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# TEST REPORT
# IEC 60601-1
# Medical Electrical Equipment Part 1: General Requirements for basic safety and essential performance

| | |
|---|---|
| **Report Number..... :** | **2601B2316SHA-001** |
| **Date of issue ..... :** | **2026-04-22** |
| **Total number of pages ..... :** | **126** |
| **Name of Testing Laboratory preparing the Report ..... :** | **Intertek Testing Services (Shanghai FTZ) Co., Ltd.**<br>**Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233 China** |
| **Applicant's name ..... :** | **GlobTek, Inc.** |
| **Address ..... :** | **186 Veterans Drive Northvale NJ 07647, USA** |
| **Test specification:** | |
| **Standard ..... :** | IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020 |
| **Test procedure..... :** | CB Scheme |
| **Non-standard test method..... :** | N/A |
| **TRF template used ..... :** | IECEE OD-2020-F1:2023, Ed.1.6 |
| **Test Report Form No. ..... :** | IEC60601_1K_PS |
| **Test Report Form(s) Originator.... :** | UL Solutions (US) |
| **Master TRF ..... :** | Dated 2024-04-12 |

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**This report is not valid as a CB Test Report unless signed by an approved IECEE 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.
This report shall not be reproduced, except in full, without the written approval of the Issuing NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

| | |
|---|---|
| **Test item description ..... :** | Medical Power Supply |
| **Trademark(s) ..... :** | GlobTek, Inc. 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<br>(Refer to general product information for details.) |

**Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):**

| | | | |
|---|---|---|---|
| ☒ | **CB Testing Laboratory:** | Intertek Testing Services (Shanghai FTZ) Co., Ltd. | |
| **Testing location/ address.....:** | | Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233 China | |
| **Tested by (name, function, signature).....:** | | Nike Yuan<br>(Engineer) | Nike Yuan |
| **Approved by (name, function, signature)...:** | | Eric Shao<br>(Mandated Reviewer) | Eric Shao |
| ☐ | **Testing procedure: CTF Stage 1:** | NA | |
| **Testing location/ address.....:** | | | |
| **Tested by (name, function, signature).....:** | | | |
| **Approved by (name, function, signature)...:** | | | |
| ☐ | **Testing procedure: CTF Stage 2:** | NA | |
| **Testing location/ address.....:** | | | |
| **Tested by (name + signature) .....:** | | | |
| **Witnessed by (name, function, signature) .:** | | | |
| **Approved by (name, function, signature)...:** | | | |
| ☐ | **Testing procedure: CTF Stage 3:** | NA | |
| ☐ | **Testing procedure: CTF Stage 4:** | NA | |
| **Testing location/ address.....:** | | | |
| **Tested by (name, function, signature).....:** | | | |
| **Witnessed by (name, function, signature) .:** | | | |
| **Approved by (name, function, signature)...:** | | | |
| **Supervised by (name, function, signature) :** | | | |

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

**Attachment 1: USA national differences (4 pages)**

**Attachment 2: Canada national differences (14 pages)**

**Attachment 3: Switzerland national differences (2 page)**

**Attachment 4: Korea national differences (1 page)**

**Attachment 5: Japan national differences (12 pages)**

**Attachment 6: Photo of EUT (6 pages)**

**Attachment 7: Circuit diagram/ layout (2 pages)**

**Summary of testing:**

| **Tests performed (name of test, test clause and date test performed):** | **Testing location:** |
|---|---|
| 4.11 Power input<br>5.9.2 Determination of ACCESSIBLE parts<br>7.1.2 Legibility of marking<br>7.1.3 Durability of marking test<br>8.4.2 Working Voltage / Power Measurement<br>8.4.3 Plug discharge test<br>8.7 Leakage current test<br>8.8.3 Dielectric strength test<br>8.8.4.1 Ball pressure test<br>8.9.4 Creepage and clearance measurements<br>11.1 Excessive temperatures in ME EQUIPMENT<br>13.2 Single fault conditions<br>15.3.2 Mechanical Strength tests<br>15.5.1.2 Transformer short-circuit test<br>15.5.1.3 Transformer overload test<br>15.5.2 Transformer dielectric strength after humidity preconditioning of 5.7 | Intertek Testing Services (Shanghai FTZ) Co., Ltd.<br>Building No. 86, 1198 Qinzhou Road (North) Shanghai 200233 China |

**Summary of compliance with National Differences:**

**The national differences for USA, Canada, Switzerland, Korea and Japan have been checked.**

**The group and national differences for CENELEC countries and national differences for United Kingdom have been checked and found to include no national differences from the IEC 60601-1:2005 + AMD1:2012 + AMD2:2020 standard, as reported on the IECEE webpage.**

☒ **The product fulfils the requirements of IEC 60601-1:2005 + AMD1:2012 + AMD2:2020 & EN 60601-1:2006 + AMD1:2012 + AMD2:2021 + AMD13:2024 & BS EN 60601-1:2006 + AMD1:2012 + AMD2:2021 + AMD13:2024 & AAMI ES60601-1:2005 + AMD1:2012 + AMD2:2021 & CAN/CSA-C22.2 No. 60601-1:14 + AMD2:2022 & SN EN 60601-1:2006 + AMD1:2013 + AMD12:2014 + AMD2:2021 + AMD13:2024 & MFDS No. 2020-12 & JIS T 0601-1:2023**

**Use of uncertainty of measurement for decisions on conformity (decision rule):**

☒ No decision rule is specified by the IEC standard, when comparing the measurement result with the applicable limit according to the specification in that standard. The decisions on conformity are made without applying the measurement uncertainty.

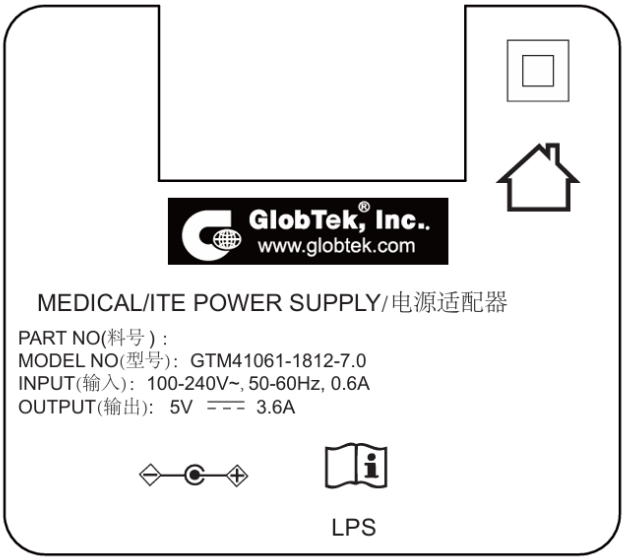
☐ Other: …

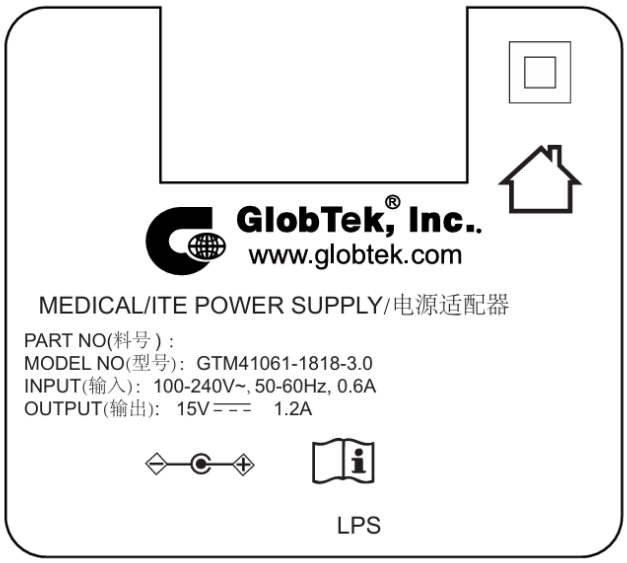
**Information on uncertainty of measurement:**
The uncertainties of measurement are calculated by the laboratory based on application of criteria given by OD-5014 for test equipment and application of test methods, decision sheets and operational procedures of IECEE.
IEC Guide 115 provides guidance on the application of measurement uncertainty principles and applying the decision rule when reporting test results within IECEE scheme, noting that the reporting of the measurement uncertainty for measurements is not necessary unless required by the test standard or customer.

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

**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.

| | |
|---|---|
| **Test item particulars.....:** | |
| **Classification of installation and use.....:** | portable |
| **Device Type .....:** | Standalone power supply |
| **Intended use (including type of patient, application location .....:** | PSU (external power adapter or internal power supply board) |
| **Mode of operation.....:** | Continuous |
| **Supply Connection .....:** | non-detachable cord |
| **Accessories and detachable parts included .....:** | None |
| **Other options include .....:** | None |
| **Possible test case verdicts:** | |
| **- test case does not apply to the test object.....:** | N/A |
| **- test object does meet the requirement.....:** | P (Pass) |
| **- test object was not evaluated for the requirement .....:** | N/E (collateral standards only) |
| **- test object does not meet the requirement.....:** | F (Fail) |
| **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 |
| **Testing.....:** | |
| **Date of receipt of test item .....:** | 2026-03-31 |
| **Date (s) of performance of tests .....:** | 2026-03-31 to 2026-04-22 |
| | |
| **General remarks:** | |
| "(See Enclosure #)" refers to additional information appended to the report.<br>"(See appended table)" refers to a table appended to the report.<br><br>**Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**<br>This Test Report Form is intended for the investigations of power supplies in accordance with IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020. | |
| **Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:** | |
| 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.
186 Veterans Drive Northvale NJ 07647, USA

2. GlobTek (Suzhou) Co., Ltd
Building 4, No. 76 Jin Ling East Road, Suzhou Industrial Park, Suzhou, Jiang Su, 215021, China

**General product information and other remarks:**

Product covered by this report is medical power supply module.
The device is direct plug-in power adapter, which is Class II apparatus. It can be used with different plug types. Two pieces of outer enclosure are enclosed by ultrasonic welding without screw. All the types are designed for continuous operation. This product is also suitable for Home Healthcare Environment.
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.
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 Differences:**

GT*41061-***
The 1st "*" part can be 'M' or '-' or 'H' for market identification.
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 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 Ratings list**

| **Model** (3rd "*" has been filled) | **Input value** | **Rated output voltage range** | **Max. rated output current** | **Max. rated output power** | **Transformer designations** |
|---|---|---|---|---|---|
| GT*41061-*12* | 100-240V~, 50-60Hz or 50/60Hz, 0.6A | 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:**

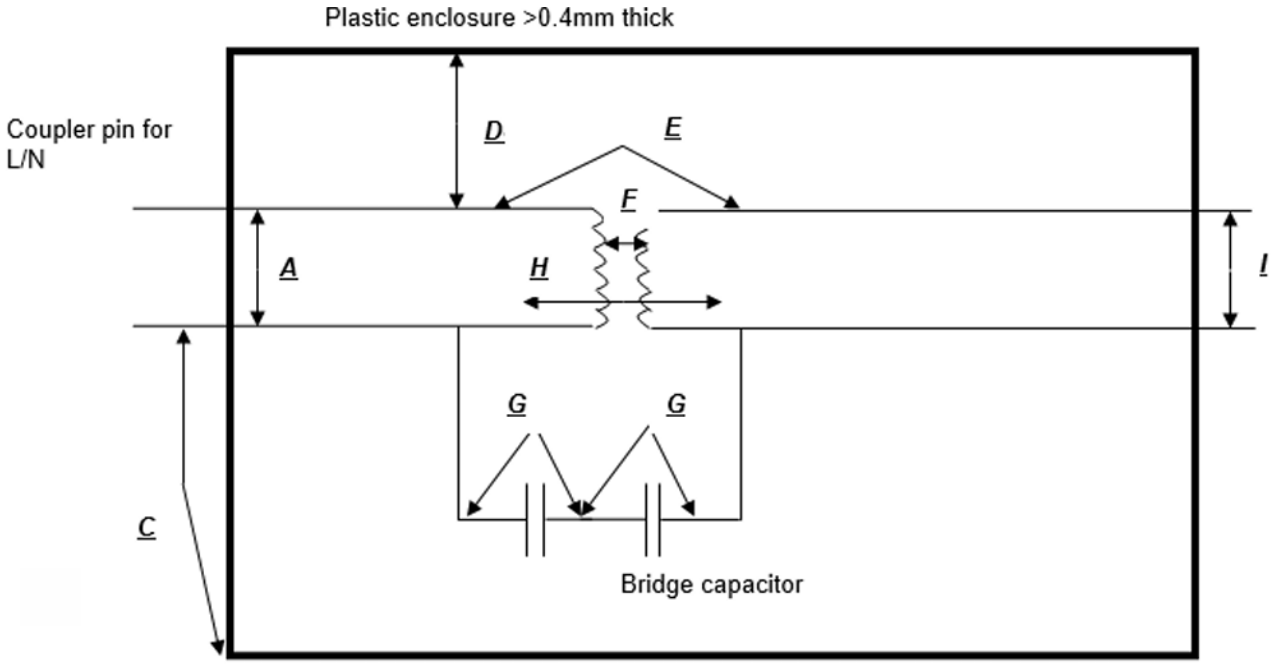
**1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:**

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

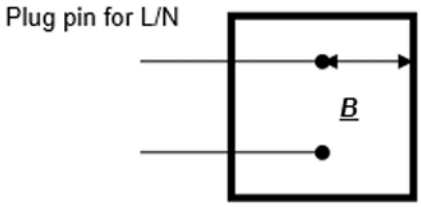
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| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

**INSULATION DIAGRAM**




Plug portion connector without the power supply correctly attached




| **TABLE: INSULATION DIAGRAM** | | P |
|---|---|---|
| **Pollution degree** | **2** | — |
| **Overvoltage category** | **II** | — |
| **Altitude** | **3000 m** | — |
| **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** | **2.3** | **3.2** | **3.2** | **Opposite polarity of mains part** |
| **B** | **2MOOP** | **IIIb** | **240** | **340** | **4.8** | **4.6** | **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** |

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

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | **supply correctly attached.** |
| **C** | **2MOPP** | **IIIb** | **240** | **340** | **7.8** | **5.0** | **9.0** | **9.0** | **Mains part (plug pin) to outer enclosure (accessible position during normal use)** |
| **D** | **2MOPP** | **IIIb** | **240** | **340** | **7.8** | **5.0** | **8.7** | **8.7** | **Internal mains part to accessible outer enclosure** |
| **E** | **2MOPP** | **IIIb** | **240** | **340** | **7.8** | **5.0** | **8.0** | **8.0** | **Mains part to secondary circuits (Optocoupler)** |
| **F** | **2MOPP** | **IIIb** | **276** | **--** | **8.7** | **5.4** | **10.0** | **10.0** | **Mains part to secondary circuits (Transformer)** |
| **G** | **1MOPP (Each) x 2** | **IIIb** | **240** | **340** | **3.9** | **2.4** | **5.4** | **5.4** | **Mains part to secondary circuits (Y capacitor x 2).** |
| **H** | **2MOPP** | **IIIb** | **240** | **340** | **7.8** | **5.0** | **8.7** | **8.7** | **Mains part to secondary circuits (Along PCB trace)** |
| **I** | **1MOPP** | **IIIb** | **--** | **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.

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. In case the measured minimum or maximum value is exceeding or is below the limit value by more than 30%, the value given in the TRF shall be >[minimum required value + 30%] or shall be < [maximum required value - 30%] and the accuracy of the used instruments shall be in line with the latest version of OD-5014, CTL Instrument Accuracy Limits (the latest version). 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 b4.10eyond 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 10 years | **P** |
| **4.5** | **Alternative RISK CONTROL methods utilized:** | All risks have been reduced to an acceptable level, no alternative risk control method used | **N/A** |
| **4.6** | **RISK MANAGEMENT PROCESS identifies parts that can come into contact with PATIENT but not defined as APPLIED PARTS, subjected to the requirements for APPLIED PARTS, except for Clause 7.2.10 ……...:** | No such parts | **N/A** |
| 4.7 | ME EQUIPMENT remained SINGLE FAULT SAFE, or the RISK remained acceptable as determined by Clause 4.2…….: | See Appended RM Results Table 4.2 | **P** |
| | Failure of any one component at a time that could result in a HAZARDOUS SITUATION, including those in 13.1, simulated physically or theoretically……..: | See Appended Table 13.2 for simulated physical test | **P** |
| 4.8 | All components and wiring whose failure could result in a HAZARDOUS SITUATION used according to their applicable ratings, unless specified ……..: | All components and wiring used according to applicable rating. | **P** |
| | Components and wiring exception in the standard or by RISK MANAGEMENT PROCESS | | **P** |
| | RISK MANAGEMENT PROCESS assesses components to identify components where the failure results in a HAZARDOUS SITUATION for components used outside their ratings ……..:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | All risks have been reduced to an acceptable level, no alternative risk control method used | **N/A** |
| | MANUFACTURER identified components where the failure results in a HAZARDOUS SITUATION ……..: | Not identified | **N/A** |
| | Components determined to be acceptable where used as a MEANS OF PROTECTION …….: | Acceptable | **P** |

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Reliability of components used as MEANS OF PROTECTION assessed for conditions of use in ME EQUIPMENT, and they complied with one of the following | | **P** |
| | a) Applicable safety requirements of a relevant IEC or ISO standard | | **P** |
| | 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 and selected appropriately……..: | No High-integrity Component | **N/A** |
| | RISK MANAGEMENT FILE includes an assessment to determine if the failure of components results in unacceptable RISK……..:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | | **N/A** |
| | Components identified and required to be COMPONENTS WITH HIGH INTEGRITY CHARACTERISTIC: | | **N/A** |
| 4.10 | **Power supply** | | **P** |
| 4.10.1 | ME EQUIPMENT is suitable for connection to indicated power source (select applicable) ……: | | **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 | | **N/A** |
| 4.11 | **Power input** | | **P** |
| | Steady-state measured input of ME EQUIPMENT or ME SYSTEM at RATED voltage or voltage range and at operating settings indicated in instructions for use didn't exceed marked rating by more than 10% ... : | See appended Table 4.11 | **P** |
| **5** | **GENERAL REQUIREMENTS FOR TESTING ME EQUIPMENT** | | **P** |
| 5.1 | Test not performed when analysis indicated condition being tested was adequately evaluated by other tests or methods ……..: | RM not provided: All test were conducted | **P** |
| | RISK MANAGEMENT FILE identifies combinations of simultaneous independent faults that could result in a HAZARDOUS SITUATION.<br>(ISO 14971 Cl. 5.2-5.5) | RM not included: End product Risk Management must determine the need for simultaneous fault tests. | **N/A** |
| 5.3 | Tests conducted within the environmental conditions specified in technical description | | **P** |

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Temperature (ºC), Relative Humidity (%) …….: | Output current not greater than 3A, 0-40 ºC, 0%-93%RH<br>Output current greater than 3A, 0-30 ºC, 0%-93%RH | — |
| | Atmospheric Pressure (kPa) ……: | 700-1060hPa (3000m altitude) | — |
| 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)……..: | 85/264V 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 |
| | 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 ..... : | 85/264V, 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 |
| 5.7 | 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 |
| | ME EQUIPMENT heated to a temperature between T and T + 4°C for at least 4 h and placed in a humidity chamber with a relative humidity of 93% +/13% and ambient within 2 °C of T in range of +20°C to +30°C for indicated time | T = 26°C<br>Time – 168 h<br>Relative humidity = 93 %RH | — |
| **5.9** | **Determination of APPLIED PARTS and ACCESSIBLE PARTS** | | P |
| 5.9.1 | APPLIED PARTS identified by inspection and reference to ACCOMPANYING DOCUMENTS ..... : | No AP | N/A |
| **5.9.2** | **ACCESSIBLE PARTS** | | P |
| 5.9.2.1 | Accessibility determined using standard test finger of Fig. 6 | See Appended Table 5.9.2 | P |
| 5.9.2.2 | Test hook of Fig. 7 inserted in all openings of ME EQUIPMENT and pulled with a force of 20 N for 10 s | | P |

