safe storage, handling, and use of portable oxygen systems in residential buildings and health care facilities<br>Z305.13-09<br>Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings<br>CAN/CSA-Z5359-10<br>Low-pressure hose assemblies for use with medical gases<br>CAN/CSA-Z9170-1-11<br>Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases, vacuum, and anaesthetic gas scavenging systems<br>CAN/CSA-Z10524-1:12<br>Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices<br>CAN/CSA-Z15002:12<br>Flow-metering devices for connection to terminal units of medical gas pipeline systems<br>**ASME (American Society of Mechanical Engineers)**<br>PTC 25-2008<br>Pressure Relief Devices<br>**CGA (Compressed Gas Association)** | | |

| IEC60601_ATTACHMENT 4 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | V-1-2013<br>Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections<br>V-5-2008 (reaffirmed 2013)<br>Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)<br>**ISO (International Organization for Standardization)**<br>32:1977<br>Gas cylinders for medical use — Marking for identification of content<br>407:2004<br>Small medical gas cylinders — Pin-index yoke-type valve connections<br>9170-2:2008<br>Terminal units for medical gas pipeline systems — Part 2: Terminal units for anaesthetic gas scavenging systems | | |

| | | | |
|---|---|---|---|
| **3** | **Terminology and definitions** | | **N/A** |
| 3.41 | **HIGH VOLTAGE** | | N/A |
| | *Replace this clause with the following]*<br><br>voltage above 750 V, as defined in the Canadian Electrical Code, Part I | Noted, but no such HV in EUT | N/A |

| | | | |
|---|---|---|---|
| **4.** | **General requirements** | | **P** |
| | [Add the following clause] | | P |
| 4.1A | General requirements applicable to ME EQUIPMENT and ME SYSTEMS are provided in CAN/CSA-C22.2 No. 0. | | |
| 4.8 | Components of ME EQUIPMENT | | P |
| | *[Replace Items a) and b) and Note 2 with the following]*<br><br>a) the applicable safety requirements of a relevant CSA Group, IEC, or ISO Standard; or | UL approved. | P |
| | b) where there is no relevant CSA Group, IEC, or ISO Standard, the requirements of this Standard shall be applied. | | P |
| | Note 2:<br>If there are neither requirements in this Standard nor in a CSA Group, IEC, or ISO Standard, any other applicable source (e.g., standards for other types of devices, national standards) could be used to demonstrate compliance with the RISK MANAGEMENT PROCESS. | | — |
| 4.10.2 | SUPPLY MAINS for ME EQUIPMENT and ME SYSTEMS | | P |
| | *[Replace the first sentence with the following]*<br><br>ME EQUIPMENT intended to be connected to SUPPLY MAINS is in accordance with the Canadian Electrical Code, Part I, and the following RATED voltages are not be exceeded: | | P |

| IEC60601_ATTACHMENT 4 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

| | | | |
|---|---|---|---|
| **7.** | **ME EQUIPMENT identification, marking and documents** | | **P** |
| 7.7 | *[Replace Clauses 7.7.1 to 7.7.5 with the following]*<br><br>Colours of the insulation of conductors are in accordance with the Canadian Electrical Code, Part I. | | P |
| | A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION of any insulation on conductors is identified by either green or green and yellow colours at least at the termination of the conductors. | UL approved. | P |
| | Identification by green or green and yellow insulation are only used for | | P |
| | - PROTECTIVE EARTH CONDUCTORS (see 8.6.2); | | P |
| | - conductors as specified in 7.7.2;<br>Note: In other safety standards such as IEC 60950-1, internal connections between conductive parts and the main protective earth are called "protective bonding conductors". | | P |
| | - POTENTIAL EQUALIZATION CONDUCTORS (see 8.6.7); | | P |
| | - FUNCTIONAL EARTH CONDUCTORS (see 8.6.9). | | P |
| | Colours of neutral conductors and POWER SUPPLY CORD conductors are in accordance with the Canadian Electrical Code, Part I,<br>CSA C22.2 No. 21, and CSA C22.2 No. 49. | | P |

| | | | |
|---|---|---|---|
| **8** | **Protection against electrical HAZARDS from ME EQUIPMENT** | | **P** |
| 8.7.3 | *[Add the following paragraph]*<br><br>Allowable values are also in accordance with the Canadian Electrical Code, Part I. | | P |
| 8.11.3.2 | *[Replace this clause with the following]*<br>The following requirements for POWER SUPPLY CORDS apply: | No power cord | N/A |
| | a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENt is | No power cord | N/A |
| | i) if moulded-on type, a hospital-grade mains plug complying with CSA C22.2 No. 21; | No power cord | N/A |
| | ii) a hospital-grade disassembly attachment plug type complying with CSA C22.2 No. 42; or | No power cord | N/A |