| IEC 60601-1 | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 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, 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 | No applied part | **N/A** |
| | TYPE B APPLIED PART | | **N/A** |
| | TYPE BF APPLIED PART | | **N/A** |
| | TYPE CF APPLIED PART | | **N/A** |
| | DEFIBRILLATION-PROOF APPLIED PARTS | | **N/A** |
| 6.3 | ENCLOSURES classified according to degree of protection against ingress of water and particulate matter as per IEC 60529..... : | IP21 | **P** |
| 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 | See appended Tables 7.1.3 and 8.10 | **P** |
| **7.2** | **Marking on the outside of ME EQUIPMENT or ME EQUIPMENT parts** | | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 7.2.1 | At least markings in 7.2.2, 7.2.5, 7.2.6, 7.2.10, and 7.2.13 were applied when size of EQUIPMENT, its part, an ACCESSORY, or ENCLOSURE did not permit application of all required markings ……..: | See 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** |
| | Single use item marked……..: | Power supply not investigated as a single use item | **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** |
| | Detachable components of the ME EQUIPMENT not marked; misidentification does not present an unacceptable risk, or | | **N/A** |
| | RISK MANAGEMENT FILE includes an assessment of the RISKS relating to misidentification of all detachable parts……..:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.3) | | **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……..: | No software | **N/A** |
| 7.2.3 | Symbol 11 on Table D.1 used, optionally, advice to OPERATOR to consult ACCOMPANYING DOCUMENTS | See the marking label. | **P** |
| | SAFETY SIGN 10 on Table D.2) 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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Markings applied to individual packaging when not practical to apply to ACCESSORIES | | **N/A** |
| 7.2.5 | ME EQUIPMENT and ME SYSTEM intended to receive power from other equipment, provided with one of the following | Component; final determination to be performed in the end-product | **N/A** |
| | - the name or trademark of the manufacturer of the other electrical equipment and type reference marked adjacent to the relevant connection point; or | Component; final determination to be performed in the end-product | **N/A** |
| | – Table D.2, SAFETY SIGN No. 10 adjacent to the relevant connection point and listing of the required details in the instructions for use; or | Component; final determination to be performed in the end-product | **N/A** |
| | – Special connector style used that is not commonly available on the market and listing of the required details in the instructions for use. | Component; final determination to be performed in the end-product | **N/A** |
| **7.2.6** | **Connection to the Supply Mains** | | **P** |
| | Marking appearing on the outside of part containing SUPPLY MAINS connection and, adjacent to connection point | | **P** |
| | For PERMANENTLY INSTALLED ME EQUIPMENT, NOMINAL supply voltage or range marked inside or outside of ME EQUIPMENT | 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)…..: | No multiple rated supply | **N/A** |
| | – Nature of supply and type of current……..: | Single phase, AC. | **P** |
| | Symbols 1-5, Table D.1 (used 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 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)……..…: | In amp | **P** |
| | RATED input in amps or volt-amps, or in watts when power factor exceeds 0.9 (A,VA,W)……..: | Not used | **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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Marking includes long-time and most relevant momentary volt-ampere ratings when provided, each plainly identified and indicated in ACCOMPANYING DOCUMENTS (VA)……..: | No such range 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 range provided. | **N/A** |
| **7.2.8** | **Output connectors** | | **P** |
| 7.2.8.2 | Output connectors are marked, except for MULTIPLE SOCKET-OUTLETS or connectors intended for specified ACCESSORIES or equipment | No MSO | **N/A** |
| | 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….: | This is a default requirement; it must be met regardless of whether it is specified or not. | **N/A** |
| 7.2.10 | Degrees of protection against electric shock as classified in 6.2 for all APPLIED PARTS marked with relevant symbols ……..: | No Applied Parts in power supply | **N/A** |
| 7.2.11 | ME EQUIPMENT 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 | Physiological effects – SAFETY SIGN and warning statements ……..: | 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……:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.2-7.3) | Component; final determination to be performed in the 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 | No such high voltage terminal device. | **N/A** |
| 7.2.15 | Requirements for cooling provisions marked……: | Component; final determination to be performed in the end-product | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 7.2.17 | Packaging marked with special handling instructions for transport and/or storage……: | Component; final determination to be performed in the end-product | **N/A** |
| | Permissible environmental conditions marked on outside of packaging……..: | Component; final determination to be performed in the end-product | **N/A** |
| | Packaging marked with a suitable SAFETY SIGN indicating premature unpacking of ME EQUIPMENT could result in an unacceptable RISK……..: | Component; final determination to be performed in the end-product | **N/A** |
| | RISK MANAGEMENT FILE includes the assessment to determine premature unpacking of ME EQUIPMENT or its parts could result in an unacceptable RISK……:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.3) | | **N/A** |
| | Packaging of sterile ME EQUIPMENT or ACCESSORIES marked sterile and indicates the methods of sterilization | Component; final determination to be performed in the 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 ……..: | Component; final determination to be performed in the end-product | **N/A** |
| | - the RATED flow rate also marked | Component; final determination to be performed in the end-product | **N/A** |
| 7.2.19 | Symbol 7 of Table D.1 marked on FUNCTIONAL EARTH TERMINAL……..: | No FE | **N/A** |
| 7.2.20 | Removable protective means marked to indicate the necessity for replacement when the function is no longer needed……..: | Component; final determination to be performed in the end-product | **N/A** |
| 7.2.21 | MOBILE ME EQUIPMENT marked with its mass including its SAFE WORKING LOAD in kilograms..... : | Component; final determination to be performed in the end-product | **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** |
| | A marking referring to ACCOMPANYING DOCUMENTS provided for heating elements or lamp-holders designed for heating lamps that can be changed only by SERVICE PERSONNEL using a TOOL | | **N/A** |
| 7.3.2 | Symbol 24 of Table D.1, or SAFETY SIGN No.3 of Table D.2 used to mark presence of HIGH VOLTAGE parts……: | No such HV part. | **N/A** |
| 7.3.3 | Type of battery and mode of insertion marked..: | No battery | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | An identifying marking provided referring to instructions in ACCOMPANYING DOCUMENTS for batteries intended to be changed only by SERVICE PERSONNEL using a TOOL……..: | | **N/A** |
| | A warning provided indicating replacement of lithium batteries or fuel cells when incorrect replacement would result in an unacceptable RISK .....: | | **N/A** |
| | RISK MANAGEMENT FILE includes an assessment to determine the replacement of lithium batteries or fuel cells leads to a HAZARDOUS SITUATION if replaced incorrectly……:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.2) | | **N/A** |
| | ACCOMPANYING DOCUMENTS contain a warning indicating the replacement of lithium batteries or fuel cells by inadequately trained personnel could result in a HAZARDOUS SITUATION……: | Component; to be determine in the end-product | **N/A** |
| 7.3.4 | Fuses, replaceable THERMAL CUT-OUTS and OVER-CURRENT RELEASES, accessible by use of a TOOL Identified ……..……..: | Not replaceable | **N/A** |
| | Voltage (V) and Current (A) rating……. | None | **—** |
| | Operating speed(s), size & breaking capacity….: | None | **—** |
| 7.3.5 | PROTECTIVE EARTH TERMINAL marked with symbol 6 of Table D.1 | No PE 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 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** |
| | Terminals exclusively for neutral supply conductor in PERMANENTLY INSTALLED ME EQUIPMENT marked with Code 1 of Table D.3 | Not permanently installed | **N/A** |
| | Marking for connection to a 3-phase supply, 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” or equivalent, marked at the point of supply connections | No such high temperature | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | 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, including mains switch, marked with symbols 12 and 13 of Table D.1 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 switch to control power to parts of ME EQUIPMENT, marked with symbols 12 and 13 of Table D.1 or | | **N/A** |
| | - marked with symbols 16 and 17 of Table D.1 or | | **N/A** |
| | – indicated by an adjacent indicator light, or | | **N/A** |
| | – indicated by other unambiguous means | | **N/A** |
| | Switches that brings ME EQUIPMENT into “stand-by” may be indicated by symbol 29 of Table D.1 | | **N/A** |
| | The “on/off” positions of push button switch with bi-stable positions marked with symbol 14 of Table D.1, 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 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** |
| | RISK MANAGEMENT FILE identifies controls where a change in setting during NORMAL USE results in an unacceptable RISK…….:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1, 7.1-7.3) | | **N/A** |
| | Controls provided with an associated indicating device when change of setting of a control could result in an unacceptable RISK to PATIENT in NORMAL USE……..: | No such device. | **N/A** |
| | – or an indication of direction in which magnitude of the function changes | No such device. | **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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | 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** |
| | RISK MANAGEMENT PROCESS identifies markings used to convey a warning, prohibition or mandatory action that mitigate a RISK not obvious to the OPERATOR……:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.3) | | **N/A** |
| | Affirmative statement together with SAFETY SIGN placed in instructions for use if insufficient space on ME EQUIPMENT | | **N/A** |
| | Specified colours in ISO 3864-1 used for SAFETY SIGNS……: | | **N/A** |
| | Safety notices include appropriate precautions or instructions on how to reduce RISK(S) | | **N/A** |
| | SAFETY SIGNs including any supplementary text or symbols described in instructions for use | | **N/A** |
| | - and in a language acceptable to the intended OPERATOR | | **N/A** |
| **7.6** | **Symbols** | | **P** |
| 7.6.1 | Meanings of symbols used for marking described in instructions for use……: | User manual “Label Markings”. | **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** |
| 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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 7.7.4 | Neutral conductors of POWER SUPPLY CORDS are "light blue" | As the product requires no wiring, there is no need to identify this colour. | **N/A** |
| 7.7.5 | Colours of conductors in POWER SUPPLY CORDS in accordance with IEC 60227-1 or IEC 60245-1 | As the product requires no wiring, there is no need to identify this colour. | **N/A** |
| 7.8 | Indicator lights and controls | | **N/A** |
| 7.8.1 | Red indicator lights, not flashing used only for Warning | No use indicator light. | **N/A** |
| | Yellow indicator lights, not flashing used only for Caution | | **N/A** |
| | Green indicator lights used only for Ready for use | | **N/A** |
| | Red flashing used only for HIGH PRIORITY ALARM CONDITION, interruption of current workflow needed | | **N/A** |
| | Yellow flashing used only MEDIUM PRIORITY ALARM CONDITION, re-planning of workflow needed | | **N/A** |
| | Yellow or Cyan, not flashing used for LOW PRIORITY ALARM CONDITION, planning of future workflow needed. | | **N/A** |
| | Other colours: Meaning other than red, yellow, cyan 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. | **N/A** |
| **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** |
| | RISK MANAGEMENT FILE identifies conductors and connectors where breaking free results in a HAZARDOUS SITUATION……: (ISO 14971 Cl. 5.4) | The following needs to be considered in the end product: - interruption of any one power-carrying conductor - unintended movement of a component - accidental detachment of conductors and connectors | **N/A** |
| **8.2** | **Requirements related to power sources** | | **N/A** |
| **8.2.1** | **Connection to a separate power source** | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | 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** | **Connection to an external d.c. power source** | | **N/A** |
| | No HAZARDOUS SITUATION as described in 13.1 developed when a connection with wrong polarity made for ME EQUIPMENT from an external d.c. source | 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** |
| **8.4.2** | **ACCESSIBLE PARTS and APPLIED PARTS** | | **P** |
| | a) Currents from, to, or between PATIENT CONNECTIONS did not exceed limits for PATIENT LEAKAGE CURRENT & PATIENT AUXILIARY CURRENT……: | No patient connections | **N/A** |
| | b) LEAKAGE CURRENTS from, to, or between ACCESSIBLE PARTS did not exceed limits for TOUCH CURRENT……: | See appended Table 8.7 | **P** |
| | c) Limits specified in b) not applied to parts when probability of a connection to a PATIENT, directly or through body of OPERATOR, is negligible in NORMAL USE, and the OPERATOR is appropriately instructed | The likelihood of the current flowing through body of OPERATOR to be determined in end-product evaluation | **P** |
| | 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** |
| | 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** |
| | Limits in b) does not apply to SIP/SOP connectors and separate power supply connectors if the voltage measured is less than or equal to 60 V d.c. or 42,4 V peak a.c | See appended Table 8.4.2 | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | d) Voltage and energy limits specified in c) above also applied to the following: | No such part. | **N/A** |
| | – internal parts 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 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** |
| | 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 45μC….: | 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, and manual discharging device specified in technical description……: | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **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** |
| | A MEANS OF PROTECTION protecting APPLIED PARTS or parts identified by 4.6 as parts subject to the same requirements, considered as MEANS OF PATIENT PROTECTION……..: | Considered as a patient protection | **P** |
| | Varnishing, enamelling, oxidation, and similar protective finishes and coatings with sealing compounds re-plasticizing at temperatures expected during operation and sterilization disregarded as MEANS OF PROTECTION | | **P** |
| | Components and wiring forming a MEANS OF PROTECTION comply with 8.10 | | **P** |
| 8.5.1.2 | MEANS OF PATIENT PROTECTION (MOPP) | | **P** |
| | Solid insulation forming a MEANS OF PATIENT PROTECTION complied with dielectric strength test……..: | See appended Table 8.8.3 | **P** |
| | CREEPAGE and CLEARANCES forming a MEANS OF PATIENT PROTECTION complied with Table 12 | | **P** |
| | PROTECTIVE EARTH CONNECTIONS forming a MEANS OF PATIENT PROTECTION complied with Cl. 8.6 | No PE | **N/A** |
| | Y1 or Y2 capacitor complying with standard IEC 60384-14 considered one MEANS OF PATIENT PROTECTION ……..: | See appended Tables 8.8.3 and 8.10 | **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)……: | At least 250V, 1000pF | **—** |
| | Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3 | See table 8.10 | **—** |
| | Measurement of Air Clearance and Creepage distance on the outside | See insulation table | **—** |
| | Dielectric strength test across optocoupler | See appended Table 8.8.3 | **—** |
| 8.5.1.3 | MEANS OF OPERATOR PROTECTION (MOOP) | | **P** |
| | Solid insulation forming a MEANS OF OPERATOR PROTECTION complied with: | | **P** |
| | – dielectric strength test ……..: | See appended Table 8.8.3 | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | – requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION | | **N/A** |
| | CREEPAGE and CLEARANCES forming a MEANS OF OPERATOR PROTECTION complied with: | | **P** |
| | – limits of Tables 13 to 16 (inclusive); or | | **P** |
| | – requirements of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 for INSULATION CO-ORDINATION | | **N/A** |
| | PROTECTIVE EARTH CONNECTIONS forming a MEANS OF OPERATOR PROTECTION complied with Cl. 8.6 | | **N/A** |
| | – or with requirements and tests of IEC 60950-1:2005, IEC 60950-1:2005/A1:2009 and IEC 60950:2005/A2:2013 or requirements of IEC 62368-1:2018 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)……..: | | **—** |
| | Optocouplers complying with IEC 60747-5-5:2007, or a later edition. Considered equivalent to requirements in 8.8.2 and 8.9.3 | | **—** |
| | Measurement of Air Clearance and Creepage distance on the outside | | **—** |
| | Dielectric strength test across optocoupler | | **—** |
| | Points and applied parts at which impedances of components, CREEPAGE, CLEARANCES, PROTECTIVE EARTH CONNECTIONS or insulation, prevent ACCESSIBLE PARTS from exceeding limits in 8.4 were examined whether a failure at any of these points is to be regarded as a NORMAL or SINGLE FAULT CONDITION | | **N/A** |
| **8.5.2** | **Separation of PATIENT CONNECTIONS** | No Patient Connections | **N/A** |
| **8.5.2.3** | **A connector on a PATIENT lead or PATIENT cable located at the end of the lead or cable distal from PATIENT, with conductive part not separated from all PATIENT CONNECTIONS by one MEANS OF PATIENT PROTECTION for a WORKING VOLTAGE equal to MAXIMUM MAINS VOLTAGE** | | **N/A** |
| | - cannot be connected to earth or hazardous voltage while the PATIENT CONNECTIONS are in contact with PATIENT…….: | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | – conductive part of connector not separated from all PATIENT CONNECTIONS did not come into contact with a flat conductive plate of not less than 100 mm diameter | | **N/A** |
| | – CLEARANCE between connector pins and a flat surface is at least 0.5 mm | | **N/A** |
| | – conductive part pluggable into a mains socket protected from contacting parts at MAINS VOLTAGE by insulation with a CREEPAGE DISTANCE of at least 1.0 mm, a 1500 V dielectric strength and complying with 8.8.4.1 | | **N/A** |
| | – required test finger did not make electrical contact with conductive part when applied against access openings with a force of 10 N, | | **N/A** |
| | Test finger test (10 N)……..: | | **N/A** |
| | Except when RISK MANAGEMENT PROCESS includes an assessment of RISKS resulting from contact with objects other than mains sockets or flat surfaces……..:<br>(ISO 14971 Cl. 5.2-5.5, 6) | | **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)……..: | 240 Vac | **P** |
| | – WORKING VOLTAGE for d.c. voltages with superimposed ripple was average value when peak-to-peak ripple less than 10% of average value or peak voltage when peak-to-peak ripple exceeding 10% of average value (V)……: | 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** |
| | – Intentional or accidental earthing of PATIENT regarded as a NORMAL CONDITION for WORKING VOLTAGE involving a PATIENT CONNECTION not connected to earth | No earthing of patient | **N/A** |
| | – WORKING VOLTAGE between PATIENT CONNECTIONS of an F-TYPE APPLIED PART and ENCLOSURE was highest voltage appearing across insulation in NORMAL USE including earthing of any part of APPLIED PART (V)……..: | No patient connections | **N/A** |
| | – WORKING VOLTAGE for DEFIBRILLATION-PROOF APPLIED PARTS determined disregarding possible presence of defibrillation voltages | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | – WORKING VOLTAGE was equal to resonance voltage in case of motors provided with capacitors between the point where a winding and a capacitor are connected together and a terminal for external conductors (V)……..: | | **N/A** |
| 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 60950-1:2005, IEC 60950-1:2005/AMD1:2009 and IEC 60950-1:2005/AMD2:2013 or IEC 62368-1:2018 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 potential equalization of me equipment | **N/A** |
| 8.6.2 | PROTECTIVE EARTH TERMINAL is suitable for connection to an external protective earthing system by a PROTECTIVE EARTH CONDUCTOR in a POWER SUPPLY CORD and a suitable plug or by a FIXED PROTECTIVE EARTH CONDUCTOR……: | | **N/A** |
| | Clamping means of PROTECTIVE EARTH TERMINAL of ME EQUIPMENT for FIXED supply conductors or POWER SUPPLY CORDS comply with 8.11.4.3, and cannot be loosened without TOOL | | **N/A** |
| | Screws for internal PROTECTIVE EARTH CONNECTIONS completely covered or protected against accidental loosening from outside……..: | | **N/A** |
| | Earth pin of APPLIANCE INLET forming supply connection to ME EQUIPMENT regarded as PROTECTIVE EARTH TERMINAL | | **N/A** |
| | PROTECTIVE EARTH TERMINAL not used for mechanical connection between different parts of ME EQUIPMENT or securing components not related to protective or functional earthing | | **N/A** |
| 8.6.3 | PROTECTIVE EARTH CONNECTION not used for a moving part, | Final determination in the end-product | **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** |
| | DETACHABLE POWER SUPPLY CORD specified by manufacturer or delivered with product | | **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 | | **N/A** |
| | Coating not removed when requirements for impedance and current-carrying capacity met | | **N/A** |
| **8.6.6** | **Plugs and sockets** | | **N/A** |
| | PROTECTIVE EARTH CONNECTION where connection between SUPPLY MAINS and ME EQUIPMENT or between separate parts of ME EQUIPMENT made via a plug and socket was made before and interrupted after supply connections | | **N/A** |
| | - applied also where interchangeable parts are PROTECTIVELY EARTHED | | **N/A** |
| **8.6.7** | **Terminal for connection of a POTENTIAL EQUALIZATION CONDUCTOR** | | **N/A** |
| | – Terminal is accessible to OPERATOR with ME EQUIPMENT in any position of NORMAL USE | | **N/A** |
| | –accidental disconnection avoided in NORMAL USE | | **N/A** |
| | – Terminal allows conductor to be detached without a TOOL | | **N/A** |
| | – Terminal not used for a PROTECTIVE EARTH CONNECTION | | **N/A** |
| | – Terminal marked with symbol 8 of Table D.1 | | **N/A** |
| | – Instructions for use contain information on function and use of POTENTIAL EQUALIZATION CONDUCTOR together with a reference to requirements of this standard | | **N/A** |
| | POWER SUPPLY CORD does not incorporate a POTENTIAL EQUALIZATION CONDUCTOR | | **N/A** |
| 8.6.8 | FUNCTIONAL EARTH TERMINAL not used to provide a PROTECTIVE EARTH CONNECTION | | **N/A** |
| **8.6.9** | **Class II ME EQUIPMENT** | | **N/A** |
| | Third conductor of POWER SUPPLY CORD connected to protective earth contact of MAINS PLUG provided with CLASS II ME EQUIPMENT with isolated internal screens used as functional earth connection to the screen's FUNCTIONAL EARTH TERMINAL, coloured green and yellow | No 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** |
| | 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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 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 100µA in NORMAL CONDITION and 500µA 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** |
| | 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……: | | **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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | f) LEAKAGE CURRENTS flowing in a FUNCTIONAL EARTH CONDUCTOR in a non-PERMANENTLY INSTALLED ME EQUIPMENT are 5 mA in NORMAL CONDITION, 10 mA in SINGLE FAULT CONDITION….: | | **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 | IEC 60950 not used | **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 at least 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** |
| | 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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | 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…….: | Examined the accompanying technical documentation | **P** |
| | RISK MANAGEMENT FILE examined in conjunction with resistance to moisture, dielectric strength, and mechanical strength tests……..:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | 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 appended Table 8.8.4.1 | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | 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 appended 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 equal to or greater than values in Tables 12 to 16 (inclusive)……: | Refer to Insulation Diagram | **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 | | **N/A** |
| 8.9.1.16 | Conductive coatings applied to non-metallic surfaces, do not result in flaking or peeling reducing any AIR CLEARANCE or CREEPAGE DISTANCE | No conductive coatings | **N/A** |
| 8.9.2 | a) Short circuiting of each single one of CREEPAGE DISTANCES and CLEARANCES in turn did not result in a HAZARDOUS SITUATION, min CREEPAGE and CLEARANCES not applied……..: | The spacing between parts of opposite polarity fulfils the values of Table 11. There is no single instance where a short circuit could occur. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **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 | Certified optocoupler. | **P** |
| | Thermal cycling, humidity preconditioning, and dielectric strength tests | 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 (cl. 8.8.3 at 1,6 x test voltage)…….: | 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 followed by dielectric strength test of cl. 8.8.3 at 1.6 x the test voltage ……..: | | **N/A** |
| | – The other two samples subjected to humidity preconditioning of 5.7, except for 48 hours only followed by a dielectric strength test of cl. 8.8.3 at 1.6 times the test voltage | | **N/A** |
| 8.9.4 | Minimum spacing of grooves transvers to the CREEPAGE DISTANCES considered a MEANS OF OPERATOR PROTECTION adjusted based on pollution degree ……..…….: | Pollution degree: 2 | **P** |
| | Force was applied between bare conductors and outside metal enclosure when measuring CREEPAGE DISTANCES and AIR CLEARANCES | Refer to Insulation Diagram supplemental information for location and force used | **P** |
| **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…….: | Risk management report Page 11 EL3 | **P** |
| | RISK MANAGEMENT FILE includes an assessment of RISKS related to unwanted movement of components……..:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | Risk management report Page 11 EL3 | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 8.10.2 | Conductors and connectors of ME EQUIPMENT adequately secured or insulated to prevent accidental detachment……: | Final determination in the end-product | **N/A** |
| | Stranded conductors are not solder-coated when secured by clamping means to prevent HAZARDOUS SITUATIONS | No stranded conductor. | **N/A** |
| 8.10.3 | Interconnecting flexible cords detachable without a TOOL used provided with means for connection to comply with requirements for metal ACCESSIBLE PARTS when a connection is loosened or broken ……: | No such 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 | Not such device. | **N/A** |
| 8.10.4.2 | Connection and anchorage of a flexible cord to a HAND-HELD or foot-operated control device of ME EQUIPMENT, at both ends of the cable to the control device, complies with the requirements for POWER SUPPLY CORDS in Cl. 8.11.3 | | **N/A** |
| | Other HAND-HELD parts, if disturbance or breaking of one or more of the connections could result in a HAZARDOUS SITUATION, also comply with tests of Cl. 8.11.3 | | **N/A** |
| **8.10.5** | **Mechanical protection of wiring** | | **N/A** |
| | a) Internal cables and wiring adequately protected against contact with a moving part or from friction at sharp corners and edges…….: | 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 | No access covers | **N/A** |
| 8.10.6 | Guiding rollers prevent bending of movable insulated conductors around a radius of less than five times the outer diameter of the lead | No guiding rollers | **N/A** |
| 8.10.7 | a) Insulating sleeve adequately secured…….: | 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 of ME EQUIPMENT subject to temperatures exceeding 70 °C……..: | See appended Table 8.10 | **P** |
| **8.11** | **MAINS PARTS, components and layout** | | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 8.11.1 | a) ME EQUIPMENT provided with means of electrically isolating its circuits from SUPPLY MAINS simultaneously on all poles…….: | See appended Table 8.10 | **P** |
| | PERMANENTLY INSTALLED ME EQUIPMENT connected to a poly-phase SUPPLY MAINS equipped with a device not interrupting neutral conductor, provided local installation conditions prevent voltage on neutral conductor from exceeding limits in 8.4.2 c) | Not permanently installed. | **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 | | **N/A** |
| | - the isolation device specified in the ACCOMPANYING DOCUMENTS | | **N/A** |
| | b) Means of isolation incorporated in ME EQUIPMENT, or if external, described in technical description ……: | See appended Table 8.10 | **P** |
| | c) A SUPPLY MAINS switch used to comply with 8.11.1 a) complies with CREEPAGE / CLEARANCES for a MAINS TRANSIENT VOLTAGE of 4 kV……: | No mains switch | **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 used in non-PERMANENTLY INSTALLED ME EQUIPMENT with no SUPPLY MAINS SWITCH……: | 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** |
| | i) Parts within ENCLOSURE of ME EQUIPMENT with a circuit > 42.4 V peak a.c. or 60 V d.c. that cannot be disconnected from its supply by an external switch or a plug device accessible at all times is protected against touch even after opening ENCLOSURE by an additional covering | | **N/A** |
| | A clear warning notice is marked on outside of ME EQUIPMENT to indicate it exceeds allowable touch voltage | | **N/A** |
| | For a part that could not be disconnected from supply by an external switch or a plug device accessible at all times, the required cover or warning notice complied with this clause | | **N/A** |
| | Standard test finger applied | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 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 separate socket-outlets. | **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 separate socket-outlets. | **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…….: | No separate socket-outlets. | **N/A** |
| | For ME EQUIPMENT utilizing POWER SUPPLY CORDS and operating at currents greater than 63 A, apply the electrical regulations appropriate for the jurisdiction in which the ME EQUIPMENT is to be used. | | **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 separate socket-outlets. | **N/A** |
| **8.11.3.5** | **Cord anchorage** | | **N/A** |
| | a) Conductors of POWER SUPPLY CORD provided with strain relief and insulation protected from abrasion at point of entry to ME EQUIPMENT or a MAINS CONNECTOR by a cord anchorage | No separate socket-outlets. | **N/A** |
| | b) Cord anchorage of POWER SUPPLY CORD is an insulating material, or | | **N/A** |
| | – metal, insulated from conductive ACCESSIBLE PARTS non-PROTECTIVELY EARTHED by a MEANS OF PROTECTION, or | | **N/A** |
| | – metal provided with an insulating lining affixed to cord anchorage | | **N/A** |
| | c) Cord anchorage prevents cord from being clamped by a screw bearing directly on cord insulation | | **N/A** |
| | d) Screws to be operated when replacing POWER SUPPLY CORD do not serve to secure any components | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | e) Conductors of POWER SUPPLY CORD arranged to prevent PROTECTIVE EARTH CONDUCTOR against strain as long as phase conductors are in contact with their terminals | | **N/A** |
| | f) Cord anchorage prevents POWER SUPPLY CORD from being pushed into ME EQUIPMENT or MAINS CONNECTOR | | **N/A** |
| | Conductors of POWER SUPPLY CORD supplied by MANUFACTURER disconnected from terminals or from MAINS CONNECTOR and cord subjected 25 times to a pull applied with no jerks, each time for 1 s, on sheath of the value in Table 18 .....: | | **N/A** |
| | Cord subjected to a torque in Table 18 for one minute immediately after pull tests | | **N/A** |
| | Cord anchorage did not allow cord sheath to be longitudinally displaced by more than 2 mm or conductor ends to move over a distance of more than 1 mm from their connected position | | **N/A** |
| | CREEPAGE and CLEARANCES not reduced below limits in 8.9 | | **N/A** |
| | It was not possible to push the cord into ME EQUIPMENT or MAINS CONNECTOR to an extent the cord or internal parts would be damaged | | **N/A** |
| 8.11.3.6 | POWER SUPPLY CORDS protected against excessive bending at inlet opening of equipment | No separate socket-outlets. | **N/A** |
| | Cord guard complied with test of IEC 60335-1:2001, Clause 25.14, or | | **N/A** |
| | ME EQUIPMENT placed such that axis of cord guard projected at an angle of 45° with cord free from stress, and a mass equal 10 x $D^2$ gram attached to the free end of cord (g)……...: | | **N/A** |
| | Cord guard of temperature-sensitive material tested at 23 °C ± 2 °C, and flat cords bent in the plane of least resistance | | **N/A** |
| | Curvature of the cord radius, immediately after mass attached, was not less than 1.5 x D ……..: | | **N/A** |
| **8.11.4** | **MAINS TERMINAL DEVICES** | | **N/A** |
| 8.11.4.1 | PERMANENTLY INSTALLED and ME EQUIPMENT with non-DETACHABLE POWER SUPPLY CORD provided with MAINS TERMINAL DEVICES ensuring reliable connection | Not MAINS terminal devices | **N/A** |
| | Terminals alone are not used to keep conductors in position | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Terminals of components other than terminal blocks complying with requirements of this Clause and marked accordingly used as terminals intended for external conductors | | **N/A** |
| | Screws and nuts clamping external conductors do not serve to secure any other component | | **N/A** |
| **8.11.4.2** | **Arrangement of MAINS TERMINAL DEVICES** | | **N/A** |
| | a) Terminals provided for connection of external cords or POWER SUPPLY CORDS together with PROTECTIVE EARTH TERMINAL grouped to provide convenient means of connection | Not MAINS terminal devices | **N/A** |
| | d) MAINS TERMINAL DEVICES not accessible without use of a TOOL | | **N/A** |
| | e) MEANS OF PROTECTION are not short circuited when one end of a flexible conductor with NOMINAL cross-sectional area is stripped 8 mm and a single free wire is bent in each possible direction | | **N/A** |
| 8.11.4.3 | Internal wiring not subjected to stress and CREEPAGE and CLEARANCES not reduced after fastening and loosening a conductor of largest cross-sectional area 10 times | Not MAINS terminal devices | **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 | Not MAINS terminal devices | **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 | Not MAINS terminal devices | **N/A** |
| | Correct connection and positioning of conductors before ACCESS COVER verified by an installation test | | **N/A** |
| **8.11.5** | **Mains fuses and OVER-CURRENT RELEASES** | | **P** |
| | A fuse or OVER-CURRENT RELEASE provided in each supply lead for CLASS I and CLASS II ME EQUIPMENT with a functional earth connection….: | See appended Table 8.10 | **P** |
| | - in at least one supply lead for other single-phase CLASS II ME EQUIPMENT…….: | | **N/A** |
| | – neutral conductor not fused for PERMANENTLY INSTALLED ME EQUIPMENT | Not permanently installed. | **N/A** |
| | – fuses or OVER-CURRENT RELEASES omitted due to provision of two MEANS OF PROTECTION between all parts within MAINS PART | | **P** |
| | Protective devices have adequate breaking capacity based on MANUFACTURER'S expectation of the highest branch circuit current and/or prospective short circuit current: | See appended Table 8.10 | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | A fuse or OVER-CURRENT RELEASE not provided in a PROTECTIVE EARTH CONDUCTOR | No PE | **N/A** |
| | Justification for omission of fuses or OVER-CURRENT RELEASES documented……: | EUT is only component, high breaking capacity fuse not used 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 suitable.....: | No such internal wire. | **N/A** |
| | b) Cross-sectional area of other wiring in MAINS PART and sizes of tracks on printed wiring circuits are sufficient……: | See appended Table 8.10 for details | **P** |
| **9** | **PROTECTION AGAINST MECHANICAL HAZARDS OF ME EQUIPMENT AND ME SYSTEMS** | | **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** | Final determination in the 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 part | **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** |
| **10.1** | **X-Radiation** | Not applicable to 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 ACCESSIBLE PARTS did not exceed values in Tables 22 and .....: | 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 |
| | RISK MANAGEMENT FILE includes an assessment of the duration of contact for all APPLIED PARTS and ACCESSIBLE PARTS.....:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | RM is not included for power supply, the acceptability of risk of the power supply is determined as part of the end product. | **N/A** |
| **11.1.2** | **Temperature of APPLIED PARTS** | No such applied part | **N/A** |
| 11.1.3 | Measurements not made when engineering judgment and rationale by MANUFACTURER indicated temperature limits could not exceed, as documented in RISK MANAGEMENT FILE .....:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | RM is not included for power supply, the acceptability of risk of the power supply is determined as part of 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 .....:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | RM is not included for power supply. Test corner used | **N/A** |
| | Probability of occurrence and duration of contact for parts likely to be touched and for APPLIED PARTS documented in RISK MANAGEMENT FILE .....:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | RM is not included for component power supply, the acceptability of risk of the power supply is determined as part of the end product. | **N/A** |
| | e) Where thermal regulatory devices make this method inappropriate, alternative methods for measurement are justified in the RISK MANAGEMENT FILE ..... : | RM is not included for power supply, the acceptability of risk of the power supply is determined as part of the end product. | **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 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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | - constructional requirements specifically analysed in RISK MANAGEMENT FILE …….. :<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | | **N/A** |
| | Justification, when requirement not met…….: | Meet the requirement | **N/A** |
| | a) Flammability classification of insulated wire and connectors within fire ENCLOSURE is minimum V-2, when test in accordance with IEC 60695-11-10 or : | See appended Table 8.10 | **P** |
| | insulated with PVC, TFE, PTFE, FEP, polychloroprene or polyimide as determined by examination of data on materials……..: | | **P** |
| | Flammability classification of printed circuit boards, and insulating material on which components are mounted is V-2, or better, based on IEC 60695-11-10 as decided by examination of materials data…….: | See appended Table 8.10 | **P** |
| | If no Certification, V 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** |
| | 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 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 | | **P** |
| | 3) ENCLOSURE, baffles, and flame barriers have adequate rigidity and are made of appropriate metal or of non-metallic materials…….: | 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 agent. | **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** | | **P** |
| **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)…….: | See Appended Table 11.6.1 | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | 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** |
| **11.6.6** | **Cleaning and disinfection of ME EQUIPMENT and ME SYSTEMS** | Final determination to be competed in the end product | **N/A** |
| **11.6.7** | **Sterilization of ME EQUIPMENT and ME SYSTEMS** | Final determination to be competed in the end product | **N/A** |
| 11.7 | ME EQUIPMENT, ME SYSTEM, and ACCESSORIES coming into direct or indirect contact with biological tissues, cells, or body fluids assessed and documented | Component, to be determined in end-product evaluation. | **N/A** |
| 11.8 | Interruption and restoration of power supply did not result in a loss of BASIC SAFETY or ESSENTIAL PERFORMANCE | Component, to be determined in end-product evaluation. | **N/A** |
| **12** | **ACCURACY OF CONTROLS AND INSTRUMENTS AND PROTECTION AGAINST HAZARDOUS OUTPUTS** | | **N/A** |
| 12.1 | RISKS associated with accuracy of controls and instruments stated.....: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | RM is not included for power supply, the acceptability of risk of the power supply is determined as part of the end product. | **N/A** |
| 12.2 | RISK of poor USABILITY, including identification, marking, and documents addressed in a USABILITY ENGINEERING……: | Usability not included for power supply. Usability is to be determined as part of the end product. | **N/A** |
| 12.3 | MANUFACTURER implemented an ALARM SYSTEM compliant with IEC 60601-1-8:2006, IEC 60601-1-8:2006/AMD1:2012 and IEC 60601-1-8:2006/AMD2:2020……..: | No alarm system in this device | **N/A** |
| **12.4** | **Protection against hazardous output** | Not applicable to power supply | **N/A** |
| **12.4.5** | **Diagnostic or therapeutic radiation** | Not applicable to power supply | **N/A** |
| **13** | **HAZARDOUS SITUATIONS AND FAULT CONDITIONS** | | **P** |
| **13.1** | **Specific HAZARDOUS SITUATIONS** | | **P** |
| **13.1.2** | **Emissions, deformation of ENCLOSURE or exceeding maximum temperature** | | **P** |
| | – Emission of flames, molten metal, poisonous or ignitable substance in hazardous quantities did not occur | | **P** |
| | – Deformation of ENCLOSURE impairing compliance with 15.3.1 did not occur | | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | – Temperatures of APPLIED PARTS did not exceed allowable values in Table 24.....: | See appended Table 11.1.1 | **P** |
| | – Temperatures of Accessible PARTS THAT ARE LIKELY TO BE TOUCHED, but not intended to be touched did not exceed limits in Table 34.....: | See appended Table 11.1.1 | **P** |
| | - Temperatures of ACCESSIBLE PARTS intended to be touched did not exceed limits in Table 23 | | **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 -V1, and | | **N/A** |
| | - Secondary circuits energized by less than 60 Vdc, 42.4 Vpeak in NC and SFC, and | | **N/A** |
| | - Secondary circuits limited to 100 VA or 6000 J in NC and SFC, and | | **N/A** |
| | - Wire insulation in secondary circuits of types PVC, TFE, PTFE, FEP, polychloroprene or polybromide | | **N/A** |
| | - or components in the circuit have HIGH INTEGRITY CHARACTERISTICS..... : | | **N/A** |
| | – or parts and components completely contained within a fire ENCLOSURE complying with 11.3 as verified by review of design documentation | | **N/A** |
| | After tests of this Clause, settings of THERMAL CUT-OUTS and OVER-CURRENT RELEASES did not change sufficiently to affect their safety function | Fuse only | **P** |
| 13.1.3 | – limits for LEAKAGE CURRENT in SINGLE FAULT CONDITION did not exceed……..: | See appended Table 8.7 | **P** |
| | – voltage limits for ACCESSIBLE PARTS and APPLIED PARTS did not exceed……..: | See appended Table 8.7 | **P** |
| **13.2** | **SINGLE FAULT CONDITIONS** | | **P** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 13.2.1 | During the application of the SINGLE FAULT CONDITIONS listed in 13.2.2 to 13.2.13 (inclusive), the NORMAL CONDITIONS identified in 8.1 a) also applied in the least favourable combination | | **P** |
| | ME EQUIPMENT complied with 13.2.2 - 13.2.12…..: | See appended Table 13.2 | **P** |
| | RISK MANAGEMENT FILE includes an assessment of RISKS associated with leakage of liquid in a SINGLE FAULT CONDITION.....:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | RM is not included for power supply, the acceptability of risk of the power supply is determined as part of the end product. | **N/A** |
| | RISK MANAGEMENT FILE defines the appropriate test conditions.....: | RM is not included for power supply, the acceptability of risk of the power supply is determined as part of the end product. | **N/A** |
| 13.2.13 | ME EQUIPMENT remained safe after tests of 13.2.13.2 to 13.2.13.4, and cooling down to within 3 °C of test environment temperature | | **P** |
| | ME EQUIPMENT examined for compliance or appropriate tests such as dielectric strength of motor insulation according to 8.8.3 conducted | | **P** |
| **13.2.13.2** | **ME EQUIPMENT with heating elements** | No heating element provided | **N/A** |
| **13.2.13.3** | **ME EQUIPMENT with motors** | No motor provided in power supply | **N/A** |
| **13.2.13.4** | **ME EQUIPMENT RATED for NON-CONTINUOUS OPERATION** | | **N/A** |
| | ME EQUIPMENT (other than HAND-HELD) operated under normal load and at RATED voltage or at upper limit of RATED voltage range until increase in temperature was ≤ 5 °C in one hour, or a protective device operated | Not 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……: | None | **—** |
| | Maximum temperature measured (°C)……..: | None | **—** |
| **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……..: | No controls and indicators. | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 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 ……..: | See Appended Table 15.3<br>Final determination to be completed in the end product | **P** |
| | No damage resulting in an unacceptable RISK sustained | | **P** |
| 15.3.3 | Impact test conducted…….: | See Appended Table 15.3<br>Final determination to be completed in the end product | **P** |
| | No damage resulting in an unacceptable RISK sustained | | **P** |
| **15.3.4** | **Drop test** | | **P** |
| 15.3.4.1 | Sample of HAND-HELD ME EQUIPMENT, ACCESSORIES and HAND-HELD part with SAFE WORKING LOAD tested ……..: | 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 withstood stress as demonstrated by test……: | See Appended Table 15.3<br>Final determination to be completed in the end product | **P** |
| | No damage resulting in an unacceptable RISK sustained | | **P** |
| 15.3.5 | MOBILE ME EQUIPMENT and MOBILE part with SAFE WORKING LOAD and in most adverse condition in NORMAL USE passed Rough Handling tests…….: | 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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | 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 | | **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** |
| | 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,……..: (ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | No such connections | **N/A** |
| | a) Plugs for connection of PATIENT leads or PATIENT cables cannot be connected to outlets on same ME EQUIPMENT intended for other functions,…….: | | **N/A** |
| | b) Medical gas connections on ME EQUIPMENT for different gases to be operated in NORMAL USE are not interchangeable inspection……: | | **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…….: (ISO 14971 Cl. 5.2-5.5, 6) | No such part. | **N/A** |
| | b) THERMAL CUT-OUTS with a safety function with reset by a soldering not fitted in ME EQUIPMENT | | **N/A** |
| | c) An additional independent non-SELF-RESETTING THERMAL CUT-OUT is provided……..: (ISO 14971 Cl. 5.2-5.5) | | **N/A** |
| | d) Operation of THERMAL CUT-OUT or OVER CURRENT RELEASE doesn't result in a HAZARDOUS SITUATION or loss of ESSENTIAL PERFORMANCE ….: (ISO 14971 Cl. 5.2-5.5) | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | e) Capacitors or other spark-suppression devices not connected between contacts of THERMAL CUT-OUTS | | **N/A** |
| | f) Use of THERMAL CUT-OUTS or OVER-CURRENT RELEASES do not affect safety as verified by following tests | | **N/A** |
| | - Positive temperature coefficient devices) complied with IEC 60730-1: 2010, Clauses 15, 17, J.15, and J.17 | | **N/A** |
| | - ME EQUIPMENT containing THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated under the conditions of Clause 13……: | | **N/A** |
| | - SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions Certified according to appropriate standards……: | | **N/A** |
| | - In the absence of Certification in accordance with IEC standards, SELF-RESETTING THERMAL CUT-OUTS and OVER-CURRENT RELEASES including circuits performing equivalent functions operated 200 times | | **N/A** |
| | Manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES Certified in accordance with appropriate IEC standards | | **N/A** |
| | manual reset THERMAL CUT-OUTS and OVER-CURRENT RELEASES operated 10 times | | **N/A** |
| | Thermal protective devices tested separately from ME EQUIPMENT when engineering judgment indicated test results would not be impacted | | **N/A** |
| | g) Protective device incorporating a fluid filled container with heating means, operated when heater switched on with container empty and prevented an unacceptable RISK due to overheating | | **N/A** |
| | h) ME EQUIPMENT with tubular heating elements provided with protection against overheating…..: (ISO 14971 Cl. 5.2-5.5) | | **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 provided with ventilation…….: (ISO 14971 Cl. 5.2-5.5) | No batteries. | **N/A** |
| | Battery compartments designed to prevent accidental short circuiting | | **N/A** |
| 15.4.3.2 | Means provided to prevent incorrect connection of polarity | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | RISK MANAGEMENT FILE includes an assessment of RISKS associated with incorrect connection or replacement of batteries……: (ISO 14971 Cl. 5.2-5.5) | | **N/A** |
| 15.4.3.3 | Overcharging of battery prevented by virtue of design……: | | **N/A** |
| | RISK MANAGEMENT FILE includes an assessment of RISKS associated with overcharging of batteries……..: (ISO 14971 Cl. 5.2-5.5) | | **N/A** |
| 15.4.3.4 | Primary lithium batteries comply with IEC 60086-4 | | **N/A** |
| | Secondary lithium batteries comply with IEC 62133 or IEC 62133-2 | | **N/A** |
| 15.4.3.5 | A properly RATED protective device provided within INTERNAL ELECTRICAL POWER SOURCE to protect against fire……..: | Final determination to be competed in the end product. | **N/A** |
| | Protective device has adequate breaking capacity | | **N/A** |
| | Justification for OVER-CURRENT RELEASES or FUSE exclusion is documented | | **N/A** |
| | Short circuit test between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) omitted where 2 MOOPs provided, or | | **N/A** |
| | Short circuit between the positive and negative poles of an INTERNAL ELECTRICAL POWER SOURCE between the output and protective device(s) does not result in any HAZARDOUS SITUATION | | **N/A** |
| 15.4.4 | Indicator lights provided to indicate ME EQUIPMENT is ready for……: | 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, | | **N/A** |
| | Indicator lights provided on ME EQUIPMENT incorporating non-luminous heaters to indicate heaters are operational | | **N/A** |
| | RISK MANAGEMENT FILE includes an assessment of RISKS associated with the use of indicator lights for EQUIPMENT incorporating non-luminous heaters……..: (ISO 14971 Cl. 5.2-5.5) | | **N/A** |
| | Requirement not applied to heated stylus-pens for recording purposes | | **N/A** |
| | Indicator lights provided on ME EQUIPMENT to indicate an output exists | | **N/A** |
| | Colours of indicator lights complied with 7.8.1 | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Charging mode visibly indicated | | **N/A** |
| 15.4.5 | RISKS associated with pre-set controls addressed in RISK MANAGEMENT PROCESS…….:<br>(ISO 14971 Cl. 5.2-5.5, 6, 7.1-7.4) | 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 parts in power supply | **N/A** |
| 15.4.9 | a) Oil container in PORTABLE ME EQUIPMENT allows for expansion of oil and is adequately sealed | No such parts in power supply | **N/A** |
| | b) Oil containers in MOBILE ME EQUIPMENT sealed to prevent loss of oil during transport | No such parts in power supply | **N/A** |
| | A pressure-release device operating during NORMAL USE is provided | No such parts in power supply | **N/A** |
| | c) Partially sealed oil-filled ME EQUIPMENT and its parts provided with means for checking the oil level to detect leakage | No such parts in power supply | **N/A** |
| | ME EQUIPMENT and technical description examined, and manual tests conducted to confirm compliance with above requirements | 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……..: | See appended Tables 15.5.1.2 and 15.5.1.3 | **P** |
| | During tests, windings did not open, no HAZARDOUS SITUATION occurred, and maximum temperatures of windings did not exceed values in Table 31 | | **P** |
| | Dielectric strength test conducted after short circuit and overload tests ……: | 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 | | **N/A** |
| 15.5.1.3 | Multiple overload tests conducted on windings: | No more than one protective device | **N/A** |
| 15.5.2 | Transformers operating at a frequency above 1kHz tested according to clause 8.8.3……: | Not above 1kHz | **N/A** |
| | Transformer windings provided with adequate insulation | | **P** |
| | Dielectric strength tests were conducted ……: | 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 | | **P** |
| | - protective earth screens with a single turn have insulated overlap | | **P** |
| | - Exit of wires form internal windings of toroid transformers protected with double sleeving | | **P** |
| | - insulation between primary and secondary windings complies with 8.8.2 | | **P** |
| | - CREEPAGE DISTANCES and AIR CLEARANCE comply with 8.9.4 | | **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** | | **N/A** |
| | **RISKS associated with items addressed in RISK MANAGEMENT PROCESS as confirmed by review .:** | Not applicable to component power supply system; to be determined in the end product | **N/A** |
| **ANNEX G** | **PROTECTION AGAINST HAZARDS OF IGNITION OF FLAMMABLE ANESTHETIC MIXTURES** | | **N/A** |
| | Parts of CATEGORY APG ME EQUIPMENT in which a FLAMMABLE ANAESTHETIC 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 | Approved TIW is used in mains transformer. | **N/A** |
| **L.2** | **Wire construction** | | **N/A** |
| | Overlap of layers when wire is insulated with two or more spirally wrapped layers of tape is adequate to ensure continued overlap during manufacture of wound component | 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** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Temperature (°C) ..... : | | — |
| | Humidity (%)..... : | | — |
| L.3.1 | Dielectric strength | | **N/A** |
| | Dielectric strength test of Clause 8.8.3 for the appropriate type and number of MOP(s) conducted with no breakdown: | | **N/A** |
| | – 3000 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... : | | **N/A** |
| | – 6000 V for REINFORCED INSULATION (V)..... : | | **N/A** |
| **L.3.2** | **Flexibility and adherence** | | **N/A** |
| | Sample subjected to flexibility and adherence | | **N/A** |
| | Sample examined per IEC 60851-3: 1997, cl. 5.1.1.4, followed by dielectric test of cl. 8.8.3, with no breakdown | | **N/A** |
| | Test voltage was at least the voltage in Tables 6 and 7 but not less than the following: | | **N/A** |
| | – 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... : | | **N/A** |
| | – 3000 V for REINFORCED INSULATION (V) ..... : | | **N/A** |
| | Tension applied to wire during winding on mandrel calculated from the wire diameter equivalent to 118 MPa ± 11.8 MPa ..... : | | **N/A** |
| **L.3.3** | **Heat Shock** | | **N/A** |
| | Sample subjected to heat shock test 9 of IEC 60851-6:1996, followed by dielectric strength test of clause 8.8.3 | | **N/A** |
| | Test voltage was at least the voltage in Tables 6 and 7, but not less than the following: | | **N/A** |
| | – 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... : | | **N/A** |
| | – 3000 V for REINFORCED INSULATION (V) ..... : | | **N/A** |
| | Oven temperature based on Table L.2 (°C)..... : | | — |
| | Mandrel diameter and tension applied as in clause L.3.2, (MPa; N/mm$^2$) ..... : | | **N/A** |
| | Dielectric strength test conducted at room temperature after removal from the oven | | **N/A** |
| **L.3.4** | **Retention of electric strength after bending** | | **N/A** |
| | Five samples prepared as in L.3.2 subjected to dielectric strength and bending tests | | **N/A** |
| | Test voltage was at least the voltage in Tables 6 and 7, but not less than the following: | | **N/A** |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | – 1500 V for BASIC and SUPPLEMENTARY INSULATION (V) ..... : | | **N/A** |
| | – 3000 V for REINFORCED INSULATION (V) ..... : | | **N/A** |
| | Test voltage applied between the shot and conductor | | **N/A** |
| | Mandrel diameter and tension applied as in L.3.2, (MPa; N/mm$^2$)..... : | | **N/A** |
| **L.4** | **Tests during manufacture** | | **N/A** |
| L.4.1 | Production line dielectric strength tests done by the manufacture per L.4.2 and L.4.3..... : | 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: | | **N/A** |
| | – 1500 V r.m.s. or 2100 V peak for BASIC and SUPPLEMENTARY INSULATION (V)..... : | | **N/A** |
| | – 3000 V r.m.s. or 4200 V peak for REINFORCED INSULATION (V) ..... : | | **N/A** |
| L.4.3 | Sampling tests conducted using twisted pair samples (IEC 60851-5:1996, clause 4.4.1) ..... : | | **N/A** |
| | Minimum breakdown test voltage at least twice the voltage in Tables 6 and 7 but not less than: | | **N/A** |
| | – 3000 V r.m.s. or 4200 V peak for BASIC and SUPPLEMENTARY INSULATION..... : | | **N/A** |
| | – 6000 V r.m.s. or 8400 V peak for REINFORCED INSULATION ..... : | | **N/A** |