| IEC60601_ATTACHMENT 4 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | iii) Class II equipment having fuses on the line side(s), and the neutral may use a non-polarized attachment plug or a polarized attachment plug. CSA configuration type 1-15P is required and meets 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 is 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: | No power cord | N/A |
| | 1) the centre contact of an Edison base lampholder; | No power cord | N/A |
| | 2) a single pole switch; | No power cord | N/A |
| | 3) an automatic control with a marked off position; | No power cord | N/A |
| | 4) a solitary fuse/fuse holder; or | No power cord | N/A |
| | 5) any other single pole overcurrent protective device. | No power cord | N/A |
| | b) A detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) is of a type | No power cord | N/A |
| | i) that 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; | No power cord | N/A |
| | ii) for which it can be shown that the impedance of the earth (ground) circuit contacts will not constitute a safety HAZARD to a PATIENT or OPERATOR; and | No power cord | N/A |
| | iii) that 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. | No power cord | N/A |
| | c) The detachable POWER SUPPLY CORD | No power cord | N/A |
| | i) comply with the applicable requirements of CSA C22.2 No. 21; and | No power cord | N/A |
| | ii) not be smaller than No. 18 AWG, and the mechanical serviceability is not less than: | No power cord | N/A |
| | 1) Type SJ or equivalent for ME EQUIPMENT that is mobile or exposed to abuse; and | No power cord | N/A |
| | 2) Type SV or equivalent for ME EQUIPMENT that is not exposed to abuse (or Type HPN if required because of temperature). | No power cord<br>No power cord | N/A<br>N/A |

| IEC60601_ATTACHMENT 4 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **Note:** See CSA C22.2 No. 49 for requirements for the cord types mentioned in Sub-item 2). | | |
| | d) Installation of POWER SUPPLY CORDS are meeting the requirements of the Canadian Electrical Code, Part I, as applicable | No power cord | N/A |
| 8.11.5 | Mains fuses and OVER-CURRENT RELEASES | | P |
| | *[Replace this clause with the following]*<br><br>Installation of overcurrent protective devices are in accordance with the Canadian Electrical Code, Part I. | See the table 8.10. | P |
| **9** | **Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS** | | N/A |
| 9.7.5 | *[Replace this clause with the following]*<br><br>Pressure vessels comply with the requirements of CSA B51, as applicable | No pressure vessel | N/A |
| 9.7.7 | *[Replace this clause with the following]*<br><br>A pressure-relief device comply, as applicable, with the requirements of ASME PTC 25 or equivalent Canadian requirements. | No pressure relief device | N/A |
| **15** | **Construction of ME EQUIPMENT.** | | P |
| 15.4.1 | *[Add the following item]*<br>bA) The point of connection of gas cylinders to ME EQUIPMENT is gas-specific and clearly identified so that errors are avoided when a replacement is made. Medical gas inlet connectors on ME EQUIPMENT is | No gas connection | N/A |
| | i)..... g<br>as-specific, yoke type, or nut and nipple type valve connections complying with CGA V-1 for pressures over 1380 kPa (200 psi); or | No gas connection | N/A |
| | ii)..... D<br>ISS type complying with CGA V-5 for pressures 1380 kPa (200 psi) or less and configured to permit the supply of medical gases from low-pressure connecting assemblies complying with CAN/CSA-Z5359. | No gas connection | N/A |
| | **Note:** Users of this Standard should consult the CSA Z305 series of Standards, CAN/CSA-Z9170-1, ISO 9170-2, CAN/CSA-Z10524, and CAN/CSA-Z15002 for further information regarding inlet connectors; ISO 407 for requirements addressing yoke type valve connections; and ISO 32 for colour coding. | | — |

| IEC60601_ATTACHMENT 4 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 15.4.8 | *[Add the following paragraph]*<br><br>Flexible cords and equipment wire of ME EQUIPMENT are in accordance with the Canadian Electrical Code, Part I | PE connection wire is approved by UL.<br>See the table 8.10. | P |

| **16** | **ME SYSTEMS** | | **N/A** |
|---|---|---|---|
| 16.1 | *[Replace the paragraph that starts with "*An ME SYSTEM shall provide:*" with the following]* | | N/A |
| | An ME SYSTEM provide | | — |
| | - within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this CSA Group Standard; and | Not medical system | N/A |
| | - outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA Group, IEC, or ISO safety Standards. | Not medical system | N/A |
| | *[Replace the third-last paragraph with the following]*<br><br>Non-ME EQUIPMENT, when used in an ME SYSTEM, complies with the CSA Group, IEC, or ISO safety Standards that are relevant to that equipment. | Not medical system | N/A |
| 16.9.2.1 | d) If the MULTIPLE SOCKET OUTLET is combined with a separating transformer, the following additional requirements apply: | | — |
| | - The separating transformer complies with this Standard. Alternatively, the separating transformer may comply with the requirements of CAN/CSA-E61558-2-1, except that the requirements of maximum RATED output power of 1 kVA and degree of protection IPX4 do not apply. | No MSO | N/A |
| | Note 1: As a separating transformer is not a MAINS SUPPLY TRANSFORMER, it does not require more than BASIC INSULATION. | No MSO | N/A |
| | Note 2: Limitation of output power is not explained in CAN/CSA-E61558-2-1 and the RATED output power is defined by the fuse in the installation and by the allowable power supply cable used. However, the characteristics of the separating transformer need to be carefully selected, taking into account the variations in the load current of the ME SYSTEM to ensure that the voltage supplied to the various items of the ME SYSTEM remains within the limits specified for the equipment. | No MSO | N/A |
| | - The separating transformer assembly is a CLASS I construction. | No MSO | N/A |
| | - The degree of protection against ingress of water as given in IEC 60529 is specified. | No MSO | N/A |

| IEC60601_ATTACHMENT 4 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | - The separating transformer assembly is marked according to the requirements of 7.2 and 7.3. | No MSO | N/A |
| | - The MULTIPLE SOCKET OUTLET is permanently connected to the separating transformer, or the socket-outlet of the separating transformer assembly is of a type that cannot accept MAINS PLUGS of any of the kinds identified in Canadian Electrical Code, Part I (see Figure I.1 and Figure I.2 of this Standard) | No MSO | N/A |
| | *[Add the following item]*<br><br>dA) The MULTIPLE SOCKET OUTLET complies with the requirements of CSA C22.2 No. 42, CSA C22.2 No. 49, and Item d) of this Standard, as applicable. | No MSO | N/A |

| IEC60601_ATTACHMENT 5 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | **National standard reference: SN EN 60601-1:2006** | | |
| | Ordinance on environmentally hazardous substances SR 814.081, Annex 1.7, Mercury - Annex 1.7 of SR 814.81 applies for mercury. Switches containing mercury such as thermostats, relays and level controllers are not allowed. Ordinance on chemical hazardous risk reduction SR 814.81, Annex 2.15 Batteries Annex 2.15 of SR 814.81 applies for batteries containing cadmium and mercury. Note: Ordinance relating to environmentally hazardous substances, SR 814.013 of 1986-06-09 is not longer in force and superseded by SR 814.81 of 2009-02-01 (ChemRRV). | No such component. | **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<br>Supply cords of portable electrical appliances having a rated current not exceeding 16 A shall be provided with a plug complying with IEC 60884-1(3.ed.) + am1, SEV 1011 and one of the following dimension sheets:<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<br>Note: 16 A plugs are not often used in Swiss domestic installation system. See TRF template regulatory requirements Switzerland on IECEE Website R.R. TRF templates. | No supply cords. | **N/A** |

| IEC60601_ATTACHMENT 6 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

# ATTACHMENT TO TEST REPORT
# IEC 60601-1
# Republic of Korea NATIONAL DIFFERENCES

(Medical electrical equipment - Part 1 : General requirements for basic safety and essential performance)

**Differences according to** ..... : Notification of MFDS No. 2020-12, Annex 1

**Attachment Form No**. ..... : KR_ND_ IEC60601_1P

**Attachment Originator.....** : KTR

**Master Attachment**..... : 2020-05-12

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| | **Special national conditions (if any)** | | — |
|---|---|---|---|
| Voltage | National supply voltages are 110, 220 V and 380 V. | | **P** |
| Frequency | Only appliances having supply frequency of 60 Hz or a frequency range including 60 Hz are accepted. | | **P** |
| Instruction | Instruction manuals and appliance markings related safety, including nameplate shall be in Korean or graphical symbols in accordance with IEC Publication 417. | Shall be checked in end product level. | **N/A** |
| Plug | Plugs for connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300) | | **P** |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