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

| 4.2.2 | RM RESULTS TABLE: General requirements for RISK MANAGEMENT | | | P |
|---|---|---|---|---|
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. paragraph/clause, version)** | | **Result - Remarks** | **Verdict** |
| | **General process** | **Particular Medical Device** | | |
| **4.1** | Risk management procedure GTQPR05000 A2 5.0 | — | Risk Management Process (excluding production and post-production) | **P** |
| **4.2** | Risk management procedure GTQPR05000 A2 5.0 | — | Adequate Resources | **P** |
| **4.2** | Risk management procedure GTQPR05000 A2 5.0 | — | Assignment of qualified personnel | **P** |
| **4.2** | Risk management procedure GTQPR05000 A2 5.0 | — | Policy for determining criteria for risk acceptability | **P** |
| **4.3** | — | Risk Management Report 2.0 | Competence of personnel | **P** |
| **4.4a** | — | Risk management plan GT-RMPLAN2013-012 | Risk Management Plan - the scope of the planned risk management activities | **P** |
| **4.4b** | — | Risk management plan GT-RMPLAN2013-012 | Risk Management Plan - assignment of responsibilities and authorities | **P** |
| **4.4c** | — | Risk management plan GT-RMPLAN2013-012 | Risk Management Plan - requirements for review of risk management activities | **P** |
| **4.4d** | — | Risk management plan GT-RMPLAN2013-012 | Risk Management Plan - criteria for risk acceptability | **P** |
| **4.4e** | — | Risk management plan GT-RMPLAN2013-012 | Risk Management Plan - a method to evaluate the overall residual risk, and criteria for acceptability of the overall residual risk | **P** |
| **4.4f** | — | Risk management plan GT-RMPLAN2013-012 | Risk Management Plan - activities for verification of the implementation and effectiveness of risk control measures | **P** |
| **4.5** | — | Risk management procedure GTQPR05000 A2 6.0 | Risk Management File | **P** |
| **5.1** | — | Risk management procedure GTQPR05000 A2 6.0 | Risk Analysis - Process | **P** |
| **5.2** | — | Risk management procedure GTQPR05000 A2 6.0 | Risk Analysis - Intended use and reasonably foreseeable misuse | **P** |

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

| 4.2.2 | RM RESULTS TABLE: General requirements for RISK MANAGEMENT | | | P |
|---|---|---|---|---|
| **Clause of ISO 14971** | **Document Ref. in RMF (Document No. paragraph/clause, version)** | | **Result - Remarks** | **Verdict** |
| | **General process** | **Particular Medical Device** | | |
| **5.3** | — | Risk Management Report GT-RM2013-012 6.1 | Risk Analysis - Identification of characteristics related to safety | **P** |
| **5.4** | — | Risk Management Report GT-RM2013-012 6.2 | Risk Analysis - Identification of hazards and hazardous situations | **P** |
| **5.5** | — | Risk Management Report GT-RM2013-012 6.4 | Risk Analysis - Risk estimation | **P** |
| **6** | — | Risk Management Report GT-RM2013-012 7 | Risk Evaluation | **P** |
| **7.1** | — | Risk Management Report GT-RM2013-012 8.1 | Risk Control - Risk control option analysis | **P** |
| **7.2** | — | Risk Management Report GT-RM2013-012 8.1 | Risk Control - Implementation of risk control measures | **P** |
| **7.3** | — | Risk Management Report GT-RM2013-012 8.2 | Risk Control - Residual risk evaluation | **P** |
| **7.4** | — | Risk Management Report GT-RM2013-012 8.3 | Risk Control - Benefit-risk analysis | **P** |
| **7.5a** | — | Risk Management Report GT-RM2013-012 8.1 | Risk Control - Risks arising from risk control measures (new hazards or hazardous situations introduced) | **P** |
| **7.5b** | — | Risk Management Report GT-RM2013-012 8.2 | Risk Control - Risks arising from risk control measures (estimated risks for previously identified hazardous situations affected) | **P** |
| **7.6** | — | Risk Management Report GT-RM2013-012 8.1 | Risk Control - Completeness of risk control | **P** |
| **8** | — | Risk Management Report GT-RM2013-012 10 | Evaluation of overall residual risk | **P** |
| **9** | — | GT-RM2013-012 A.0 | Risk management review | **P** |
| **Supplementary Information:**<br>**Document Ref should be with regards to the policy/procedure documents and documents containing Risk Management Process-specific output.** | | | | |

| 4.3 | **TABLE:** ESSENTIAL PERFORMANCE | 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** | | **85** | **50/60** | **0.399** | **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** | | **85** | **50/60** | **0.499** | **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** | | **85** | **50/60** | **0.454** | **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** | | **85** | **50/60** | **0.451** | **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** | **0.164** | **21.7** | **0.486** |
| **Model: GTM41061-1830** | | | | | | |
| **Normal condition** | | **85** | **50/60** | **0.443** | **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 |

| 5.9.2 | TABLE: Determination of ACCESSIBLE parts | | P |
|---|---|---|---|
| **Location** | **Determination method (NOTE1)** | **Comments** | |
| **Enclosure** | **Test finger, test hook** | **Can't insert** | |
| | | | |

**Supplementary information:**

[1)] NOTE: 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:**

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** | **Test Pass** |
| **Ink/other printing material or process ..... :** | | **Heat transfer print** | **Test Pass** |
| **Material (composition) of Warning Label ..... :** | | -- | **N/A** |
| **Ink/other printing material or process ..... :** | | -- | **N/A** |
| **Other ..... :** | | -- | **N/A** |

**Supplementary information:**

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

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

| 8.4.2 | TABLE: TABLE: Working Voltage / Power Measurement | | | | | P |
|---|---|---|---|---|---|---|
| Test supply voltage/frequency (V/Hz)[1] .....: | | | | | | 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 276V | -- | -- | -- | -- | For all models |
| Optocoupler primary to secondary | Max 240V | -- | -- | -- | -- | For all models |
| Y capacitor primary to secondary | Max 240V | -- | -- | -- | -- | For all models |
| Secondary output connector | -- | ≤60 Vdc | <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

[3] Voltage measurement of all conductive ACCESSIBLE PARTS of the SIP/SOP connection or separate power supply output connections to earth used a resistor of 10 kΩ + 500 Ω. See clause 8.4.2

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

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

| | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **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:** | | | | | | | | | | |

| **8.4.4** | **TABLE: Internal capacitive circuits – measurement of residual voltage or calculation of the stored charge in capacitive circuits (i.e., accessible capacitors or circuit parts) after de-energizing ME EQUIPMENT** | **N/A** |
|---|---|---|

| **Maximum allowable residual voltage (V) .....:** | **60 V** |
|---|---|
| **Maximum allowable stored charge when residual voltage exceeded 60 V .....:** | **45 μC** |

| **Description of the capacitive circuit (i.e., accessible capacitor or circuit parts)** | **Measured residual voltage (V)** | **Calculated stored charge (μC)** | **Remarks** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |
| **Supplementary information:** | | | |

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

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

| 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**

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

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

| Type of leakage current and test condition (including single faults) | Supply voltage (V) | Supply frequency (Hz) | Measured max. value (µA) | Remarks |
|---|---|---|---|---|
| Fig. 13 - Earth Leakage (ER) | — | — | — | Maximum allowed values:<br>5 mA NC; 10 mA SFC |
| -- | | | | |
| Fig. 14 - Touch Current (TC) | — | — | — | Maximum allowed values:<br>100 µA NC; 500 µA SFC |
| NC | 264 | 60 | 10.7 | For all models, from L/N to accessible enclosure, weighted data, after pre-treatment |
| SFC, interrupt one conductor | 264 | 60 | 21.3 | |
| SFC, one Y1 capacitor is short circuited. | 264 | 60 | 24.3 | |
| NC | 264 | 60 | 167.6 | For all models, from L/N to accessible enclosure, not weighted data, after pre-treatment |
| SFC, interrupt one conductor | 264 | 60 | 189.5 | |
| SFC, one Y1 capacitor is short circuited. | 264 | 60 | 195.2 | |
| NC | 264 | 60 | 59.2 | For all models, from L/N to output terminal (+), weighted data, after pre-treatment |
| SFC, interrupt one conductor | 264 | 60 | 61.3 | |
| SFC, one Y1 capacitor is short circuited. | 264 | 60 | 85.2 | |
| NC | 264 | 60 | 168.7 | For all models, from L/N to output terminal (+), not weighted data, after pre-treatment |
| SFC, interrupt one conductor | 264 | 60 | 198.6 | |
| SFC, one Y1 capacitor is short circuited. | 264 | 60 | 205.8 | |
| NC | 264 | 60 | 28.4 | For all models, from L/N to output terminal (-), weighted data, after pre-treatment |
| SFC, interrupt one conductor | 264 | 60 | 43.7 | |
| SFC, one Y1 capacitor is short circuited. | 264 | 60 | 61.6 | |
| NC | 264 | 60 | 165.7 | For all models, from L/N to output terminal (-), not weighted data, after pre-treatment |
| SFC, interrupt one conductor | 264 | 60 | 194.1 | |
| SFC, one Y1 capacitor is short circuited. | 264 | 60 | 200.4 | |
| Fig. 15 - Patient Leakage Current (P) | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current);<br>100 µA NC; 500 µA SFC (a.c.)<br>Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current) |
| -- | | | | |
| Fig. 16 - Patient leakage current with mains on the F-type applied parts (PM) | — | — | — | Maximum allowed values:<br>Type B: N/A<br>Type BF AP: 5000 µA<br>Type CF AP: 50 µA |

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

| Type of leakage current and test condition (including single faults) | Supply voltage (V) | Supply frequency (Hz) | Measured max. value (µA) | Remarks |
|---|---|---|---|---|
| -- | | | | |
| Fig. 17 - Patient leakage current with external voltage on Signal Input/Output part (SIP/SOP) | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC(d.c. current);<br>100 µA NC; 500 µA SFC (a.c.) ;<br>Type CF AP: 10 µA NC; 50 µA SFC (d.c. or a.c. current) |
| -- | | | | |
| Fig. 18 - Patient leakage current with external voltage on metal Accessible Part that is not Protectively Earthed | — | — | — | Maximum allowed values:<br>Type B or BF AP: 500 µA<br>Type CF: N/A |
| -- | | | | |
| Fig. 19 – Patient Auxiliary Current | — | — | — | Maximum allowed values:<br>Type B or BF AP: 10 µA NC; 50 µA SFC (d.c. current);<br>100 µA NC; 500 µA SFC (a.c.) ;<br>Type CF AP: 10 µA NC;50 µA SFC (d.c. or a.c. current) |
| -- | | | | |
| Fig. 15 and 20 – Total Patient Leakage Current with all AP of same type connected together | — | — | — | Maximum allowed values:<br>Type B or BF AP: 50 µA NC;<br>100µA SFC (d.c. current);<br>500 µA NC; 1000 µA SFC (a.c.);<br>Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current) |
| -- | | | | |
| Fig. 17 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on SIP/SOP | — | — | — | Maximum allowed values:<br>Type B or BF AP: 50 µA NC;<br>100µA SFC (d.c. current);<br>500 µA NC;1000 µA SFC (a.c.);<br>Type CF AP: 50 µA NC; 100 µA SFC (d.c. or a.c. current) |
| -- | | | | |
| Fig. 16 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on F-type AP | — | — | — | Maximum allowed values:<br>Type B: NA<br>Type BF: 5000 µA<br>Type CF: 100 µA |
| -- | | | | |
| Fig. 18 and 20 – Total Patient Leakage Current with all AP of same type connected together with external voltage on metal Accessible Part not Protectively Earthed | — | — | — | Maximum allowed values:<br>Type B & BF: 1000 µA<br>Type CF: N/A |
| -- | | | | |
| Function Earth Conductor Leakage Current (FECLC) | — | — | — | Maximum allowed values:<br>5 mA NC; 10 mA SFC |
| -- | | | | |
| **Supplementary information:**<br>Note 1: For EARTH LEAKAGE CURRENT see 8.7.3 d) and 8.7.4.5; | | | | |

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

| Type of leakage current and test condition (including single faults) | Supply voltage (V) | Supply frequency (Hz) | Measured max. value (µA) | Remarks |
|---|---|---|---|---|
| Note 2: For TOUCH CURRENT see 8.7.3 c) and 8.7.4.6;<br>Note 3: For PATIENT LEAKAGE CURRENT SEE 8.7.3.b) and 8.7.4.7<br>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.<br>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<br>TC – Touch current<br>P - Patient leakage current<br>PA – Patient auxiliary current<br>TP – Total Patient current<br>PM - Patient leakage current with mains on the applied parts<br>MD - Measuring device | | | A - After humidity conditioning<br>B - Before humidity conditioning<br>1 - Switch closed or set to normal polarity<br>0 - Switch open or set to reversed polarity<br>NC - Normal condition<br>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 |
| B | 2MOOP | 340 | -- | 3000 | No |
| C | 2MOPP | 340 | -- | 4000 | No |
| D | 2MOPP | 340 | -- | 4000 | No |
| E | 2MOPP | 340 | -- | 4000 | No |
| F | 2MOPP | 340 | -- | 4000 | No |
| G | 2MOPP | 340 | -- | 4000 | No |
| H | 2MOPP | 340 | -- | 4000 | No |

**Supplementary information:**

[1] Alternatively, per the Table (i.e., __dc), a d.c. test voltage equal to the peak value of the a.c. test voltage used.
[2] A) Immediately after humidity treatment of 5.7, ME EQUIPMENT de-energized, B) after required sterilization PROCEDURE, ME EQUIPMENT de-energized, C) after reaching steady state operating temperature as during heating test of 11.1.1, and D) after relevant tests of 11.6 (i.e., overflow, spillage, leakage, ingress of water, cleaning, disinfection, and sterilization).

| 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** | | |
| **945 (GG) 1** | **125** | **1.3** |
| **945 (GG) 2** | **125** | **1.3** |
| **Bobbin of Mains transformer** | | |
| **T375J** | **125** | **1.3** |
| **T375HF** | **125** | **1.2** |
| **4130** | **125** | **1.2** |
| **PM-9820** | **125** | **1.3** |
| **CP-J-8800** | **125** | **1.4** |

**Supplementary information:**

resistance to heat for insulation of thermoplastic materials that used as SUPPLEMENTARY INSULATION or REINFORCED INSULATION established by performing the ball-pressure test in at a temperature 25 °C higher than the temperature of the insulation measured during the tests of 13.2.2 to 13.2.13 (inclusive).

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

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

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

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

| 8.9.3.2 | **Table: Thermal cycling tests on one sample of insulating compound forming solid insulation between conductive parts** | **N/A** |
|---|---|---|

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

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

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

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

**Supplementary information:**

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

| 8.10 | TABLE: Critical components information | | | | P |
|---|---|---|---|---|---|
| **Object / part No.** | **Manufacturer/ trademark** | **Type / model** | **Technical data** | **Standard** | **Mark(s) of conformity[1)]** |
| Plug for power supply (for EU) | GlobTek,Inc. | Q-EU | Two-pole plug 2.5 A 250 V for Class II appliances | EN 50075 | Test report No. WTX25D0718 3782Z |
| Plug for power supply (for Australia) | GlobTek,Inc. | Q-SAA | Two-pole plug 10 A 250 V for Class II appliances | AS/NZS 3112 | Test report No. WTX24D0102 3115Z |
| PCB | WALEX ELECTRONIC (WUXI) CO LTD | T2, T4, T2A, T2B | Min. 1.6mm thickness, Min. V-0, Min. 130ºC | IEC/EN 60601-1 UL 796 | UL E154355 Tested with appliance |

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

| | | | | | |
|---|---|---|---|---|---|
| Alt. | SUZHOU CITY YILIHUA ELECTRONICS CO LTD | YLH-1 | Min. 1.6mm thickness, Min. V-0, Min. 130ºC | IEC/EN 60601-1<br>UL 796 | UL E251781<br>Tested with appliance |
| Alt. | Dafeng Arex Electronics Technology Co Ltd | 02V0, 03V0, 04V0 | Min. 1.6mm thickness, Min. V-0, Min. 130ºC | IEC/EN 60601-1<br>UL 796 | UL E186016<br>Tested with appliance |
| Alt. | SHENZHEN TONGCHUANGXIN ELECTRONICS CO LTD | TCX | Min. 1.6mm thickness, Min. V-0, Min. 130ºC | IEC/EN 60601-1<br>UL 796 | UL E250336<br>Tested with appliance |
| Alt.) | Interchangeable | Interchangeable | Min. V-0, min 1.6 mm thickness, 130°C | UL 796 | UL approved |
| Insulating tape wrapping around the PCB edge<br>(Optional) | 3M COMPANY | 1350F-1, 1350T-1, 44 | 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 |
| Fuse (F1, F2)<br>(F2 is optional.) | Conquer Electronics Co., Ltd. | MST | T2A, 250V | IEC/EN 60601-1<br>IEC 60127-1<br>IEC 60127-3<br>UL 248-1<br>UL 248-14 | VDE 40017118<br>UL E82636<br>Tested with appliance |
| Alt. | Suzhou Walter Electronic Co. Ltd. | 2010 | T2A, 250V | IEC/EN 60601-1<br>IEC 60127-1<br>IEC 60127-3<br>UL 248-1<br>UL 248-14 | VDE 40018781<br>UL E56092<br>Tested with appliance |

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

| | | | | | |
|---|---|---|---|---|---|
| Alt. | Bel Fuse Ltd. | RST | T2A, 250V | IEC/EN 60601-1<br>IEC 60127-1<br>IEC 60127-3<br>UL 248-1<br>UL 248-14 | VDE 40011144<br>UL E20624<br>Tested with appliance |
| Alt. | Shenzhen Lanson Electronics Co. Ltd. | SMT | T2A, 250V | IEC/EN 60601-1<br>IEC 60127-1<br>IEC 60127-3<br>UL 248-1<br>UL 248-14 | VDE 40012592<br>UL E221465<br>Tested with appliance |
| X capacitor (CX1) (optional) | Cheng Tung Industrial Co., Ltd. | CTX | Max. 0.47µF, Min. 250V, min. 105°C Min. X2 type | IEC/EN 60601-1<br>IEC/EN 60384-14<br>UL 60384-14 | ENEC 15 (ENEC-02671-M1)<br>UL E193049<br>Tested with appliance |
| Alt. | Tenta Electric Industrial Co. Ltd. | MEX | Max. 0.47µF, Min. 250V, min. 105°C Min. X2 type | IEC/EN 60601-1<br>IEC/EN 60384-14<br>UL 60384-14 | VDE 119119<br>UL E222911<br>Tested with appliance |
| Alt. | Ultra Tech Xiphi Enterprise Co. Ltd. | HQX | Max. 0.47µF, Min. 250V, min. 105°C Min. X2 type | IEC/EN 60601-1<br>IEC/EN 60384-14<br>UL 60384-14 | VDE 40015608<br>UL E183780<br>Tested with appliance |
| Alt. | Dain Electronics Co., Ltd. | MPX, MEX, NPX | Max. 0.47µF, Min. 250V, min. 105°C Min. X2 type | IEC/EN 60601-1<br>IEC/EN 60384-14<br>UL 60384-14 | VDE 40018798<br>UL E147776<br>Tested with appliance |
| Alt. | Sinhua Electronics (Huzhou) Co., Ltd. | MPX | Max. 0.47µF, Min. 250V, min. 105°C Min. X2 type | IEC/EN 60601-1<br>IEC/EN 60384-14<br>UL 60384-14 | VDE 40014686<br>UL E237560<br>Tested with appliance |
| Alt. | Shantou High-New Technology Dev. Zone Songtian Enterprise Co., Ltd. | MPX | Max. 0.47µF, Min. 250V, min. 105°C Min. X2 type | IEC/EN 60601-1<br>IEC/EN 60384-14<br>UL 60384-14 | VDE 40034679<br>UL E208107<br>Tested with appliance |
| Y-Capacitor (CY1, CY2) (optional) | TDK Corporation | CD | Max.1000pF, Min. 250V, Min. 125°C, Y1 type | IEC/EN 60601-1<br>IEC/EN 60384-14,<br>UL 60384-14 | VDE 40029780<br>UL E37861<br>Tested with appliance |

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

| | | | | | |
|---|---|---|---|---|---|
| Alt. | Success Electronics Co., Ltd. | SE, SB | Max.1000pF, Min. 250V, Min. 125°C, Y1 type | IEC/EN 60601-1 IEC/EN 60384-14, UL 60384-14 | VDE 40008996 UL E114280 UL E530176 Tested with appliance |
| Alt. | Walsin Technology Corp. | AH | Max.1000pF, Min. 250V, Min. 125°C, Y1 type | IEC/EN 60601-1 IEC/EN 60384-14, UL 60384-14 | VDE 40001804 UL E146544 Tested with appliance |
| Alt. | Haohua Electronic Co. | CT7 | Max.1000pF, Min. 250V, Min. 125°C, Y1 type | IEC/EN 60601-1 IEC/EN 60384-14, UL 60384-14 | VDE 40003902 UL E233106 Tested with appliance |
| Alt. | Murata Mfg. Co., Ltd. | KX | Max.1000pF, Min. 250V, Min. 125°C, Y1 type | IEC/EN 60601-1 IEC/EN 60384-14, UL 60384-14 | VDE 40002831 UL E37921 Tested with appliance |
| Alt. | JYA-NAY CO LTD | JN | Max.1000pF, Min. 250V, Min. 125°C, Y1 type | IEC/EN 60601-1 IEC/EN 60384-14, UL 60384-14 | VDE 40001831 UL E201384 Tested with appliance |
| Alt. | Guangdong Huiwan Electronics Technology Co Ltd | AR | Min.125°C, Max.1000pF Min.500V, Y1 | IEC/EN 60601-1 IEC/EN 60384-14, UL 60384-14 | VDE 40043989 UL E480105 Tested with appliance |
| Alt. | SHANTOU HIGH-NEW TECHNOLOGY DEVELOPMNT ZONE SONGTIAN ENTERPRISE CO LTD | CD | Min.125℃, Max.1000pF, Min.250V, Y1 type | IEC/EN 60601-1 IEC/EN 60384-14, UL 60384-14 | VDE 40025754 UL E208107 Tested with appliance |
| Varistor (MOV1, MOV2) (optional) | SHANTOU HIGH-NEW TECHNOLOGY DEVELOPMNT ZONE SONGTIAN ENTERPRISE CO LTD | 10D621K 14D621K | Max. Continuous voltage: 385Vac(rms), Min. 125°C, The coating is Min. V-0 | IEC/EN 60601-1 IEC/EN 61051-1 IEC/EN 61051-2 UL 1449 | VDE 40023049 UL E330837 Tested with appliance |