# ATTACHMENT TO TEST REPORT IEC 60601-1
# JAPAN NATIONAL DIFFERENCES

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

**Differences according to** ..... : National standard JIS T 0601-1:2017 (IEC 60601-1:2005 + A1:2012(MOD))

**Attachment Form No**. ..... : JP_ND_IEC60601_1P

**Attachment Originator**..... : TÜV Rheinland Japan Ltd.

**Master Attachment**..... : 2019-05-03

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| | **National Differences** | | P |
|---|---|---|---|
| 1.3 | In NOTE 3, add the following:<br>In Japan, to check the corresponding Japanese Industrial Standard(s) is required. | | — |
| 1.4 | At the end of NOTE, add the following:<br>In Japan, to check the corresponding Japanese Industrial Standard(s) is required. | | — |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | Replace the listed standards with the followings:<br>JIS B 7761-3, Hand-transmitted vibration - Part 3: General requirements for measurement and evaluation<br>NOTE: ISO 5349-1, Mechanical vibration - Measurement and evaluation of human exposure to hand-transmitted vibration - Part 1: General requirements (IDT)<br>JIS B 9718:2013, Safety of machinery - Safety distances to prevent hazard zone being reached by upper and lower limbs<br>NOTE: ISO 13857:2008, Safety of machinery -- Safety distances to prevent hazard zones being reached by upper and lower limbs (IDT)<br>JIS C 0445, Identification of equipment terminals and of terminations of certain designated conductors, including general rules for an alphanumeric system<br>NOTE: IEC 60445, Basic and safety principles for man-machine interface, marking and identification - Identification of equipment terminals, conductor terminations and conductors (IDT)<br>JIS C 0447, Man-machine interface (MMI) - Actuating principles<br>NOTE: IEC 60447, Basic and safety principles for man-machine interface, marking and identification - Actuating principles (IDT)<br>JIS C 0920:2003, Degrees of protection provided by enclosures (IP Code)<br>NOTE 1: IEC 60529:2001, Degrees of protection provided by enclosures (IP Code) (IDT)<br>NOTE 2: According to IEC60601-1:2005, IEC 60529:1989 and Amendment 1:1999 are listed as Normative references, however, the latest edition is edition 2.1 issued in 2001 and the corresponding Japanese Industrial standard was listed as normative reference.<br>JIS C 1509-1, Electroacoustitcs - Sound level meters - Part 1: Specifications<br>NOTE: IEC 61672-1, Electroacoustics - Sound level meters - Part 1: Specifications (IDT)<br>JIS C 1509-2, Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests<br>NOTE: IEC 61672-2, Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests (IDT) | | — |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | JIS C 2134, Method for the determination of the proof and the comparative tracking indices of solid insulating materials<br>NOTE: IEC 60112, Method for the determination of the proof and the comparative tracking indices of solid insulating materials (IDT)<br>JIS C 3301:2000, Rubber insulated flexible cords<br>NOTE: IEC 60245-4:1994, Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 4: Cords and flexible cables, Amendment 1:1997 (NEQ)<br>JIS C 3306:2000, Polyvinyl chloride insulated flexible cords<br>NOTE: IEC 60227-5:1997, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V - Part 5: Flexible cables (cords) (NEQ)<br>JIS C 4003, Electrical insulation - Thermal evaluation and designation<br>NOTE: IEC 60085, Electrical insulation - Thermal evaluation and designation (MOD)<br>JIS C 5101-14:2009, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification - Fixed capacitors for electromagnetic interference suppression and connection to the supply mains<br>NOTE: IEC 60384-14:2005, Fixed capacitors for use in electronic equipment - Part 14: Sectional specification: Fixed capacitors for electromagnetic interference suppression and connection to the supply mains (IDT)<br>JIS C 6065:2013, Audio, video and similar electronic apparatus - Safety requirements<br>NOTE: IEC 60065:2001, Audio, video and similar electronic apparatus - Safety requirements, Amendment 1:2005 and Amendment 2:2010 (MOD)<br>JIS C 6802:2011, Safety of laser products<br>NOTE: IEC 60825-1:2007, Safety of laser products - Part 1: Equipment classification and requirements (IDT)<br>JIS C 6950-1:2012, Information technology equipment - Safety - Part 1: General requirements<br>NOTE: IEC60950-1:2005, Information technology equipment - Safety - Part 1: General requirements (MOD)<br>JIS C 6965, Mechanical safety of cathode ray tubes<br>NOTE: IEC 61965, Mechanical safety of cathode ray tubes (IDT) | | — |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | JIS C 8282-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements<br>NOTE: IEC 60884-1, Plugs and socket-outlets for household and similar purposes - Part 1: General requirements (MOD)<br>JIS C 8303, Plugs and receptacles for domestic and similar general use<br>NOTE: No corresponding International standard exists. This standard has been listed as normative reference corresponding to IEC/TR 60083, Plugs and socket-outlets for domestic and similar general use standardized in member countries of IEC, which has been listed in IEC 60601-1:2005. Refer to JIS T 1021, too.<br>JIS C 60068-2-2:2010, Environmental testing - Part 2-2: Tests - Test B: Dry heat<br>NOTE: IEC 60068-2-2:2007, Environmental testing - Part 2-2: Tests - Tests B: Dry heat (IDT)<br>JIS C 60079-0, Explosive atmospheres - Part 0: Equipment - General requirements<br>NOTE: IEC 60079-0, Explosive atmospheres - Part 0: Equipment - General requirements (IDT)<br>JIS C 60079-2, Electrical apparatus for explosive gas atmospheres - Part 2: Pressurized enclosure "p"<br>NOTE: IEC 60079-2, Explosive atmospheres - Part 2: Equipment protection by pressurized enclosures “p” (IDT)<br>JIS C 60079-6, Electrical apparatus for explosive gas atmospheres - Part 6: Oil immersion "o"<br>NOTE: IEC 60079-6, Explosive atmospheres - Part 6: Equipment protection by oil immersion “o” (IDT)<br>JIS C 60364-4-41, Low-voltage electrical installations - Part 4-41: Protection for safety - Protection against electric shock<br>NOTE: IEC 60364-4-41, Low- voltage electrical installations - Part 4-41: Protection for safety - Protection against electric shock (IDT)<br>JIS C 60664-1:2009, Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests<br>NOTE: IEC 60664-1:2007, Insulation coordination for equipment within low-voltage systems - Part 1: Principles, requirements and tests (IDT) | | — |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | JIS C 60695-11-10, Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods<br>NOTE: IEC 60695-11-10, Fire hazard testing - Part 11-10: Test flames - 50 W horizontal and vertical flame test methods (IDT)<br>JIS T 0601-1-3, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment<br>NOTE: IEC60601-1-3, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment (IDT)<br>JIS T 0801-1:2010, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices<br>NOTE: ISO 11135-1:2007, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT)<br>JIS T 0806-1:2010, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices<br>NOTE: ISO 11137-1:2006, Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (IDT)<br>JIS T 0816-1:2010, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices<br>NOTE: ISO 17665-1:2006, Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (IDT)<br>JIS T 2304:2012, Medical device software - Software life cycle processes<br>IEC62304:2006, Medical device software - Software life cycle processes (IDT)<br>JIS T 14971:2012, Medical devices - Application of risk management to medical devices<br>NOTE: ISO 14971:2007, Medical devices - Application of risk management to medical devices (IDT) | | — |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | JIS T 60601-1-8, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems<br>NOTE: IEC60601-1-8, Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IDT)<br>JIS Z 8000 (all parts), Quantities and units<br>NOTE: ISO 80000-1, Quantities and units - Part 1: General<br>JIS Z 8736-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points<br>NOTE: ISO 9614-1, Acoustics - Determination of sound power levels of noise sources using sound intensity - Part 1: Measurement at discrete points (IDT)<br>JIS Z 9101:2005, Safety colours and safety signs - Design principles for safety signs in workplaces and public areas<br>NOTE: ISO 3864-1:2002, Graphical symbols - Safety colours and safety signs - Part 1: Design principles for safety signs in workplaces and public areas (IDT)<br>ISO 780, Packaging - Distribution packaging - Graphical symbols for handling and storage of packages<br>NOTE: JIS Z 0150 Packaging - Distribution packaging - Graphical symbols for handling and storage of packages (MOD)<br>ISO 1853, Conducting and dissipative rubbers, vulcanized or thermoplastic - Measurement of resistivity<br>NOTE: JIS K 6271-2 Rubber, vulcanized or thermoplastic - Determination of resistivity – Part 2: Parallel terminal electrode system (MOD)<br>ISO 2878, Rubber, vulcanized or thermoplastic - Antistatic and conductive products - Determination of electrical resistance<br>ISO 2882:1979, Rubber, vulcanized - Antistatic and conductive products for hospital use - Electrical resistance limits | | — |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | ISO 3746, Acoustics - Determination of sound power levels and sound energy levels of noise sources using sound pressure – Survey method using an enveloping measurement surface over a reflecting plane<br>ISO 7000-DB:2004, Graphical symbols for use on equipment - Index and synopsis<br>NOTE: “DB” indicated ISO-IEC jointed online database.<br>ISO 7010:2011, Graphical symbols - Safety colours and safety signs - Registered safety signs<br>ISO 10993 (all parts), Biological evaluation of medical devices<br>NOTE: JIS T 0993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (MOD). However, other Parts than Part 1 and Part 7 have still not been published as JIS.