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

| | | | | | |
|---|---|---|---|---|---|
| Alt. | Guangdong Huiwan Electronics Technology Co.Ltd. | V-621K-10DEH<br>V-621K-14DEH for VDE<br>V-621K-10D, V-621K-14D for UL | Max. Continuous voltage: 385Vac(rms), Min. 125°C,<br>The coating is Min. V-0 | IEC/EN 60601-1<br>IEC/EN 61051-1<br>IEC/EN 61051-2<br>UL 1449 | VDE 40043880<br>UL E480104<br>Tested with appliance |
| Alt. | Thinking Electronic Industrial Co., Ltd. | TVR10621<br>TVR14621 | Max. Continuous voltage:<br>395Vac(rms),<br>Min. 125°C,<br>The coating is Min. V-0 | IEC/EN 60601-1<br>IEC/EN 61051-1<br>IEC/EN 61051-2<br>UL 1449 | VDE 005944<br>UL E314979<br>Tested with appliance |
| Alt. | Xiamen Set Electronics Co.,Ltd | TFV8S471K | Max. Continuous voltage: 300Vac(rms), Min. 105°C,<br>The coating is Min. V-0 | IEC/EN 60601-1<br>IEC 61051-1,<br>IEC 61051-2,<br>IEC 61051-2-2, | TUV-RH J 50554061<br>UL E322662<br>Tested with appliance |
| Alt. | Xiamen Set Electronics Co.,Ltd | TFV10S471K | Max. Continuous voltage: 300Vac(rms), Min. 105°C,<br>The coating is Min. V-0 | IEC/EN 60601-1<br>IEC 61051-1,<br>IEC 61051-2,<br>IEC 61051-2-2,<br>IEC 62368-1<br>UL 1449 | TUV-RH J 50554091<br>UL E322662<br>Tested with appliance |
| Alt. | GUANGDONG JORDUN ELECTRONIC CO., LTD. | VCRR10D621K #<br>VCCR14D621K # | Max. Continuous voltage: 385Vac(rms), Min. 125°C,<br>The coating is Min. V-0 | IEC/EN 60601-1<br>IEC/EN 61051-1<br>IEC/EN 61051-2<br>UL 1449 | TUV-SUD B 119967 0002<br>UL E531647<br>Tested with appliance |
| Optocoupler (U1) | Everlight Electronics Co., Ltd. | EL817 | External Cr. & Cl. ≥7.6mm<br>DTI ≥0.4mm<br>Min. 110°C<br>Thermal cycling test | IEC/EN 60747-5-2<br>IEC/EN 60950-1<br>UL 1577<br>IEC/EN 60601-1 | VDE 132249<br>UL E214129<br>Tested with appliance |
| Alt. | LITE-ON Technology Corporation | LTV-817 | External Cr. & Cl. ≥7.0mm<br>DTI ≥0.4mm<br>Min. 115°C<br>Thermal cycling test | IEC/EN 60747-5-2<br>IEC/EN 60950-1<br>UL 1577<br>IEC/EN 60601-1 | VDE 40015248<br>UL E113898<br>Tested with appliance |
| Alt. | Bright Led Electronics Corp. | BPC-817 A/B/C/D/L<br>BPC-817 M<br>BPC-817 S | External Cr. & Cl. ≥7.6mm<br>DTI ≥0.4mm<br>Min. 110°C<br>Thermal cycling test | IEC/EN 60747-5-2<br>IEC/EN 60950-1<br>UL 1577<br>IEC/EN 60601-1 | VDE 40007240<br>UL E236324<br>Tested with appliance |

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

| | | | | | |
|---|---|---|---|---|---|
| Alt. | Sharp Corporation | PC817 | External<br>Cr. & Cl. ≥6.4mm<br>DTI ≥0.4mm<br>Min. 110°C<br>Thermal cycling test | IEC/EN 60747-5-5<br>UL 1577<br>IEC/EN 60601-1 | VDE 40008087<br>UL E64380<br>Tested with appliance |
| Line filter (LF1) (Optional) | GlobTek BOAM HAOPUWEI HEJIA | NF00030 | Min. 130°C | IEC/EN 60601-1 | Tested with appliance |
| Plastic Enclosure and Plug holder material | SABIC INNOVATIVE PLASTICS B V | 945 (GG) | Min. V-0,<br>Min. thickness: 2.0mm, 120°C | IEC/EN 60601-1<br>UL 94<br>UL 746 | Tested with appliance<br>UL E45329 |
| Alt. | SABIC JAPAN L L C | 945 (GG) | Min. V-0,<br>Min. thickness: 2.0mm, 120°C | IEC/EN 60601-1<br>UL 94<br>UL 746 | Tested with appliance<br>UL E207780 |
| Output cable | GlobTek Inc | 1185 | VW-1, 300V,<br>Min.22AWG,<br>min.80°C | IEC/EN 60601-1<br>UL 758 | Tested with appliance<br>UL E464257 |
| Alt. | Interchangeable | Interchangeable | VW-1 or FT-1,<br>Min 80°C,<br>Min. 60V,<br>Min. 22AWG | UL 758 | UL approved |
| Transformer (T1) | GlobTek BOAM Haopuwei | TF001 (For output 5-12vdc))<br>TF002 (For output 12.1-18Vdc)<br>TF003 (For 18.1-24Vdc)<br>TF004 (For 24.1-30Vdc) | Class E, with critical component listed below | IEC/EN 60601-1 | Tested with appliance |
| -Triple-insulated wire | Great Leoflon Industrial Co., Ltd. | TRW (B)*,<br>TRW(B)-I* | Min.130°C | IEC/EN 60601-1<br>UL 2353 | UL E211989<br>Tested with appliance |
| -Alt. | TOTOKU INC | THL-F-xx,<br>THL-F-SB-xx | Min.130°C | IEC/EN 60601-1<br>UL 2353 | UL E166483<br>Tested with appliance |
| -Alt. | HOI LUEN ELECTRICAL MFR CO LTD | T375J<br>T375HF | Min.155°C | IEC/EN 60601-1<br>UL 2353 | UL E257525<br>Tested with appliance |
| -Alt. | Furukawa Electric Co., Ltd | TEX-E | 130°C | IEC/EN 60601-1<br>UL 2353 | UL E206440<br>Tested with appliance |

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

| | | | | | |
|---|---|---|---|---|---|
| -Alt. | KBI COSMOLINK CO., LTD. | TIW-M(XX) | Min.130°C | IEC/EN 60601-1<br>UL 2353 | UL E213764<br>Tested with appliance |
| -Alt. | Great Leoflon Industrial Co., Ltd. | TRW (B)*, TRW(B)-I* | Min.130°C | IEC/EN 60601-1<br>UL 2353 | UL E211989<br>Tested with appliance |
| -Bobbin | CHANG CHUN PLASTICS CO LTD | T375J, T375HF | Phenolic, V-0, Min. 150°C, Min. 0.45mm thickness | IEC/EN 60601-1<br>UL 94<br>UL 746 | UL E59481<br>Tested with appliance |
| -Alt. | CHANG CHUN PLASTICS CO LTD | 4130 | PBT, V-0, Min. 140°C, Min. 0.45mm thickness | IEC/EN 60601-1<br>UL 94<br>UL 746 | UL E59481<br>Tested with appliance |
| -Alt. | SUMITOMO BAKELITE CO LTD | PM-9820 | Phenolic, V-0, Min. 150°C, Min. 0.45mm thickness | IEC/EN 60601-1<br>UL 94<br>UL 746 | UL E41429<br>Tested with appliance |
| -Alt. | Resonac Techno Service Corporation | CP-J-8800 | Phenolic, V-0, Min. 150°C, Min. 0.45mm thickness | IEC/EN 60601-1<br>UL 94<br>UL 746 | UL E514814<br>Tested with appliance |
| -Insulating tape | 3M COMPANY | 1350F-1, 1350T-1, 44 | 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 |

**Supplementary information:**

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

For all transformers and all filters under all manufacturers

2) Plug test report for EU and Australia has been provided. For requirements for other countries, an approved plug for power supply which complies with relevant national requirements, will be provided by the manufacturer when marketing in the specified countries.

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

| 8.10 b | TABLE: List of identified components with HIGH INTEGRITY CHARACTERISTICS | | | | N/A |
|---|---|---|---|---|---|
| **Object / part No.** | **Manufacturer/ trademark** | **Type / model** | **Technical data** | **Standard** | **Mark(s) of conformity[1)]** |
| | | | | | |
| | | | | | |

Supplementary information:

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

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

Supplementary information:

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

Supplementary information:

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

| 9.2.3.2 | TABLE: Over-travel End Stop Test | 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 |
|---|---|---|

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

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

| | | |
|---|---|---|
| **9.7.5** | **TABLE: Pressure vessels** | **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** |

| | | |
|---|---|---|
| **10.1.1** | **TABLE: Measurement of X - radiation** | **N/A** |

| **11.1.1** | **TABLE: Excessive temperatures in ME EQUIPMENT** | | | | | **P** |
|---|---|---|---|---|---|---|
| **Model No. .....:** | **See below** | **--** | **--** | **--** | | **--** |
| **Test ambient (°C) .....:** | **See below** | **--** | **--** | **--** | | **--** |
| **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: 85Vac / 60Hz, GTM41061-1812-7.0, output 5Vdc/3.6A** | | | | | |
| **1** | **1** | **CX1 body** | **100** | **58.9** | **See table 8.10** |
| **1** | **2** | **LF1** | **105** | **78.5** | **--** |
| **1** | **3** | **C1 body** | **105** | **71.2** | **T marking on capacitor body** |
| **1** | **4** | **CY1 body** | **85** | **69.4** | **--** |
| **1** | **5** | **U1 body** | **100** | **70.1** | **See table 8.10** |
| **1** | **6** | **T1 winding** | **110** | **77.4** | **Thermocouples are used, so the limit is to be reduced by 10°C.** |
| **1** | **7** | **T1 core** | **120** | **73.5** | **--** |
| **1** | **8** | **PCB near D7** | **130** | **75.8** | **See table 8.10** |
| **1** | **9** | **PCB near primary heatsink** | **130** | **63.8** | **See table 8.10** |

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

| | | | | | |
|---|---|---|---|---|---|
| **1** | **10** | **Plastic enclosure** | **60** | **45.2** | **Table 23 used, enclosure is likely to be touched for 10s to 1min.** |
| **1** | **11** | **Output cord inside enclosure** | **70** | **33.5** | **8.10.7 c)** |
| **1** | **12** | **Tamb** | **--** | **30.0** | **--** |
| **Input: 264Vac / 60Hz, GTM41061-1812-7.0, output 5Vdc/3.6A** | | | | | |
| **1** | **1** | **CX1 body** | **100** | **59.8** | **See table 8.10** |
| **1** | **2** | **LF1** | **105** | **61.7** | **--** |
| **1** | **3** | **C1 body** | **105** | **69.7** | **T marking on capacitor body** |
| **1** | **4** | **CY1 body** | **85** | **69.1** | **--** |
| **1** | **5** | **U1 body** | **100** | **73.4** | **See table 8.10** |
| **1** | **6** | **T1 winding** | **110** | **85.4** | **Thermocouples are used, so the limit is to be reduced by 10°C.** |
| **1** | **7** | **T1 core** | **120** | **81.4** | **--** |
| **1** | **8** | **PCB near D7** | **130** | **79.4** | **See table 8.10** |
| **1** | **9** | **PCB near primary heatsink** | **130** | **75.8** | **See table 8.10** |
| **1** | **10** | **Plastic enclosure** | **60** | **47.5** | **Table 23 used, enclosure is likely to be touched for 10s to 1min.** |
| **1** | **11** | **Output cord inside enclosure** | **70** | **35.4** | **8.10.7 c)** |
| **1** | **12** | **Tamb** | **--** | **30.0** | **--** |
| **Input: 85Vac / 60Hz, GTM41061-1512-7.0, output 5Vdc/3.0A** | | | | | |
| **1** | **1** | **CX1 body** | **100** | **69.4** | **See table 8.10** |
| **1** | **2** | **LF1** | **105** | **87.1** | **--** |
| **1** | **3** | **C1 body** | **105** | **84.1** | **T marking on capacitor body** |
| **1** | **4** | **CY1 body** | **85** | **80.4** | **--** |
| **1** | **5** | **U1 body** | **100** | **79.5** | **See table 8.10** |
| **1** | **6** | **T1 winding** | **110** | **90.4** | **Thermocouples are used, so the limit is to be reduced by 10°C.** |

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

| | | | | | |
|---|---|---|---|---|---|
| **1** | **7** | **T1 core** | **120** | **86.9** | **--** |
| **1** | **8** | **PCB near D7** | **130** | **83.9** | **See table 8.10** |
| **1** | **9** | **PCB near primary heatsink** | **130** | **72.8** | **See table 8.10** |
| **1** | **10** | **Plastic enclosure** | **60** | **55.4** | **Table 23 used, enclosure is likely to be touched for 10s to 1min.** |
| **1** | **11** | **Output cord inside enclosure** | **70** | **45.4** | **8.10.7 c)** |
| **1** | **12** | **Tamb** | **--** | **40.0** | **--** |
| **Input: 264Vac / 60Hz, GTM41061-1512-7.0, output 5Vdc/3.0A** | | | | | |
| **1** | **1** | **CX1 body** | **100** | **69.4** | **See table 8.10** |
| **1** | **2** | **LF1** | **105** | **71.2** | **--** |
| **1** | **3** | **C1 body** | **105** | **82.5** | **T marking on capacitor body** |
| **1** | **4** | **CY1 body** | **85** | **77.7** | **--** |
| **1** | **5** | **U1 body** | **100** | **83.7** | **See table 8.10** |
| **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** | **91.5** | **--** |
| **1** | **8** | **PCB near D7** | **130** | **88.9** | **See table 8.10** |
| **1** | **9** | **PCB near primary heatsink** | **130** | **82.7** | **See table 8.10** |
| **1** | **10** | **Plastic enclosure** | **60** | **55.1** | **Table 23 used, enclosure is likely to be touched for 10s to 1min.** |
| **1** | **11** | **Output cord inside enclosure** | **70** | **45.4** | **8.10.7 c)** |
| **1** | **12** | **Tamb** | **--** | **40.0** | **--** |
| **Input: 85Vac / 60Hz, GTM41061-1830, output 30Vdc/0.6A** | | | | | |
| **1** | **1** | **CX1 body** | **100** | **60.9** | **See table 8.10** |
| **1** | **2** | **LF1** | **105** | **81.0** | **--** |
| **1** | **3** | **C1 body** | **105** | **75.5** | **T marking on capacitor body** |
| **1** | **4** | **CY1 body** | **85** | **74.1** | **--** |
| **1** | **5** | **U1 body** | **100** | **72.9** | **See table 8.10** |

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

| | | | | | |
|---|---|---|---|---|---|
| **1** | **6** | **T1 winding** | **110** | **80.2** | **Thermocouples are used, so the limit is to be reduced by 10°C.** |
| **1** | **7** | **T1 core** | **120** | **77.9** | **--** |
| **1** | **8** | **PCB near D7** | **130** | **80.1** | **See table 8.10** |
| **1** | **9** | **Plastic enclosure** | **60** | **50.9** | **Table 23 used, enclosure is likely to be touched for 10s to 1min.** |
| **1** | **10** | **Output cord inside enclosure** | **70** | **40.9** | **8.10.7 c)** |
| **1** | **11** | **Tamb** | **--** | **40.0** | **--** |
| **Input: 264Vac / 60Hz, GTM41061-1830, output 30Vdc/0.6A** | | | | | |
| **1** | **1** | **CX1 body** | **100** | **57.9** | **See table 8.10** |
| **1** | **2** | **LF1** | **105** | **78.9** | **--** |
| **1** | **3** | **C1 body** | **105** | **72.9** | **T marking on capacitor body** |
| **1** | **4** | **CY1 body** | **85** | **72.1** | **--** |
| **1** | **5** | **U1 body** | **100** | **70.2** | **See table 8.10** |
| **1** | **6** | **T1 winding** | **110** | **74.9** | **Thermocouples are used, so the limit is to be reduced by 10°C.** |
| **1** | **7** | **T1 core** | **120** | **75.4** | **--** |
| **1** | **8** | **PCB near D7** | **130** | **78.1** | **See table 8.10** |
| **1** | **9** | **Plastic enclosure** | **60** | **50.1** | **Table 23 used, enclosure is likely to be touched for 10s to 1min.** |
| **1** | **10** | **Output cord inside enclosure** | **70** | **40.7** | **8.10.7 c)** |
| **1** | **11** | **Tamb** | **--** | **40.0** | **--** |

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

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 85 % 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 85 % of the minimum RATED voltage.

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

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

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

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

| 11.2.2.1 | TABLE: Alternative method to 11.2.2.1 a) 5) to determine existence of an ignition source | N/A |
|---|---|---|

| 11.6.1 | TABLE: overflow, spillage, leakage, ingress of water, cleaning, disinfection, sterilization, compatibility with substances | P |
|---|---|---|

| Clause / Test Name | Test Condition | Part under test | Remarks |
|---|---|---|---|
| **11.6.5** | **Test the EUT in accordance with the IP21 test requirements** | **Whole EUT** | **Following completion of the test, no dust or water ingress was detected in the EUT, no risk.** |
| **11.6.6** | **Clean the EUT in accordance with the instructions** | **Whole EUT** | **Cleaning will not cause damage to the casing or pose an electric shock hazard, no risk.** |
| | | | |

Supplementary information:

Information from Risk Management, as applicable:

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

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

| Part or component tested | Measured power dissipated (W) | Calculated energy dissipated (J) | SINGLE FAULT CONDITIONS waived (Yes/No) | Remarks |
|---|---|---|---|---|
| | | | | |
| | | | | |
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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |

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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 Cl. 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-circuited** | **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** |

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

| Clause No. | Description of SINGLE FAULT CONDITION | Results observed | HAZARDOUS SITUATION (Yes/No) |
|---|---|---|---|
| 13.2.6 | Leakage of liquid - RISK MANAGEMENT FILE examined to determine the appropriate test conditions (sealed rechargeable batteries exempted) | — | — |
| | | No Leakage of liquid | No |
| 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 motor | V MEASURED = | N/A |
| | | V MEASURED = | |
| 13.2.10 | Additional test criteria for motor operated me equipment in 13.2.8 &13.2.9: | — | — |
| | For every test in single fault condition of 13.2.8 and 13.2.9, motor-operated equipment stared from cold condition at rated voltage or upper limit of rated voltage range for specified time: | NO MOTOR | 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 |

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

| Clause No. | Description of SINGLE FAULT CONDITION | Results observed | HAZARDOUS SITUATION (Yes/No) |
|---|---|---|---|
| | | | |
| **13.2.12** | **Failure of parts that might result in a mechanical hazard (See 9 & 15.3):** | **—** | **—** |
| | **See clause 9 and clause 15.3** | **TO BE CHECKED ON END PRODUCT** | **N/A** |
| | | | |

Supplementary information:
[1] Test with short-circuited capacitor not performed when motor provided with a capacitor complying with IEC 60252-1 and the ME EQUIPMENT not intended for unattended use including automatic or remote control. See Attachment # and appended Table 8.10.

Information from Risk Management, as applicable:

| 15.3 | TABLE: Mechanical Strength tests [1] | | P |
|---|---|---|---|
| **Clause** | **Name of Test** | **Test conditions** | **Observed results/Remarks** |
| **15.3.2** | **Push Test** | **Force = 250 N ± 10 N for 5 s** | **No damage** |
| **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** | **Drop Test** | **Free fall height (m) = 1 m** | **No damage** |
| **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** |
| | | | |

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

| 15.4.6 | TABLE: actuating parts of controls of ME EQUIPMENT – torque & axial pull tests | N/A |
|---|---|---|

| 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 85 % to 110 % of RATED voltage)(V)[1] ...** | | | | | | **264 Vac** | **—** |
| **RATED input frequency (Hz)** ..... | | | | | | **60 Hz** | **—** |
| **Winding tested** | **Class of insulation (A, B, E, F, or H)** | **Type of protective device (fuse, circuit breaker) /Ratings** | **Protective device operated Yes/No** | **Time to THERMAL STABILITY (when protective device did not operate) (Min)** | **Maximum allowed temp from Table 31 (ºC)** | **Maximum winding temp measured (ºC)** | **Ambient (ºC)** |
| **TF001** | **B** | **Fuse 2.0A(S.C. current 0.01A)** | **No** | **5 mins[2]** | **175[3]** | **32.1** | **25** |
| **TF002** | **B** | **Fuse 2.0A(S.C. current 0.01A)** | **No** | **5 mins[2]** | **175[3]** | **31.1** | **25** |

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

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **TF003** | **B** | **Fuse 2.0A(S.C. current 0.01A)** | **No** | **5 mins[2]** | **175[3]** | **30.2** | **25** |
| **TF004** | **B** | **Fuse 2.0A(S.C. current 0.01A)** | **No** | **5 mins[2]** | **175[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 by 10 ºC.

| **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 85 % to 110 % of RATED voltage (V)[1)].....:** | | **264 Vac** |
| **RATED input frequency (Hz).....:** | | **60 Hz** |
| **Test current just below minimum current that would activate protective device and 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** | **B** | **Fuse 2.0A (OL current 0.453A)** | **175[3]** | **78.6** | **25** |
| **TF002** | **B** | **Fuse 2.0A (OL current 0.433A)** | **175[3]** | **76.8** | **25** |
| **TF003** | **B** | **Fuse 2.0A (OL current 0.443A)** | **175[3]** | **77.2** | **25** |
| **TF004** | **B** | **Fuse 2.0A (OL current 0.438A)** | **175[3]** | **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.

| **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*** | **1200** | **300** | **No** | **No** |
| **All models** | **Primary winding & frame** | **1200** | **300** | **No** | **No** |

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

| | | | | | |
|---|---|---|---|---|---|
| **All models** | **Secondary winding & frame** | **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<br>The other tests were completed in clause 8.8.3. | | | | | |

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

| **SP** | **TABLE: Additional or special tests conducted** | **N/A** |
|---|---|---|

| Clause and Name of Test | Test type and condition | Observed results |
|---|---|---|
| | | |
| | | |
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Supplementary information:

**ATTACHMENT 1: USA national differences**

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **ATTACHMENT TO TEST REPORT**<br>**IEC 60601-1:2005, IE60601-1:2005/AMD1:2012, IEC60601-1:2005/AMD2:2020**<br>**US NATIONAL DIFFERENCES**<br>**Medical electrical equipment - Part 1: General requirements for basic safety and essential performance** | | | |
| **Differences according to**.....: | National standard AAMI ES60601-1:2005,<br>AAMI ES60601-1:2005/AMD1:2012, AAMI ES60601-1:2005/AMD2:2021 | | |
| **TRF template used: .....:** | IECEE OD-2020-F3:2022, Ed. 1.2 | | |
| **Attachment Form No**.....: | US_ND_IEC60601_1U | | |
| **Attachment Originator .....**: | UL Solutions (US) | | |
| **Master Attachment**.....: | 2024-05-17 | | |
| **Copyright © 2024 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.** | | | |
| | **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 |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | *(Addition to reflect agreement with NFPA 70)*<br>X-Ray systems are marked as long time operation or momentary operation. | | N/A |
| 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. | | 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. | Not such device | 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 | | 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 |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| 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 | | 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. | | 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 |
| 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 |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| 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 |

**ATTACHMENT 2: Canada national differences**

| IEC60601_1U ATTACHMENT | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **ATTACHMENT TO TEST REPORT**<br>**IEC 60601-1**<br>**CANADA NATIONAL DIFFERENCES**<br>Medical electrical equipment — Part 1: General requirements for basic safety and essential performance | | | |
| **Differences according to**.....: | Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14 | | |
| **TRF template used: .....:** | IECEE OD-2020-F3, Ed. 1.1 | | |
| **Attachment Form No**.....: | CA_ND_IEC60601_1U | | |
| **Attachment Originator .....**: | CSA Group | | |
| **Master Attachment**.....: | Dated 2022-08-12 | | |
| **Copyright © 2022 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.** | | | |
| **Note *: IEC CANADIAN NATIONAL DIFFERENCES in Canada are called CANADIAN DEVIATIONS.** | | | |
| | **Canadian National Differences** | | P |
| **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 |

| IEC60601_1U ATTACHMENT | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | *[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 |
| | In this CSA Group adoption, any reference to International Standards shall be replaced by the relevant National Standard of Canada.<br><br>**Note 1DV:** *For additional information about normative Standards in Canada, refer to the* Canadian Electrical Code, Part I, *Appendix A.*<br><br>Where reference is made to CSA Group Standards, such reference are considered to refer 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><br>B51-09<br>Boiler, pressure vessel, and pressure piping code<br><br>C22.1-21<br>Canadian Electrical Code, Part I<br><br>C22.2 No. 0:20<br>General requirements — Canadian Electrical Code, Part II<br><br>C22.2 No. 0.4-17<br>*Bonding of electrical equipment*<br><br>C22.2 No. 21-95 (R2009)<br>Cord sets and power supply cords<br><br>C22.2 No. 42-10<br>General use receptacles, attachment plugs, and similar wiring devices<br><br>C22.2 No. 49-10<br>Flexible cords and cables<br><br>C22.2 No. 100:14 (R2019) | | P |

| IEC60601_1U ATTACHMENT | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | *Motors and generators*<br><br>C22.2 No. 248 series of Standards<br>Low-voltage fuses<br><br>C22.2 No. 308-18<br>Cord reels and multi-outlet assemblies<br><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><br>CSA C22.2 No. 62368-1:19<br>Audio/video, information and communication technology equipment — Part 1: Safety requirements<br><br>Z32-09<br>Electrical safety and essential electrical systems in health care facilities<br><br>CAN/CSA-Z305.8-03 (R2013)<br>Medical supply units<br><br>Z305.12-06 (R2012)<br>Safe storage, handling, and use of portable oxygen systems in residential buildings and health care facilities<br><br>Z305.13-09<br>Plume scavenging in surgical, diagnostic, therapeutic, and aesthetic settings<br><br>CAN/CSA-Z5359-10<br>Low-pressure hose assemblies for use with medical gases<br><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><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><br>CAN/CSA-Z15002:12<br>Flow-metering devices for connection to terminal | | |

| IEC60601_1U ATTACHMENT | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | units of medical gas pipeline systems<br><br>**ASME (American Society of Mechanical Engineers)**<br><br>PTC 25-2008<br>Pressure Relief Devices<br><br>**CGA (Compressed Gas Association)**<br><br>V-1-2013<br>Standard for Compressed Gas Cylinder Valve Outlet and Inlet Connections<br><br>V-5-2008 (reaffirmed 2013)<br>Diameter Index Safety System (Noninterchangeable Low Pressure Connections for Medical Gas Applications)<br><br>**ISO (International Organization for Standardization)**<br><br>32:1977<br>Gas cylinders for medical use — Marking for identification of content<br><br>407:2004<br>Small medical gas cylinders — Pin-index yoke-type valve connections<br><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 in the Canadian deviations in the adopted Standard with the following]*<br><br>voltage above 1000 V ac for ac circuits or voltage above 1060 V dc for dc circuits, as defined in the *Canadian Electrical Code, Part I* | No such high voltage in this EUT | N/A |
| **4.** | **General requirements** | | P |
| **4.1A** | *[Add the following clause]*<br><br>General requirements applicable to ME EQUIPMENT and ME SYSTEMS are provided in CAN/CSA-C22.2 No. 0. | | P |
| **4.8** | **Components of ME EQUIPMENT** | | P |

| IEC60601_1U ATTACHMENT | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | *[Replace Items a) and b) and Note 2 with the following]* | UL approved | P |
| | a) The applicable safety requirements of a relevant CSA Group, IEC, or ISO Standard; or | | 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 shall be in accordance with the Canadian Electrical Code, Part I, and the following RATED voltages shall not be exceeded: | | P |
| **7.** | **ME EQUIPMENT identification, marking and documents** | | P |
| 7.5 | **Safety signs** | | P |
| | *[Replace the paragraph starting with "When supplementary text" in IEC Amendment 1 with the following]*<br><br>When supplementary text is placed together with safety signs, the supplementary text shall be in English and French for the intended OPERATOR. | It has been confirmed that the requirements for French-speaking regions have been met. | P |
| **7.7** | **Colours of the insulation of conductors** | | N/A |
| **7.7.1** | **PROTECTIVE EARTH CONDUCTOR** | | N/A |
| | *[Replace Clause 7.7.1 in the adopted Standard with the following]*<br><br>A PROTECTIVE EARTH CONDUCTOR shall be identified throughout its length by green or green and yellow coloured insulation. | No insulated wiring has been used before the transformer. | N/A |
| **7.7.2** | **PROTECTIVE EARTH CONNECTIONS** | | N/A |
| | *[Replace Clause 7.7.2 in the adopted Standard with the following]*<br><br>A PROTECTIVE EARTH CONDUCTOR or a PROTECTIVE EARTH CONNECTION of any insulation on conductors shall be identified by either green or green and yellow colours at least at the termination of the conductors. | | N/A |

| IEC60601_1U ATTACHMENT | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **7.7.3** | **Green or green and yellow insulation** | | N/A |
| | *[Replace Clause 7.7.3 in the adopted Standard, as modified by IEC Amendment 1, with the following]* | | N/A |
| | Identification by green or green and yellow insulation shall only be used for: | | N/A |
| | - PROTECTIVE EARTH CONDUCTORS (see Clause 8.6.2); | | N/A |
| | - conductors as specified in Clause 7.7.2;<br><br>**Note:** In other safety Standards such as CSA C22.2 No. 62368-1, internal connections between conductive parts and the main protective earth are called "protective bonding conductors". | | N/A |
| | - POTENTIAL EQUALIZATION CONDUCTORS (see Clause 8.6.7); | | N/A |
| | - FUNCTIONAL EARTH CONDUCTORS (see Clause 8.6.9). | | N/A |
| **7.7.4** | **Neutral conductor** | | N/A |
| | *[Replace Clause 7.7.4 in the adopted Standard with the following]*<br><br>Colours of neutral conductors and POWER SUPPLY CORD conductors shall be in accordance with the *Canadian Electrical Code, Part I*, CSA C22.2 No. 21, and CSA C22.2 No. 49. | | N/A |
| **7.7.5** | **POWER SUPPLY CORD conductors** | | N/A |
| | *[Replace Clause 7.7.5 in the adopted Standard with the following]*<br><br>Colours of conductors in POWER SUPPLY CORDS shall be in accordance with the Canadian Electrical Code, Part I, CSA C22.2 No. 21, and CSA C22.2 No. 49. | No such cord | N/A |
| | Compliance with the requirements of Clause 7.7 is checked by inspection. | | N/A |
| **7.9** | **ACCOMPANYING DOCUMENTS** | | P |
| **7.9.2.1** | **General** | | P |
| | *[Replace the last paragraph in the adopted Standard with the following]*<br><br>The instructions for use shall be in English and French for the intended OPERATOR. | | P |
| **8** | **Protection against electrical HAZARDS from ME EQUIPMENT** | | P |
| **8.6** | **Protective earthing, functional earthing and potential equalization of ME EQUIPMENT** | | N/A |
| **8.6.4** | **Impedance and current-carrying capability** | | N/A |

| IEC60601_1U ATTACHMENT | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | *[Replace Clause 8.6.4 in the adopted Standard, as modified by IEC Amendments 1 and 2, with the following]* | | N/A |
| | PROTECTIVE EARTH CONNECTIONS shall be able to carry fault currents reliably and without excessive voltage drop. | No potential equalization | N/A |
| | Impedance and current-carrying capability shall comply with CSA C22.2 No. 0.4. | | N/A |
| | For PERMANENTLY INSTALLED ME EQUIPMENT and ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD, the impedance between the PROTECTIVE EARTH TERMINAL (inside the ME EQUIPMENT) and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ. For ME EQUIPMENT with an APPLIANCE INLET, the impedance between the earth pin of the APPLIANCE INLET and any part that is PROTECTIVELY EARTHED shall not exceed 100 mΩ……..: | | N/A |
| | In addition to the test above, for ME EQUIPMENT with a non-DETACHABLE POWER SUPPLY CORD or any DETACHABLE POWER SUPPLY CORD (supplied or specified by the MANUFACTURER), the impedance between the protective earth pin of the MAINS PLUG and the PROTECTIVE EARTH TERMINAL (inside the ME EQUIPMENT) shall not exceed 100 mΩ……..: | | N/A |
| | Where an APPLIANCE INLET forms the supply connection to ME EQUIPMENT, the earth pin of the APPLIANCE INLET is regarded as the PROTECTIVE EARTH TERMINAL.<br><br>The combined testing requirements above are equivalent to 200 mΩ impedance testing requirements as described in IEC 60601-1. Separate testing is required to comply with CSA C22.2 No. 0.4. | | N/A |
| | *Testing shall be carried out using a DETACHABLE POWER SUPPLY CORD as provided or specified (length and cross-sectional area as per the Canadian Electrical Code, Part I) by the MANUFACTURER.* | | N/A |
| | The test current shall have the following characteristics:<br><br>— for cord-connected equipment, twice the rating of the attachment plug cap, but not less than 40 A;<br>— for equipment for permanent connection to the supply, twice the rating of the fuse that is required by the *Canadian Electrical Code*, *Part I* for the branch circuit to which the equipment is connected, up to 250 A; and<br>— 500 A for equipment for permanent connection to the supply when a branch circuit fused at over 250 A is required. | | N/A |

<table>
<tr><td colspan="4">IEC60601_1U ATTACHMENT</td></tr>
<tr><td>Clause</td><td>Requirement + Test</td><td>Result - Remark</td><td>Verdict</td></tr>
<tr><td></td><td>Compliance is checked by the following test:<br><br>— for test currents up to 500 A, the measured potential drop shall not exceed 4 V;<br>— for equipment that requires branch circuit fusing over 250 A, the measured potential drop multiplied by the required fusing and divided by 250 shall not exceed 4 V;<br>— there shall be no melting of any metal in the bond and no heating or burning that is likely to create a fire hazard; and<br>— the time duration— the time duration for testing is indicated in Table 8.6.4A:</td><td></td><td>N/A</td></tr>
<tr><td></td><td>Table 8.6.4A<br>Time duration of impedance test current<br><table><tr><th>Fusing of branch circuit required for equipment (A)</th><th>Time (min)</th></tr><tr><td>0–30</td><td>2</td></tr><tr><td>31–60</td><td>4</td></tr><tr><td>61–100</td><td>6</td></tr><tr><td>101–200</td><td>8</td></tr><tr><td>201 and over</td><td>10</td></tr></table>Note: Additional information can be found in CSA C22.2 No. 0.4.</td><td></td><td>N/A</td></tr>
<tr><td></td><td>Alternatively, dc may be used for this test, if the ME EQUIPMENT is rated dc.</td><td></td><td>N/A</td></tr>
<tr><td></td><td>Note: When protective earth is relied on as a MEANS OF PROTECTION, the test current is determined based on the location where a fault could occur. If the prospective fault is in the mains supply circuit prior to the overcurrent protection included in the ME EQUIPMENT, the test current for that part of the protective earth circuit is based on the rating of the external overcurrent protection included in the building infrastructure or specified in the ACCOMPANYING DOCUMENTS (two times the interrupt rating of the external overcurrent protection). If the prospective fault is in the mains supply circuit after the overcurrent protection included in the ME EQUIPMENT, the test current is based on the rating of the overcurrent protection included in the ME EQUIPMENT (two times the interrupt rating of the ME EQUIPMENT overcurrent protection). In either case, the minimum test current is 40 A.<br><br>The voltage drop between the parts described is measured and the impedance determined from the current and voltage drop.<br><br>If the measured impedance is within the permitted limit, either the impedance measurement is then repeated using a current source with a no-load voltage sufficient to deliver the specified current into the total impedance, or the current-carrying ability of the relevant protective earth conductor and protective earth connection is confirmed by checking that their cross-sectional area is at least equal to that of the relevant current-carrying</td><td></td><td>N/A</td></tr>
</table>

| IEC60601_1U ATTACHMENT | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | conductors. | | |
| **8.7** | **LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS** | | P |
| **8.7.3** | **Allowable values** | | P |
| | *[Add the following paragraph]*<br><br>Allowable values shall be in accordance with the Canadian Electrical Code, Part I. | | P |
| **8.11** | **MAINS PARTS, components and layout** | | N/A |
| **8.11.3.2** | **Types** | | N/A |
| | *[Replace this clause with the following]* | | N/A |
| | The following requirements for POWER SUPPLY CORDS shall apply: | | N/A |
| | a) The MAINS PLUG of non-PERMANENTLY INSTALLED EQUIPMENt shall be: | | 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 | | N/A |
| | 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 shall be 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: | | N/A |
| | 1) the centre contact of an Edison base lampholder; | | N/A |
| | 2) a single pole switch; | | N/A |
| | 3) an automatic control with a marked off position; | | N/A |
| | 4) a solitary fuse/fuse holder; or | | N/A |
| | 5) any other single pole overcurrent protective device. | | N/A |
| | b) A detachable POWER SUPPLY CORD for non-PERMANENTLY INSTALLED EQUIPMENT (cord-connected equipment) shall be of a type: | | 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; | | 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 | | 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. | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | c) The detachable POWER SUPPLY CORD shall: | | N/A |
| | i) comply with the applicable requirements of CSA C22.2 No. 21; and | | N/A |
| | ii) not be smaller than No. 18 AWG, and the mechanical serviceability is not less than: | | N/A |
| | 1) Type SJ or equivalent for ME EQUIPMENT that is mobile or exposed to abuse; and | | N/A |
| | 2) Type SV or equivalent for ME EQUIPMENT that is not exposed to abuse (or Type HPN if required because of temperature).<br><br>**Note:** See CSA C22.2 No. 49 for requirements for the cord types mentioned in Sub-item 2). | | N/A |
| | d) Installation of POWER SUPPLY CORDS shall meet the requirements of the Canadian Electrical Code, Part I, as applicable. | | N/A |
| | *[Add the following to this Canadian deviation in the adopted Standard]*<br><br>The POWER SUPPLY CORD used with the ME EQUIPMENT shall be in accordance with the temperature rating to which it has been RATED.<br><br>**Note 1DV:** Refer to the Canadian Electrical Code, Part I, Tables 11 and 12 for additional information. | | N/A |
| | Compliance is checked by inspection and measurement……..: | | N/A |
| **8.11.3.3** | **Cross-sectional area of POWER SUPPLY CORD conductors** | | N/A |
| | *[Replace Clause 8.11.3.3 in the adopted Standard, as modified by Amendment 2, with the following]*<br><br>The NOMINAL cross-sectional area of conductors of any POWER SUPPLY CORD of ME EQUIPMENT shall be not less than the requirements of the Canadian Electrical Code, Part I, and CSA C22.2 No. 21.<br><br>**Note:** Table 17 can be used for European countries or other countries where the nominal cross-sectional area is measured in mm2 (HAR); American Wire Gauge (AWG) is the nominal cross-sectional area used in Canada as per the Canadian Electrical Code, Part I. | No such area | N/A |
| | Compliance is checked by inspection……..: | | N/A |
| **8.11.5** | **Mains fuses and OVER-CURRENT RELEASES** | | P |
| | *[Replace Clause 8.11.5 in the Canadian deviations in the adopted Standard with the following]*<br><br>Installation of overcurrent protective devices shall be in accordance with the Canadian Electrical Code, Part I | | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **9** | **Protection against MECHANICAL HAZARDS of ME EQUIPMENT and ME SYSTEMS** | | N/A |
| **9.7** | **Pressure vessels and parts subject to pneumatic and hydraulic pressure** | | N/A |
| **9.7.5** | **Pressure vessels** | | N/A |
| **9.7.5** | *[Replace this clause with the following]*<br><br>Pressure vessels shall comply with the requirements of CSA B51, as applicable | No pressure vessel | N/A |
| **9.7.7** | **Pressure-relief device** | | N/A |
| | *[Add the following as the first paragraph of this Clause]*<br><br>A pressure-relief device shall comply, as applicable, with the requirements of ASME PTC 25 or equivalent Canadian requirements. | No pressure relief device | N/A |
| **13** | **HAZARDOUS SITUATIONS and fault conditions** | | N/A |
| **13.2** | **SINGLE FAULT CONDITIONS** | | N/A |
| **13.2.9** | **Interruption and short circuiting of motor capacitors** | | N/A |
| | *[Replace the second paragraph of the compliance statement in the adopted Standard with the following]*<br><br>The test with a short-circuited capacitor is not performed if the motor is provided with a capacitor that complies with IEC 60252-1 or is included as part of the evaluation of the motor in accordance with CSA C22.2 No. 100, and the ME EQUIPMENT is not intended for unattended use (including automatic or remote control). | No motor capacitors | N/A |
| | For additional test criteria, see Clause 13.2.10. | | N/A |
| **15** | **Construction of ME EQUIPMENT** | | P |
| **15.4** | **ME EQUIPMENT components and general assembly** | | N/A |
| **15.4.1** | **Construction of connectors** | | N/A |
| | *[Add the following item]* | | N/A |
| | 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 shall be: | | N/A |
| | i) gas-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 |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | ii) DISS 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 | | 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. | | --- |
| **15.4.8** | **Internal wiring of ME EQUIPMENT** | | P |
| | *[Replace this Clause with the following]* | | P |
| | Internal wiring of ME EQUIPMENT shall be in accordance with the Canadian Electrical Code, Part I. | | P |
| | Except for flexible cord, equipment wire, control circuit insulated conductors, and cable, insulated conductors shall be not smaller than No. 14 AWG when made of copper and not smaller than No. 12 AWG when made of aluminium.<br><br>**Note 1:** See the Canadian Electrical Code, Part I, Rule 4-002. | | P |
| | The maximum current that an equipment wire of a given size may carry shall be as specified in Table 12 of the Canadian Electrical Code, Part I.<br><br>**Note 2:** For additional information refer to the Canadian Electrical Code, Part I, Rule 4-014. | | P |
| **15.5** | **MAINS SUPPLY TRANSFORMERS of ME EQUIPMENT and transformers providing separation in accordance with 8.5** | | P |
| **15.5.1.3** | **Overload test** | | P |
| | *[Replace the second and third dashed items of Item b) of Clause 15.5.1.3 in the adopted Standard with the following]* | | P |
| | - Fuses not in accordance with IEC 60127-1 but in accordance with the CSA C22.2 No. 248 series of Standards:<br><br>30 min at the current according to the characteristics supplied by the fuse manufacturer, specifically the 30 min clearing-time current. If no 30 min clearing-time current data is available, the test current from Table 32 is used until THERMAL STABILITY is achieved. | | P |
| | - Other protective device as per the Canadian | | P |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | Electrical Code, Part I: until THERMAL STABILITY at a current just below that which caused the device to operate in Item a). | | |
| | This portion of the overload test is concluded at the specified time or when a second protective device opens. | | P |
| **16** | **ME SYSTEMS** | | N/A |
| **16.1** | **General requirements for the ME SYSTEMS** | | N/A |
| | *[Replace the paragraph that starts with "*An ME SYSTEM shall provide:*" with the following]* | | N/A |
| | An ME SYSTEM shall be provided: | | N/A |
| | - within the PATIENT ENVIRONMENT, the level of safety equivalent to ME EQUIPMENT complying with this CSA Group Standard; and | Not **ME SYSTEMS** | N/A |
| | - outside the PATIENT ENVIRONMENT, the level of safety equivalent to equipment complying with their respective CSA Group, IEC, or ISO safety Standards. | | N/A |
| | *[Replace the third-last paragraph with the following]*<br><br>Non-ME EQUIPMENT, when used in an ME SYSTEM, shall comply with the CSA Group, IEC, or ISO safety Standards that are relevant to that equipment. | | N/A |
| **16.9** | **ME SYSTEM connections and wiring** | | N/A |
| **16.9.2.1** | **MULTIPLE SOCKET-OUTLET** | | N/A |
| | *[Replace the first sentence of Item c) of Clause 16.9.2.1 in the adopted Standard with the following]* | | N/A |
| | c) The MULTIPLE SOCKET-OUTLET shall comply with CSA C22.2 No. 308 as applicable and the following requirements. | | N/A |
| | *[Add the following note to Item d) in the Canadian deviations in the adopted Standard]* | | N/A |
| | d) If the MULTIPLE SOCKET OUTLET is combined with a separating transformer, the following additional requirements shall apply: | | N/A |
| | The separating transformer complies with this Standard. | | N/A |
| | Alternatively, the separating transformer may | | N/A |

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|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| | 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. | | |
| | Note 1: As a separating transformer is not a MAINS SUPPLY TRANSFORMER, it does not require more than BASIC INSULATION.<br><br>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.<br><br>Note 3: For additional details refer to the Canadian Electrical Code, Part I, Diagrams 1 and 2. | | N/A |
| | The separating transformer assembly shall be a CLASS I construction. | | N/A |
| | The degree of protection against ingress of water as given in IEC 60529 is specified. | | N/A |
| | The separating transformer assembly shall be marked according to the requirements of 7.2 and 7.3. | | N/A |
| | The MULTIPLE SOCKET OUTLET is permanently connected to the separating transformer or, | | N/A |
| | The socket-outlet of the separating transformer assembly shall be 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) | | 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. | | N/A |

**ATTACHMENT 3: Switzerland national differences**

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| **ATTACHMENT TO TEST REPORT**<br>**IEC60601-1:2005, IEC60601-1:2005/AMD1:2012, IEC60601-1:2005/AMD2:2020**<br>**SWITZERLAND NATIONAL DIFFERENCES**<br>Medical electrical equipment — Part 1: General requirements for basic safety and essential performance | | | |
| **Differences according to**.....: | SN EN 60601-1:2006+A1:2013+A12:2014+A2:2021+A13:2024 | | |
| **TRF template used: .....:** | IECEE OD-2020-F3:2024, Ed. 1.3 | | |
| **Attachment Form No**.....: | CH_ND_IEC60601_1U | | |
| **Attachment Originator .....**: | EMC-TESTCENTER AG | | |
| **Master Attachment**.....: | Dated 2025-06-20 | | |