<br>ISO 15223-1:2012 , Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements<br>ISO 23529, Rubber -- General procedures for preparing and conditioning test pieces for physical test methods<br>NOTE: JIS K 6250, Rubber -- General procedures for preparing and conditioning test pieces for physical test methods (MOD)<br>IEC 60079-5, Explosive atmospheres — Part 5: Equipment protection by powder filling “q”<br>IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries<br>NOTE: JIS C 8513 Safety of primary lithium batteries (MOD)<br>IEC 60127-1, Miniature fuses - Part 1: Definitions for miniature fuses and general requirements for miniature fuse-links<br>NOTE: JIS C 6575-1 Miniature fuses - Part 1: Definitions of miniature fuses and general requirements for miniature fuse-links (MOD) | | — |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | IEC 60227-1:2007, Polyvinyl chloride insulated cables of rated voltages up to and including 450/750 V – Part 1: General requirements<br>NOTE: JIS C 3662-1:2009 Polyvinyl chloride insulated cables of rated voltages up to and including 450/750V - Part 1: General requirements (MOD)<br><br>IEC 60245-1:2003, Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 1: General requirements and Amendment 1:2007<br>NOTE: The corresponding JIS standard: None<br>JIS C 3663-1:2010 Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 1: General requirements (MOD) corresponds to IEC 60245-1:2008.<br><br>IEC 60252-1, AC motor capacitors - Part 1: General - Performance, testing and rating - Safety requirements - Guidance for installation and operation<br><br>IEC 60320-1, Appliance couplers for household and similar general purposes - Part 1: General requirements<br>NOTE: JIS C 8283-1 Appliance couplers for household and similar general purposes - Part 1: General requirements (MOD)<br><br>IEC 60335-1:2010, Household and similar electrical appliances - Safety - Part 1: General requirements<br>NOTE: The corresponding JIS standard: None<br>JIS C 9335-1:2003 Household and similar electrical appliances - Safety - Part 1 : General requirements (MOD) corresponds to IEC 60335-1:2001.<br><br>IEC 60417, Graphical symbols for use on equipment<br><br>IEC 60601-1-2:2001, Medical electrical equipment - Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests<br>NOTE 1: The current “JIS T 0601-1-2:2012 Medical electrical equipment - Part 1-2: General requirements for safety - Electromagnetic compatibility - Requirements and tests” corresponds to IEC 60601-1-2:2001 and Amendment 1:2004.<br>NOTE 2: Currently, IEC 60601-1-2 Ed 2.1:2004 or IEC 60601-1-2 Ed 3:2007 is used in other countries. | | — |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | IEC 60601-1-6, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability<br>NOTE: As the corresponding international standard, IEC 62336 is applicable.<br><br>IEC 60730-1:2010, Automatic electrical controls for household and similar use - Part 1: General requirements<br><br>NOTE: The corresponding JIS standard: None<br>JIS C 9730-1:2010 Automatic electrical controls for household and similar use - Part 1:General requirements (MOD) corresponds to IEC 60730-1:1999, Amendment 1: 2003 and Amendment 2:2007<br><br>IEC 60851-3:2009, Winding wires - Test methods - Part 3: Mechanical properties<br>NOTE: JIS C 3216-3:2011, Winding wires - Test methods - Part 3: Mechanical properties (MOD)<br><br>IEC 60851-5:2008, Winding wires - Test methods - Part 5: Electrical properties<br>NOTE: JIS C 3216-5:2011, Winding wires - Test methods - Part 5: Electrical properties (MOD)<br><br>IEC 60851-6:1996, Methods of test for winding wires - Part 6: Thermal properties and Amendment 1:1997<br><br>IEC 61058-1:2000, Switches for appliances - Part 1: General requirements, Amendment 1:2001 and Amendment 1:2007<br>NOTE: The corresponding JIS standard: None<br>JIS C 4526-1:2013 Switches for appliances - Part 1: General requirements (MOD) corresponds to IEC 61058-1:2008<br><br>IEC 61558-2-1, Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications<br>NOTE: JIS C 61558-2-1 Safety of power transformers, power supplies, reactors and similar products - Part 2-1: Particular requirements and tests for separating transformers and power supplies incorporating separating transformers for general applications (MOD) | | — |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | IEC 62133, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications<br>NOTE: JIS C 8712:2015 Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications (MOD) was created changing the technical contents of IEC 62133:2012.<br><br>IEC 62366:2014, Medical devices - Application of usability engineering to medical devices | | — |
| 3.9 | Add NOTE as follows:<br>NOTE 2 IEV stands for International Electrotechnical Vocabulary | | — |
| 3.50 | Replace NOTE 2 as follows:<br>NOTE 2 See also JIS C 8303 and IEC 60309-1 and JIS T 1021. | | — |
| 3.61 | Add NOTE as follows:<br>NOTE In this standard, MECHANICAL HAZARD is suitably understandable by replacing mechanical HAZARD with mechanical HAZARDOUS SITUATION, HARM or unacceptable RISK. | | — |
| 3.70 | Replace the existing text with:<br>condition in which all means provided for protection against HAZARDOUS SITUATIONS or HARM are intact | | — |
| 4.10.1 | In the existing text, replace “a separate power supply” with “a separate power supply (e.g. a power supply of other equipment)”. | | — |