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| Clause | Requirement + Test | Result - Remark | Verdict |
|---|---|---|---|
| | **National Differences** | | N/A |
| 8.11.3 | Supply cords of portable electrical appliances having a rated current not exceeding 10 A is provided with a plug complying with IEC 60884-1 (Ed. 3.2) and one of the following dimension sheets of SN 441011 series: | No supply cords | N/A |
| | - Standard sheet 2015-2 (SN 441011-2-1:2024)<br>Plug Type 15: 3L + N + PE, 250/400 V, 10 A | | N/A |
| | - Standard sheet 2011-2<br>Plug Type 11: L + N, 250 V, 10 A | | N/A |
| | - Standard sheet 2012-2<br>Plug Type 12: L + N + PE, 250 V, 10 A | | N/A |
| | Supply cords of portable electrical appliances having a rated current not exceeding 16 A is provided with a plug complying with IEC 60884-1 (Ed. 3.2) and one of the following dimension sheets of SN 441011 series: | | N/A |
| | - Standard sheet 2025-2<br>Plug Type 25: 3L + N + PE, 250/400 V, 16 A | | N/A |
| | - Standard sheet 2021-2<br>Plug Type 21: L + N, 250 V, 16 A | | N/A |
| | - Standard sheet 2023-2<br>Plug Type 23: L + N + PE, 250 V, 16 A | | N/A |
| | NOTE 16 A plugs are not often used in Swiss domestic installation system | | — |

| Clause | Requirement + Test | Result - Remark | Verdict |
|---|---|---|---|
| | Non removable adapters to Swiss plugs:<br><br>Non removable adapters are fixed to the original plug and cannot be removed without damage the plug. These adapters can be used for products intended for sale in Switzerland. The following restrictions have to be considered: | | N/A |
| | - power rating 10 A/ 16 A | | N/A |
| | - earth pin corresponds with the protection class | | N/A |
| | - assembly note has to be attached to the equipment | | N/A |

**ATTACHMENT 4: Korea national differences**

| IEC60601_1S ATTACHMENT | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **ATTACHMENT TO TEST REPORT**<br>**IEC 60601-1**<br>**Republic of Korea NATIONAL DIFFERENCES**<br>(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_1S<br>**Attachment Originator .....**: KTR<br>**Master Attachment**.....: 2020-12-17 | | | |
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| | **Special national conditions (if any)** | | — |
| Voltage | National supply voltages are 110, 220 V and 380 V. | MEET THE VOLTAGE REQUIREMENT | **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. | | **P** |
| Plug | Plugs for connection of the equipment to the supply mains shall comply with the Korean Standard (KSC 8305 and 8300) | | **P** |

**ATTACHMENT 5: Japan national differences**

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **ATTACHMENT TO TEST REPORT**<br>**IEC 60601-1**<br>**IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020**<br>**JAPAN NATIONAL DIFFERENCES**<br>Medical electrical equipment — Part 1: General requirements for basic safety and essential performance | | | |
| **Differences according to**..... National standard JIS T 0601-1:2023 | | | |
| **TRF template used .....** IECEE OD-2020-F3:2022, Ed. 1.2 | | | |
| **Attachment Form No**. ..... JP_ND_IEC60601_1U<br>**Attachment Originator .....** TÜV Rheinland Japan Ltd.<br>**Master Attachment** ..... Dated 2023-08-22 | | | |
| **Copyright © 2023 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.** | | | |
| | **National Differences** | | P |
| **1** | **Scope, object and related standards** | | P |
| 1.3 | In NOTE 3, add the following:<br>In Japan, to check the corresponding Japanese Industrial Standard(s) is required. | | P |
| 1.4 | At the end of NOTE, add the following:<br>In Japan, to check the corresponding Japanese Industrial Standard(s) is required. | | P |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **2** | **Normative references** | | P |
| 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<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<br>JIS C 0920:2003, Degrees of protection provided by enclosures (IP Code)<br>NOTE 1: IEC 60529: 1989+AMD1:1999, Degrees of protection provided by enclosures (IP Code)<br>NOTE 2: According to the corresponding international standard, IEC 60529:1989+AMD1:1999 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 (Noise meter) - Part 1: Specifications<br>NOTE: IEC 61672-1, Electroacoustics - Sound level meters - Part 1: Specifications<br>JIS C 1509-2, Electroacoustics - Sound level meters (Noise meter) - Part 2: Pattern evaluation tests<br>NOTE: IEC 61672-2, Electroacoustics - Sound level meters - Part 2: Pattern evaluation tests | | P |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | JIS C 4003, Electrical insulation - Thermal evaluation and designation<br>NOTE: IEC 60085, Electrical insulation - Thermal evaluation and designation<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<br>JIS C 6065:2013, Audio, video and similar electronic apparatus - Safety requirements<br>NOTE: IEC 60065:2001+AMD1:2005+A2:2010, Audio, video and similar electronic apparatus - Safety requirements<br>JIS C 6802:2018, Safety of laser products<br>NOTE: IEC 60825-1:2014, Safety of laser products - Part 1: Equipment classification and requirements<br>JIS C 6950-1:2016, Information technology equipment - Safety - Part 1: General requirements<br>NOTE: IEC60950-1:2005+AMD1:2009+AMD2:2013, Information technology equipment - Safety - Part 1: General requirements<br>JIS C 6965, Mechanical safety of cathode ray tubes<br>NOTE: IEC 61965, Mechanical safety of cathode ray tubes<br>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<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,. Refer to JIS T 1021, too. | | P |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | JIS C 9335-1:2014 Household and similar electrical appliances – safety – Part 1: General requirements<br>NOTE: IEC 60335-1:2010 Household and similar electrical appliances – safety – Part 1: General requirements<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<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<br>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<br>JIS C 62368-1:2021, Audio/video information and communication technology equipment – Part 1: Safety requirements<br>NOTE: IEC 62368-1:2018, Audio/video information and communication technology equipment – Part 1: Safety requirements<br>JIS T 0601-1-2:2023, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – collateral standard electromagnetic disturbances – requirements and tests<br>NOTE: IEC 60601-1-2:2014+AMD1:2020, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – collateral standard electromagnetic disturbances – requirements and tests<br>JIS T 0601-1-3:2015, 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: IEC60601-1-3:2008+AMD1:2013, Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment | | P |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | JIS T 0801:2016, Sterilization of health care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices<br>NOTE 1: ISO 11135-1:2014, Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices<br>NOTE 2: The cited standard ISO 11135-1:2007 and its corresponding JIS JIS T 0801-1:2010 in the corresponding international standard are both obsolete, so their successors have been added to the cited standards.<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 1: 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<br>NOTE 2: JIS T 0801-1:2010 and ISO11135-1:2007 are obsolete standards and have been replaced by JIS T 0801:2016 and ISO11135:2014, respectively.<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<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<br>JIS T 2304:2017, Medical device software - Software life cycle processes<br>IEC62304:2006+AMD1:2015, Medical device software - Software life cycle processes<br>JIS T 14971:2020, Medical devices - Application of risk management to medical devices<br>NOTE: ISO 14971:2019, Medical devices - Application of risk management to medical devices | | P |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | JIS T 60601-1-6:2023, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability<br>NOTE: IEC60601-1-6:2010+AMD1:2013+AMD2:2020, Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability<br>JIS T 60601-1-8:2023, 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: IEC 60601-1-8:2006+AMD1:2012+AMD2:2020, 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>JIS Z 8000-1:2014, Quantities and units- Part 1: General<br>NOTE: ISO 80000-1:2009, 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<br>IEC 60079-0, Explosive atmospheres – Part 0: Equipment – General requirements”<br>IEC 60079-2, Explosive atmospheres – Part 2: Equipment protection by pressurized enclosure “p”<br>IEC 60079-5, Explosive atmospheres – Part 5: Equipment protection by powder filling “q”<br>IEC 60079-6, Explosive atmospheres – Part 6: Equipment protection by liquid immersion “o”<br>IEC 60086-4, Primary batteries - Part 4: Safety of lithium batteries<br>NOTE: JIS C 8513 Safety of primary lithium batteries<br>IEC 60112, Methods for the determination of the proof and the comparative tracking indices of solid insulating materials | | P |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | 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<br>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<br>IEC 60245-1:2003+AMD1:2007, Rubber insulated cables - Rated voltages up to and including 450/750 V - Part 1: General requirements<br>IEC 60252-1, AC motor capacitors - Part 1: General - Performance, testing and rating - Safety requirements - Guidance for installation and operation<br>IEC 60320-1, Appliance couplers for household and similar general purposes - Part 1: General requirements<br>IEC 60364-4-41, Low-voltage electrical installations – Part4-41: Protection for safety – Protection against electric shock<br>IEC 60445, Basic and safety principles for man-machine interface markings and identification – Identification of equipment terminals, conductor terminations and conductors<br>IEC 60447, Basic and safety principles for man-machine interface markings and identification – Actuating principles<br>IEC 60730-1:2010, Automatic electrical controls for household and similar use – Part 1:Genral requirements<br>IEC 60747-5-5:2007, Semiconductor devices – Discrete devices – Part 5-5: Optoelectronic devices – Photocouplers<br>IEC 60851-3:2009, Winding wires - Test methods - Part 3: Mechanical properties | | P |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 2 | IEC 60851-5:2008, Winding wires - Test methods - Part 5: Electrical properties<br>IEC 60851-6:1996+AMD1:1997, Methods of test for winding wires - Part 6: Thermal properties<br>IEC 61058-1:2000+AMD1:2001+AMD2:2007, Switches for appliances - Part 1: General requirements<br>IEC 62133:2012, 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: Although a withdrawn standard, it is cited in 15.4.3.4 of this standard<br>IEC 62133-2, 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 – Part 2: Lithium systems<br>ISO 1853, Conducting and dissipative rubbers, vulcanized or thermoplastic - Measurement of resistivity<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<br>NOTE: Although it is a withdrawn standard, it is referenced in Annex G of this standard.<br>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 7010:2019, Graphical symbols - Safety colours and safety signs - Registered safety signs | | P |
| 2 | 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. However, other Parts than Part 1 and Part 7 have still not been published as JIS.<br>ISO 23529, Rubber -- General procedures for preparing and conditioning test pieces for physical test methods | | P |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **3** | **Terminology and definitions** | | P |
| 3.70 | Replace the existing text with:<br>condition in which all means provided for protection against HAZARDOUS SITUATIONS or HARM are intact | | P |
| **7** | **ME EQUIPMENT identification, marking and documents** | | P |
| **7.3** | **Marking on the inside of ME EQUIPMENT or ME EQUIPMENT parts** | | P |
| 7.3.4 | Add the following NOTE<br>NOTE Corresponding Japanese Industrial Standard for IEC 60127-1: JIS C 6575-1 | | P |
| **7.4** | **Marking of controls and instruments** | | N/A |
| 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 8000-1:2014 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 8000-1:2014. | No numeric indications of parameters. | N/A |
| **7.6** | **Symbols** | | P |
| 7.6.2 | Replace the existing text with the following:<br>Symbols require by this standard shall conform to the requirements in the referenced JIS, IEC or ISO publication. Annex D provides the symbol graphic and description for these symbols as a quick references. | | P |
| 7.6.3 | Replace the existing text with the following:<br>Symbols used for controls and performance shall confirm to the requirements of the JIS, IEC or ISO publication where the symbol is defined, when applicable. See also 7.2.13. | | P |
| **7.7** | **Colours of the insulation of conductors** | | N/A |
| 7.7.4 | Under the existing text, add the following:<br>If polyvinyl chloride insulated flexible cord of JIS C 3306:2000 or rubber insulated flexible cord of JIS C 3301:2000 is used, the conductor may be coloured "white". | No such cord | N/A |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| 7.7.5 | Under the existing text, add the following:<br>If polyvinyl chloride insulated flexible cord of JIS C 3306:2000 or rubber insulated flexible cord of JIS C 3301:2000 is used, conductors may be of the colour specified in these standards. | | N/A |
| **7.8** | **Indicator lights and controls** | | N/A |
| 7.8.1 | Replace the description of “Accompanied by sound” column of “HIGH PRIORITY ALARM CONDITION” with the following:<br>Typically, combine<br><br>Replace the description of “Accompanied by sound” column of “MEDIUM PRIORITY ALARM CONDITION” with the following:<br>Typically, combine<br><br>Add “e” of Table 2 with the following note:<br>Note: “Cyan” is a common colour name for “bright greenish blue” (see Appendix 1 of JIS Z 8102: 2001). | Light and controls not used | N/A |
| **7.9** | **ACCOMPANYING DOCUMENTS** | | N/A |
| 7.9.3.2 | Replace the fourth dash with the following:<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. | No such condition | N/A |
| **8** | **Protection against electrical hazards from me equipment** | | P |
| **8.4** | **Limitation of voltage, current or energy** | | P |
| 8.4.4 | Replace the non-automatic discharging device with the means of manual discharge of the non-automatic discharging device in the 2nd paragraph.<br>Replace a non-automatic discharging device with a means of manual discharge of the non-automatic discharging device in the last paragraph. | No such discharge device | N/A |
| **8.8** | **Insulation** | | 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 |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **8.11** | **Mains parts, components and layout** | | N/A |
| 8.11.3.2 | Add the following between the first paragraph and the second paragraph:<br>And, rubber insulated flexible cords of JIS C 3301:2000, polyvinyl chloride insulated flexible cords of JIS C 3306:2000 or cords of which the robustness is equal to or more than those may be used<br>Add the following between the second paragraph and the last paragraph:<br>And, in the case of cords of JIS C 3306:2000, shall not use;<br>Polyvinyl chloride insulated flexible cords shall not be used if the temperature of the above-mentioned external metal part exceeds 60 °C, and;<br>Heat-resistant polyvinyl chloride insulated flexible cords shall not be used if the temperature of the above-mentioned external metal part exceeds 75 °C. | | N/A |
| **9** | **Protection against mechanical hazards of me equipment and me systems** | | N/A |
| **9.2** | **Hazards associated with moving parts** | | N/A |
| 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. | No moving parts | N/A |
| **9.4** | **Instability HAZARDS** | | N/A |
| 9.4.4 | Add "(four times the weight of the equipment)" to the last sentence of 7th paragraph. | | N/A |
| **10** | **Protection against unwanted and excessive radiation hazards** | | P |
| 10.4 | Replace the last paragraph with the following:<br>Compliance is checked by following the relevant PROCEDURES of JIS C 6802:2018. | | P |
| **11** | **Protection against excessive temperatures and other hazards** | | P |
| **11.6** | **Overflow, spillage, leakage, ingress of water or particulate matter, cleaning, disinfection, sterilization and compatibility with substances used with the me equipment** | | P |
| 11.6.7 | Replace “ISO 11135-1, ISO 11137-1 or ISO 17665-1” with “JIS T 0801-1:2010, JIS T 0801:2016, JIS T 0806-1:2010 or JIS T 0816-1:2010” | | P |
| 11.6.8 | Replace “the application of appropriate ISO or IEC standards” with “the application of appropriate JIS, ISO or IEC standards” | | P |

| ATTACHMENT to TRF IEC60601_1U | | | |
|---|---|---|---|
| Clause | Requirement + Test | Result - Remark | Verdict |
| **16** | **ME systems** | | N/A |
| 16.1 | Replace in paragraph 3; 2nd dash: “IEC or ISO standards” by “JIS, IEC or ISO standards”<br>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 Appliances and Materials 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. in the case combined with a separating transformer having DOUBLE INSULATION or REINFORCED INSULATION, equipment only with BASIC INSULATION may be used.<br>*Compliance is checked by inspection of appropriate documents or certificates.* | No ME systems | N/A |
| **16.9** | **ME system connections and wiring** | | N/A |
| **16.9.2** | **Mains parts, components and layout** | | N/A |
| 16.9.2.1 | In the text of a) replace “IEC/TR 60083” with “JIS C 8303”<br>In the text of c), replace “IEC 60884-1” with “IEC 60884-1 or JIS C 8282-1”.<br>In the text of d) replace “IEC/TR 60083” with “JIS C 8303” | No ME systems | N/A |

**ATTACHMENT 6: Photo of EUT**

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



**Photo 2: External view of EUT**



**Photo 3: Internal view of EUT**



**Photo 4: Component side view of model type 1 (Mains transformer shall be mounted as shown in the following figures)**



**Photo 5: Component side view of model type 2 (Mains transformer shall be mounted as shown in the following figures)**

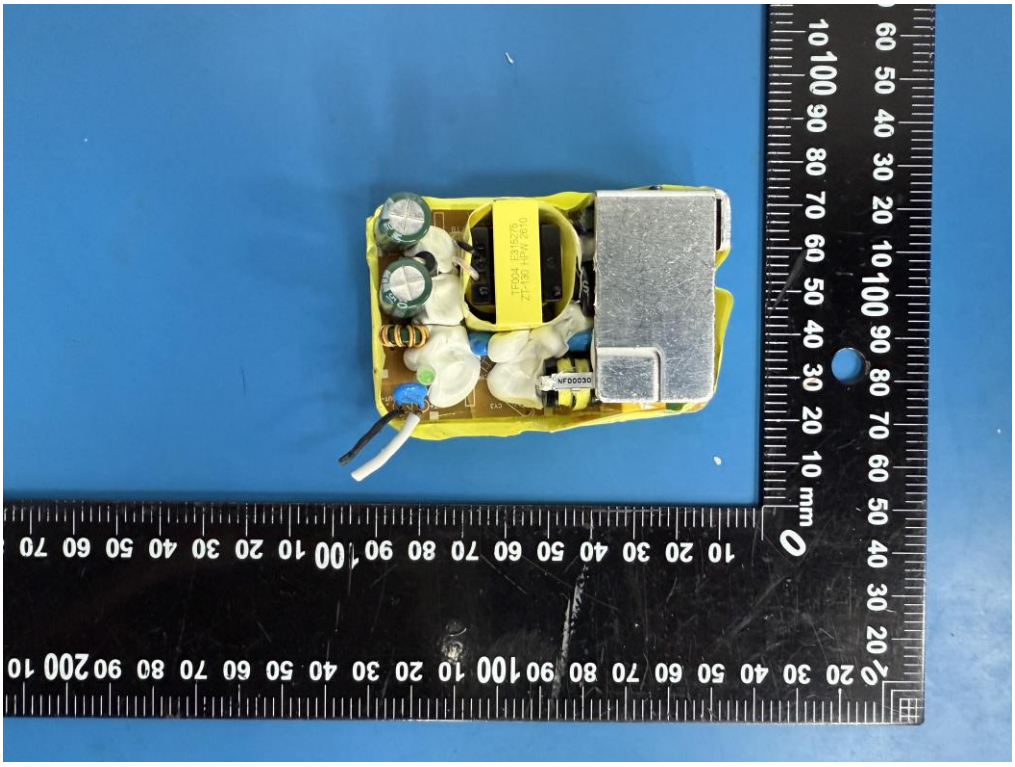


**Photo 6: Secondary wire installation view of mains transformer (Jump lead wire)**

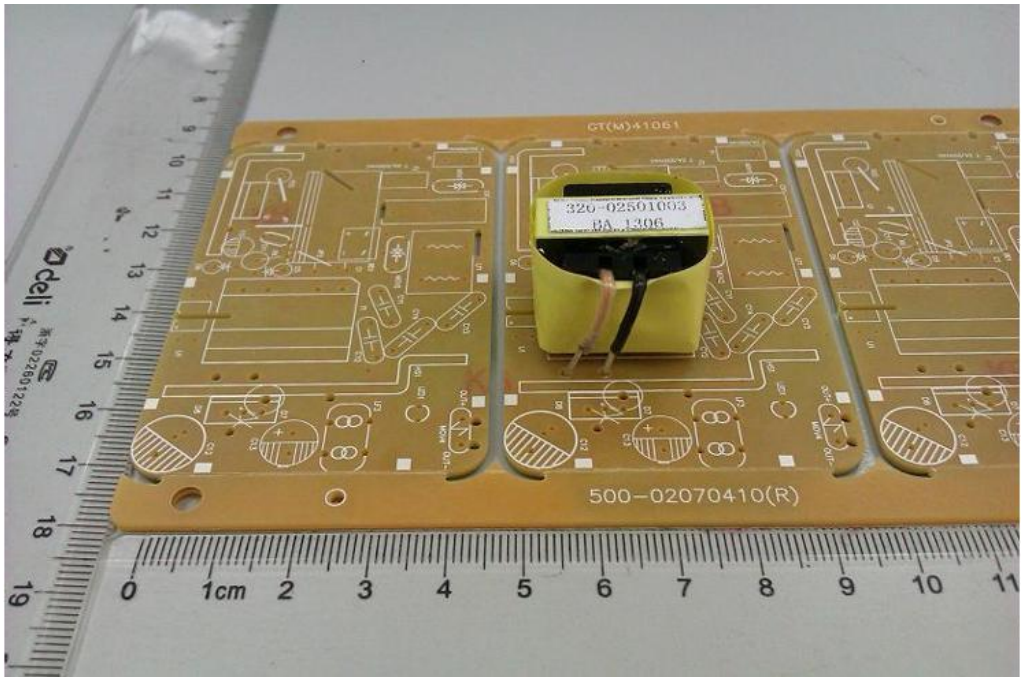


**Photo 7: Installation view of mains transformer (without secondary pin-outs on the bobbin)**

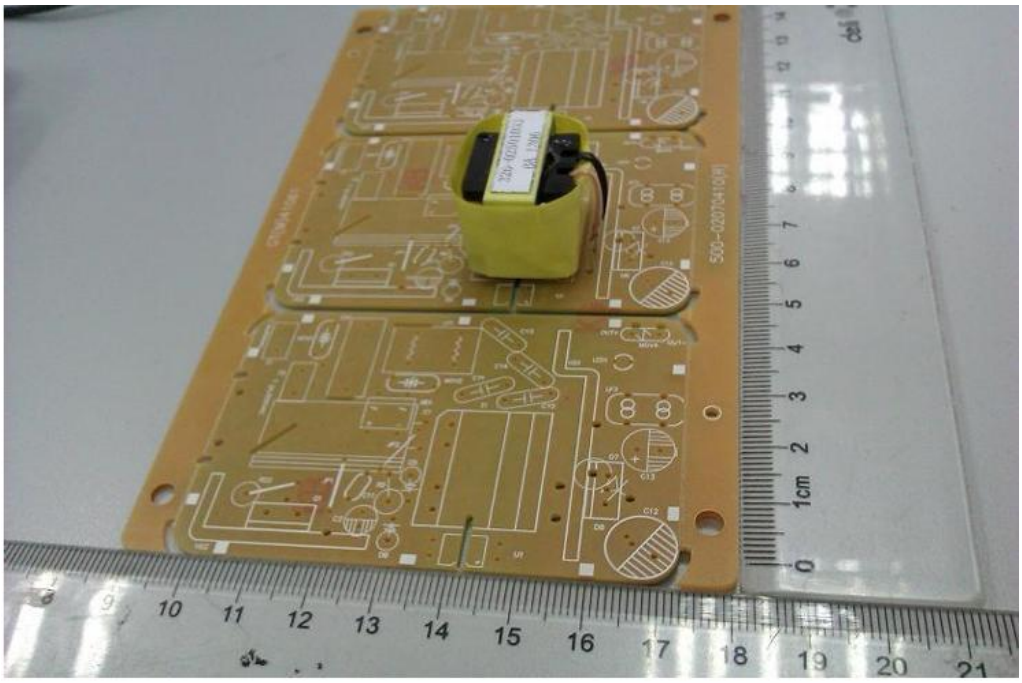


**Photo 8: Soldering side view of PCB**

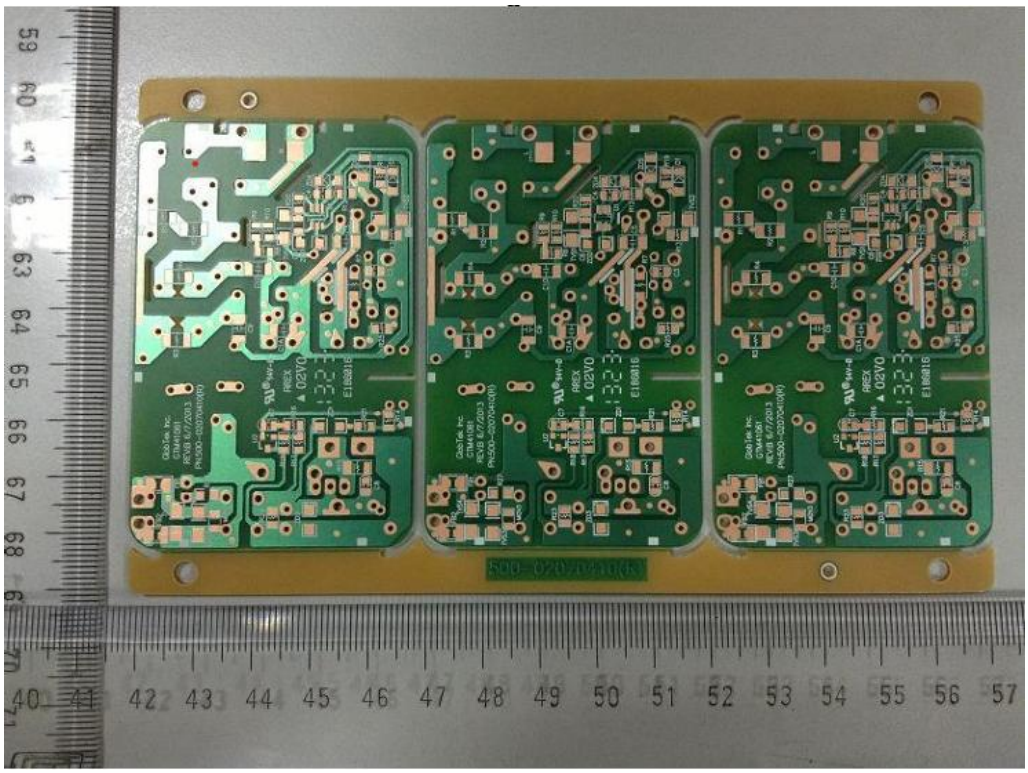


**Photo 9: External view of mains transformer**




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

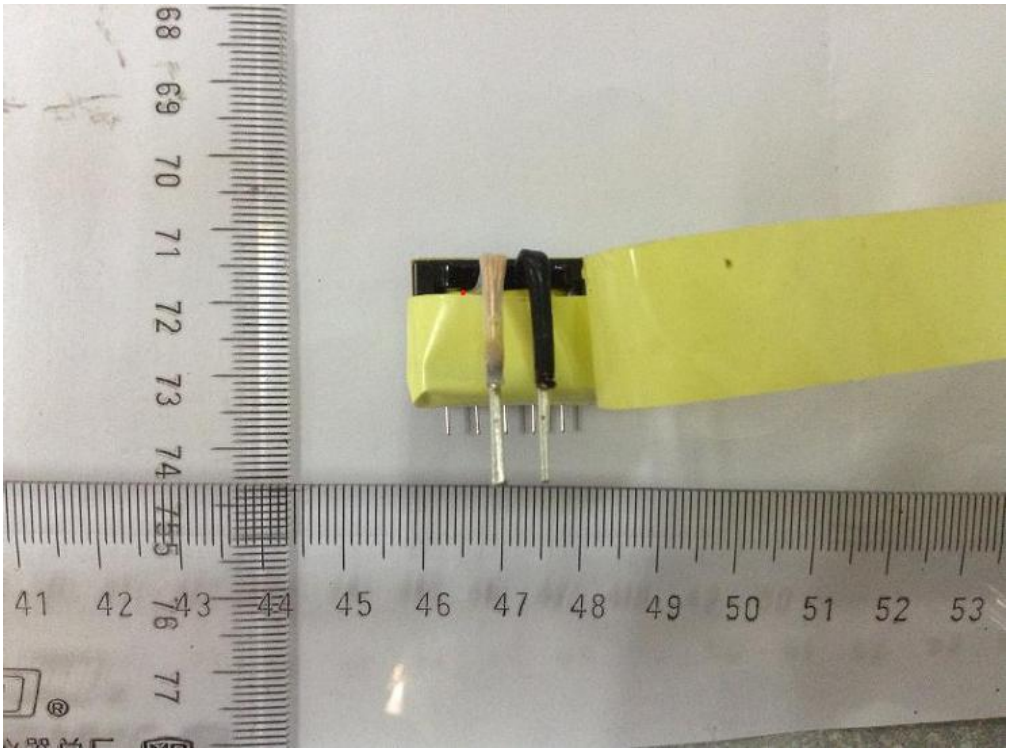


**Photo 11: External view of mains transformer**

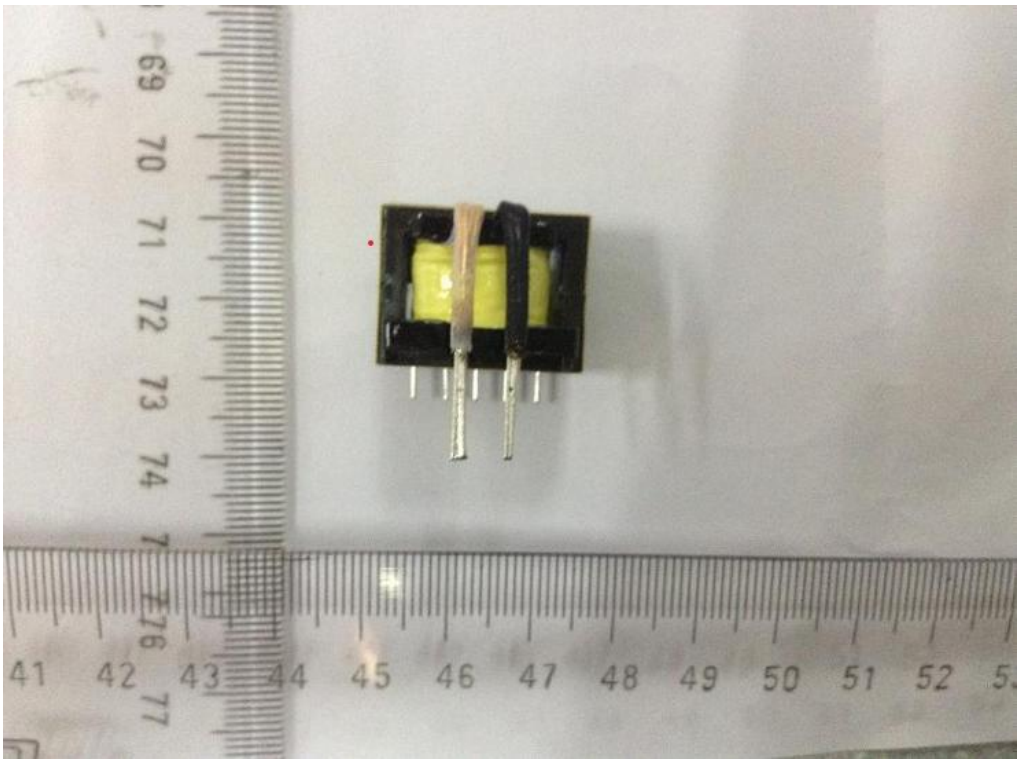


**Photo 12: External view of mains transformer**

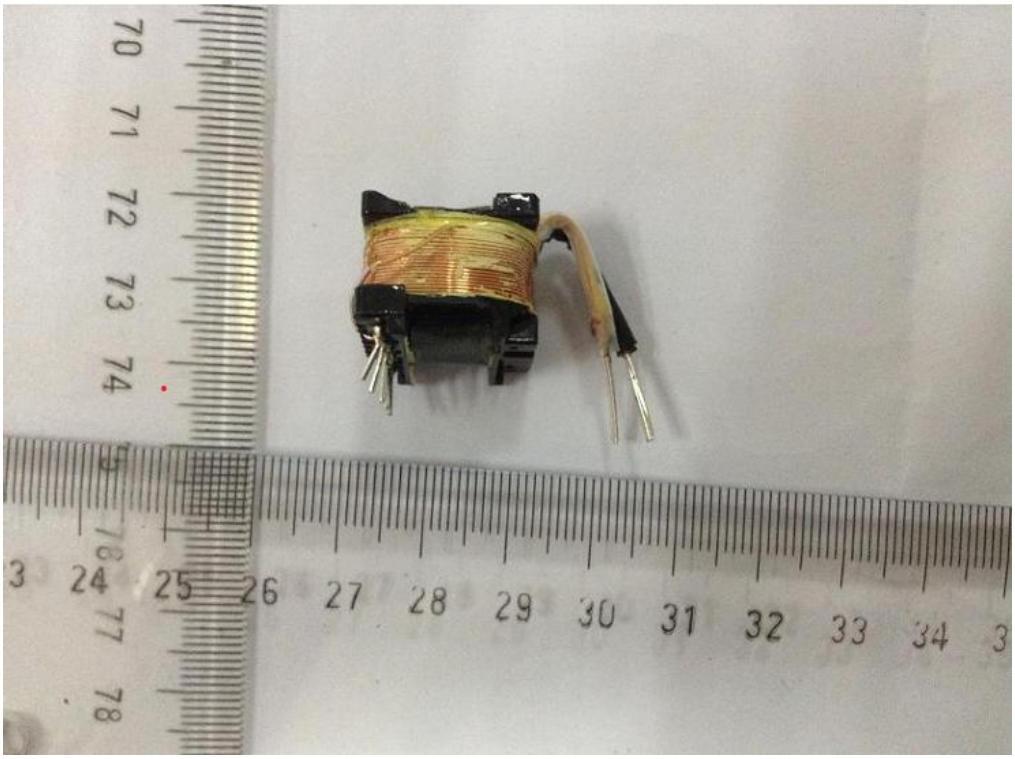


**Photo 13: External view of mains transformer with pin-out support (Optional)**

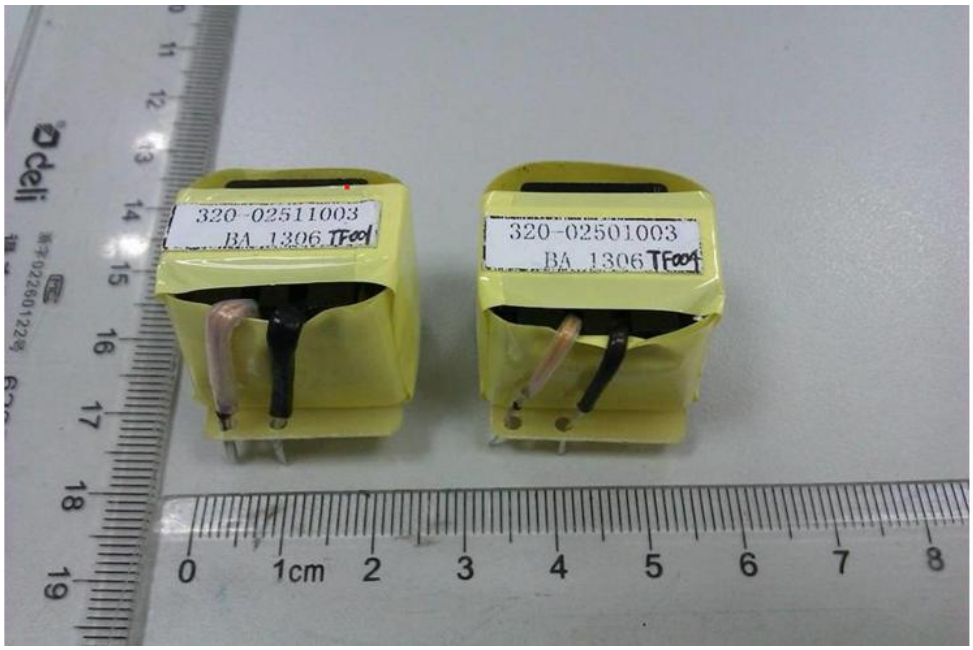
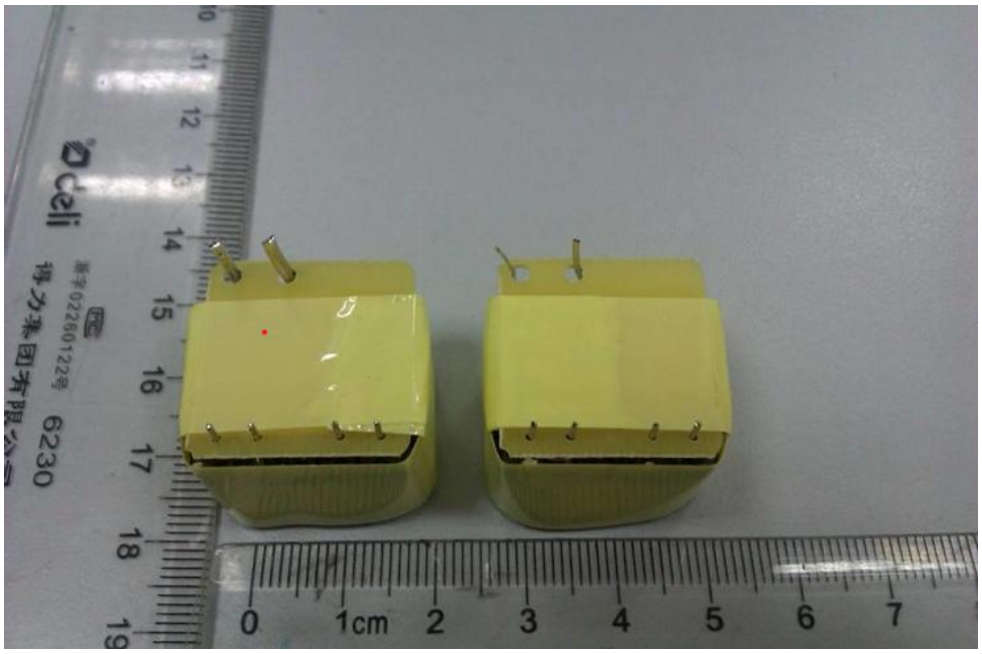
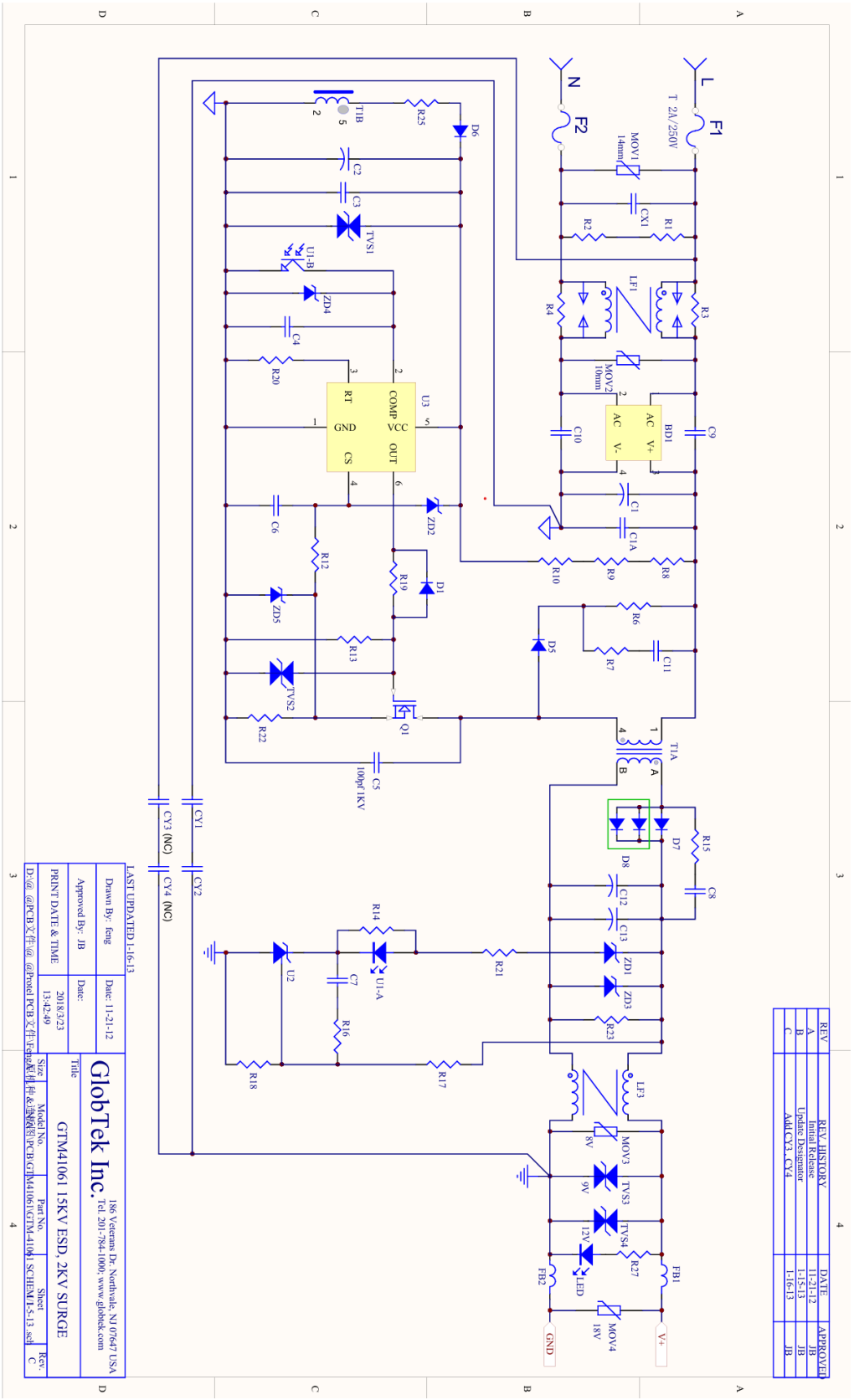
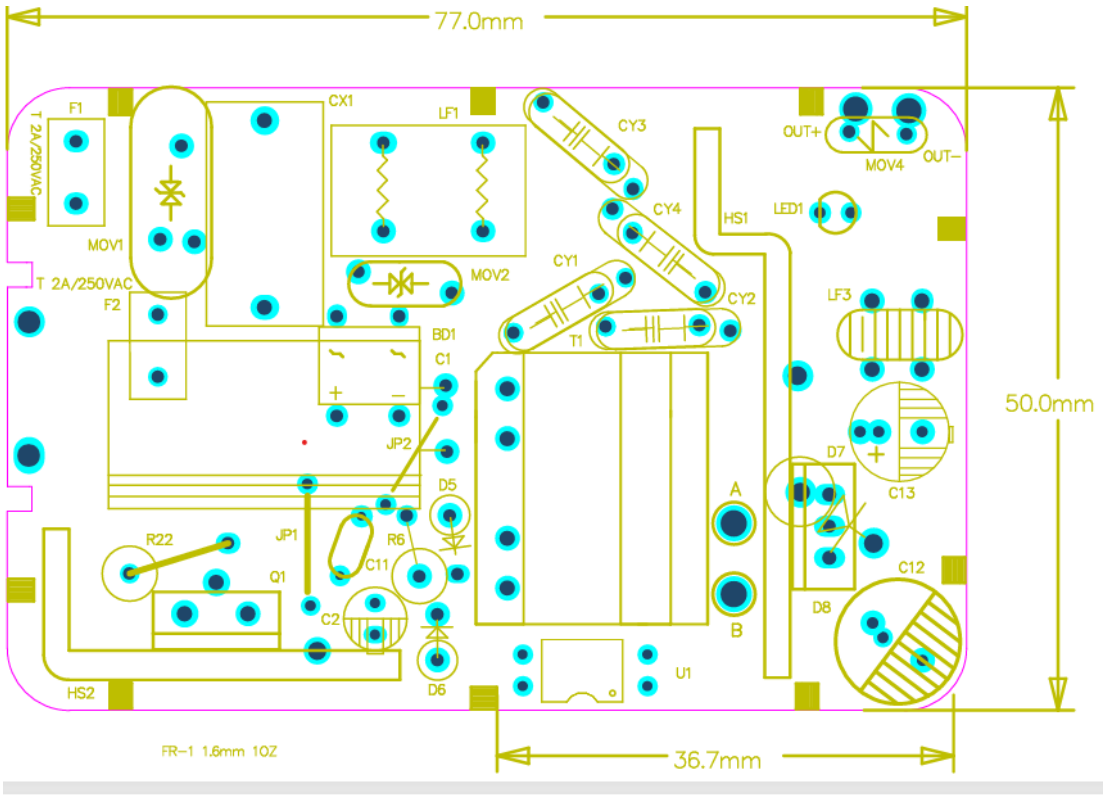


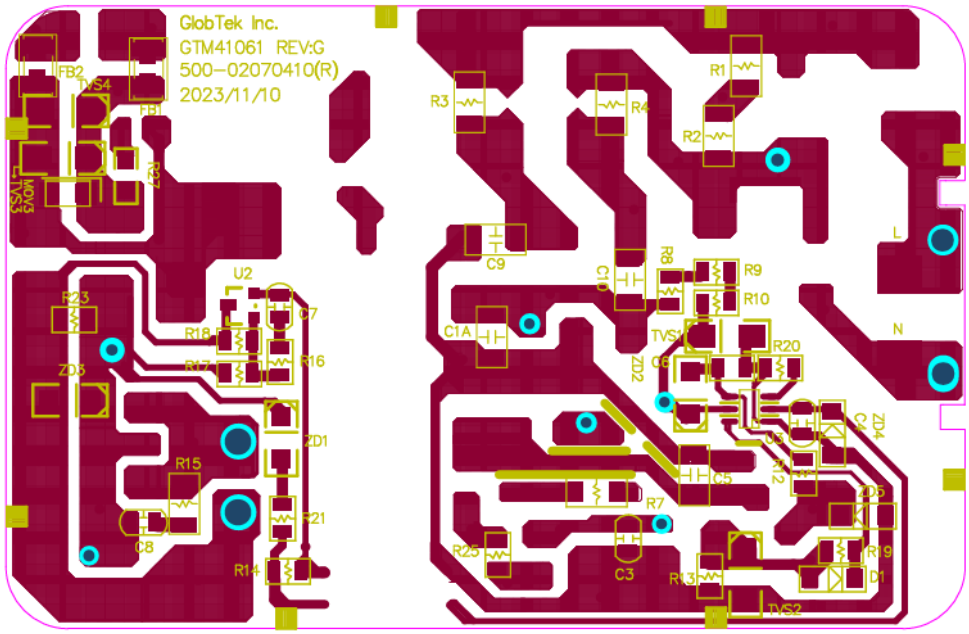

**Photo 14: External view of mains transformer with pin-out support (Optional)**



**ATTACHMENT 7: Circuit diagram/ layout**




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


GlobTek Inc.
GTM41061 REV:G
500-02070410(R)
2023/11/10
FB2
TVS4
HB1
MOV3
TVS3
R27
U2
R23
R18
R17
R16
ZD5
ZD1
R15
C8
R21
R14
C7
R3
R4
R1
R2
C9
C10
C1A
R8
R9
R10
TVS1
R20
ZD2
C6
ZD4
C5
R7
R25
C3
R13
TVS2
R19
D1
L
N