| 7.3.3 | Replace the third paragraph with:<br>Where lithium batteries or fuel cells are incorporated and where incorrect replacement would result in an unacceptable RISK, a warning indicating that replacement by inadequately trained personnel could result in a HAZARDOUS SITUATION (such as excessive temperatures, fire or explosion) shall be given in addition to the identifying marking referring to information stated in the ACCOMPANYING DOCUMENTS. | No lithium batteries or fuel cells. | N/A |
| 7.3.4 | Add the following NOTE<br>NOTE Corresponding Japanese Industrial Standard for IEC 60127-1: JIS C 6575-1:2009 | | — |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 7.4.3 | Replace the existing first paragraph with the following:<br>Numeric indications of parameters on ME EQUIPMENT shall be expressed in SI units according to JIS Z 8000 (all parts) except the base quantities listed in Table 1 may be expressed in the indicated units, which are used in conjunction with the SI units system or as the approved combination.<br>Replace the title of Table 1 with the following:<br>Units which are used in conjunction with the SI units system or as the approved combination<br>Replace “a” of Table 1 with the following note:<br>Note: For consistency, in international standards only the symbol “l” is used for litre, although the symbol “L” is also given in JIS Z 8000 (all parts). | No numeric indications of parameters. | N/A |
| 7.7.4 | Under the existing text, add the following:<br>If polyvinyl chloride insulated flexible cord of JIS C 3306 or rubber insulated flexible cord of JIS C 3301 is used, the conductor may be coloured "white". | | N/A |
| 7.7.5 | Under the existing text, add the following:<br>If polyvinyl chloride insulated flexible cord of JIS C 3306 or rubber insulated flexible cord of JIS C 3301 is used, conductors may be of the colour specified in the these standards. | | N/A |
| 7.9.3.2 | Replace the fourth dash with:<br>- where replacement of a component could result in an unacceptable RISK, appropriate warnings that identify the nature of the HAZARDOUS SITUATION and, if the MANUFACTURER specifies the component as replaceable by SERVICE PERSONNEL, all information necessary to safely replace the component. | | N/A |
| 8.8.2 | For a), add the following NOTE:<br>NOTE – Generally, “distance through insulation” means the thickness of insulation. However, for example, if a transformer installed into a metal case is insulated by filler, the thickness is not always uniformly. Therefore, such expression was used. | | P |
| 8.8.3 | Between the third dash and the paragraph of “Initially, not more than --”, add the following new paragraph.<br>During the above-mentioned tests, the state of the power switch shall be kept closed. | | P |
| 8.9.1.2 | At the end of the title of this sub-clause, add “(Apply to MOOP)”. | | — |
| 8.9.1.3 | At the end of the title of this sub-clause, add “(Apply to MOOP)”. | | — |
| 8.9.1.4 | At the end of the title of this sub-clause, add “(Apply to MOOP)”. | | — |
| 8.9.1.5 | At the end of the title of this sub-clause, add “(Apply to MOOP and MOPP)”. | | — |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 8.9.1.6 | At the end of the title of this sub-clause, add "(Apply to MOOP and MOPP)". | | — |
| 8.9.1.7 | At the end of the title of this sub-clause, add "(Apply to MOOP)". | | — |
| 8.9.1.8 | At the end of the title of this sub-clause, add "(Apply to MOOP)". | | — |
| 8.9.1.9 | At the end of the title of this sub-clause, add "(Apply to MOOP)". | | — |
| 8.9.1.10 | At the end of the title of this sub-clause, add "(Apply to MOOP)". | | — |
| 8.9.1.11 | At the end of the title of this sub-clause, add "(Apply to MOOP)". | | — |
| 8.9.1.12 | At the end of the title of this sub-clause, add "(Apply to MOOP)". | | — |
| 8.9.1.13 | At the end of the title of this sub-clause, add "(Apply to MOOP)". | | — |
| 8.9.1.14 | At the end of the title of this sub-clause, add "(Apply to MOOP)". | | — |
| 8.11.3.2 | Add the following between the first paragraph and the second paragraph:<br>And, rubber insulated flexible cords of JIS C 3301, polyvinyl chloride insulated flexible cords of JIS C 3306 or cords of which the robustness is equal to or more than those are usable.<br>Add the following between the second paragraph and the last paragraph:<br>And, in the case of cords of JIS C 3306, shall not use;<br>for polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 60 °C, and;<br>for grade heat-resistant polyvinyl chloride insulated flexible cords, if the temperature of the above-mentioned external metal part exceeds 75 °C. | | N/A |
| 9.2.2.2 | In the bottom column of Table 20, replace the existing text with the following:<br>[a] The values in this table are taken from JIS B 9718:2013. | | — |
| 9.2.4 | In e), replace a further "MECHANICAL HAZARD" and the original "HAZARD" with a further "HAZARDOUS SITUATION" and the original "HAZARDOUS SITUATION", respectively. | | — |
| 9.3 | Replace the NOTE 2:<br>A sharp edge MECHANICAL HAZARD could cut wire insulation which could lead to an electrical HAZARDOUS SITUATION. This requirement is intended to cover all these HAZARDS. | | N/A |

| IEC60601_ATTACHMENT 7 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 9.8.3.3 | Figure 33:<br>Replace the fourth sentence of the existing NOTE with the following and change “NOTE” to “NOTE 1”:<br>The resiliency or spring factor of the foam (ILD or IFD ratings) has not been specified.<br>Add the following NOTE:<br>NOTE 2: NOTE 1 above stated that in the corresponding international standards, "when dropping the weight, the characteristics of the foam are probably not important, therefore The resiliency or spring factor of the foam (ILD or IFD ratings) is not specified." However, This expression is confusing, and it was modified. | | N/A |
| 10.1.1 | Add in NOTE 1 “Current irradiation dose unit is not R unit, but Gy unit (air kerma), which corresponds to 1 mR/h ≈ 10 μGy/h.”<br>Replace (0,1 mR/h) with (0.1 mR/h ≈ 1 μGy/h) in NOTE 2.” | | — |
| 10.5 | Replace “other than that produced by lasers and light emitting diodes” with “other than that produced by lasers” | | — |
| 10.6 | Replace “other than that produced by lasers and light emitting diodes” with “other than that produced by lasers” | | — |
| 10.7 | Replace “other than that produced by lasers and light emitting diodes” with “other than that produced by lasers” | | — |
| 11.1.1 | To the existing text of a in the Table 22, add the following:<br>(For example, the maximum temperature limit of a transformer with three insulating materials of Class A, Class B and Class E shall be the lowest limit 105 °C of Class A.) | | P |
| 13.2.10 | In Table 26, replace the existing NOTE with the following:<br>NOTE The temperature limits in this table were derived from Table B.1 of JIS C 6950-1:2012 (in the corresponding international standard, IEC 61010-1:2001 [22]). | | — |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 16.1 | Replace the last two paragraphs with the following:<br>Otherwise, non-ME EQUIPMENT shall be those which are in compliance with relevant JIS standards or the Technical Requirements of the Electrical Appliance and Material Safety Act or which ensure safety equivalent to the said standards/technical requirements.<br>Equipment in which protection against electric shock relies only on BASIC INSULATION shall not be used in an ME SYSTEM.<br>For the measures for ensuring safety, e.g. the case combined with a separating transformer with DOUBLE INSULATION or RAINFORCED INSULATION, equipment only with BASIC INSULATION may be used.<br>*Compliance is checked by inspection of appropriate documents or certificates.* | | N/A |
| 16.6.4.1 | In NOTE, replace “no possibility of any HAZARD” with “no possibility of any HAZARDOUS SITUATION”. | | — |
| 16.9.2.1 | In the text of c), replace “IEC 60884-1” with “IEC 60884-1 or JIS C 8282-1”. | | — |
| Annex I | In I.1.3, replace the first dash with the following:<br>- PATIENTS should only be connected to APPLIED PARTS of ME EQUIPMENT complying with this standard. Other equipment should comply with relevant IEC or ISO standards or comply with relevant JIS safety standards or the Technical Requirements of the Electrical Appliance and Material Safety Act, or ensure safety equivalent to the said standards/technical requirements.<br>Replace the existing NOTE 2 with the following:<br>NOTE 2 IEC 60601: MEDICAL ELECTRICAL EQUIPMENT in compliance with IEC 60601 (all parts) or JIS T 0601 (all parts).<br>Replace the existing NOTE 3 with the following:<br>NOTE 3 IEC xxxxx: Non-medical equipment in compliance with relevant IEC safety standards. Include non-medical equipment in compliance with relevant JIS safety standards or the Technical Requirements of the Electrical Appliance and Material Safety Act, or non-medical equipment ensuring safety equivalent to the said standards/technical requirements. | | N/A |
| Annex L | In the first paragraph, replace “wound components” with “wound components (e.g. transformers, motors, etc.)” | | — |