

UL TEST REPORT AND PROCEDURE

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| Standard: | ANSI/AAMI ES60601-1 (2005/(R)2012 + A1:2012, C1:2009/(R)2012 + A2:2010/(R)2012) - Amendment 1 - Revision Date 2012/08/21 CAN/CSA-C22.2 No. 60601-1:14 - Edition 3 - Revision Date 2014/03 |
| Certification Type: | Component Recognition |
| CCN: | QQHM2, QQHM8 (Power Supplies, Medical and Dental) |
| Product: | Switching Power Supply |
| Model: | LPS53-M |
| Rating: | Rated Input: 100-240 V, 50/60Hz, 2 A. Rated Output: 12 Vdc, 5A, 60 W. |
| Applicant Name and Address: | ASTECH INTERNATIONAL LTD - PHILIPPINE BRANCH 16TH FL LU PLAZA 2 WING YIP ST KWUN TONG KOWLOON HONG KONG |

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Cary Hu

Reviewed by: Sammi Liang

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

- A. Authorization - The Authorization page may include additional Factory Identification Code markings.
- B. Generic Inspection Instructions -
 - i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.
 - ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.
 - iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

Product Description

Switching type power supply, which electronic components are mounted on PWB with no enclosure. 2 MOOP insulations were provided between primary and secondary.

Model Differences

N/A

Technical Considerations

- Classification of installation and use : Built in - to be evaluated in end product
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Component - to be evaluated in end product
- Mode of operation : Continuous
- Supply connection : Appliance coupler
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards: N/A
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is: Ordinary
- The mode of operation is: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No
- The product is Recognized only to the following hazards: Fire, Shock.
- The risk management requirements of the standard were not addressed.

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. When installed in an end-product, consideration must be given to the following:

- The power supply is a built-in device as parts of medical equipment. The date of manufacture & S/N marked needs to be evaluated in the end-product.
- This power supply has been judged on the basis of the required creepage and clearances in the First Edition of the Standard for Medical Electrical Equipment, ANSI/AAMI ES 60601-1, Sub clause 8.9.
- This power supply has been evaluated as a Class I, continuous operation and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Additional evaluation shall be made if the power supply is intended for use in other than Class I equipment.
- This power supply was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The power supply was evaluated as 2 MOOP provided between Primary and Secondary, 1 MOOP provided between the polarity of mains parts and 1 MOOP provided between Primary and Grounding; see insulation diagram for details.
- Consideration shall be given to measuring the temperatures on power electronic components and transformer windings when the power supply is installed in/with the end-use equipment. The transformer (T1) is provided with a Class F(OBJY2) insulation system.

- The ambient temperature of the product is 50°C.
- This power supply has not been evaluated for patient connected applications.
- The end-product Electric Strength Test is to be based upon a maximum working voltage of 288.7 Vrms, 487 Vpk.
- Instructions and equipment marking shall be provided in a language, which is acceptable in the country in which the equipment is to be installed.
- The end product should ensure that the requirements related to accompanying documents, clause 7.9, are met.
- The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
- The end-use product shall ensure that the power supply is used within its ratings.
- The marking legibility test should be evaluated in end system.
- The following tests shall be reconsidered in the end-product evaluation: Temperature Test, Dielectric Voltage Withstand Tests, Leakage Test, Interruption of Power Supply and Protective Grounding Test.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component
- End product Risk Management Process to consider the need for simultaneous fault condition testing
- End product Risk Management Process to consider the need for different orientations of installation during testing.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat.
- End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply
- End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply
- End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply
- End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply
- End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply
- The end-product evaluation shall ensure that the requirements of Clause 8.4.2 c) are met.
- This unit is intended to be used at 3050m high altitude
- Fuse of Littelfuse, type 392 does not have adequate breaking capacity 100A; Overcurrent releases of adequate breaking capacity must be employed in the end product
- The secondary output circuit is SELV

Additional Information

Original 4787022260: upgrade standard to ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10 + A1:12) and CAN/CSA-C22.2 No. 60601-1 (2014).

The product is certified previously by ANSI/AAMI ES60601-1: 2005 and CAN/CSA-C22.2 No.60601-1:08, 2nd Edition, Refer to E182560-A102 for details.

The risk management requirements of the standard were not addressed.



Comparison previous report, Just modification to some minor information below :

- a. Changed all "various" to "interchangeable" in CCL.
- b. Changed all "Astec" to "Astec/ARTESYN" in CCL.

Additional Standards

The product fulfills the requirements of: N/A

Markings and instructions

| Clause Title | Marking or Instruction Details |
|--|---|
| Company identification | Classified or Recognized company's name, Trade name, Trademark or File |
| Model | Model number |
| Supply Connection | Voltage range, ac/dc, phases if more than single phase |
| Alternating current |  |
| Supply Frequency | Rated frequency range in hertz |
| Power Input | Amps, VA, or Watts |
| Output | Rated output voltage, power, frequency. |
| Fuses | Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure) |
| Protective earth ground |  |
| Special Instructions to UL Representative | |
| N/A | |

| Production-Line Testing Requirements | | | |
|--|----------------------|------------------------------|--|
| Test Exemptions - The following models are exempt from the indicated test | | | |
| Model | Grounding Continuity | Dielectric Voltage Withstand | Patient Circuit Dielectric Voltage Withstand |
| LPS53-M | No exemptions | No exemptions | Exempted |
| Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test: | | | |
| Component | | | |
| -- | | | |
| Sample and Test Specifics for Follow-Up Tests at UL | | | |
| The following tests shall be conducted in accordance with the Generic Inspection Instructions | | | |
| Plastic Enclosure or Part | Test | Sample(s) | Test Specifics |
| -- | -- | -- | -- |

TABLE: List of Critical Components

| Object/part or Description | Manufacturer/trademark | type/model | technical data | CCN /Standard | Marks of Conformity |
|----------------------------------|--|-------------------------|--|---|---------------------|
| Marking plate | 3M (MH16411) | 7815 | 100 °C, for application to Polycarbonate. | PGJ12/8 UL969 | UL/cUL |
| Connector (SK1) | MOLEX | 5414 (Marked 41790A) | 7A, 250V | ECBT2 UL1977 | UL |
| Fuse (F1, F2) | LITTELFUSE WICKMANN WERKE (E67006) | 392 | T3.15A, 250 V. Marked "F1 T3.15AL 250V" and "F2 T3.15AL 250V" on PWB respectively. 50A breaking capacity. | JDYX2/8 UL248-14 | UL/cUL |
| Fuse (F1, F2)-Alternate | interchangeable | interchangeable | Listed, T3.15 AL, 250 Vac. Min. 100A breaking capacity. | JDYX/7 UL248-14 | UL/cUL |
| X-Cap. (C1) (optional) | interchangeable | interchangeable | Min.250 V, Max. 0.33 µF, Class X1 or Class X2, provided with VDE or SEV marking. | FOKY2/8, FOWX2/8 UL60384-14, IEC60384-14 | UL/cUL |
| Thermistor (TH1) | interchangeable | interchangeable | 7ohm, 5A at 25°C | - | - |
| Discharging resistor (R4, R5) | interchangeable | interchangeable | 470 kohm, 1/4 W respectively. | - | - |
| Common Mode Choke (L1) | Astec/ARTESYN | Part No. 85200037410 | 130°C. Consists of (OBMW2), copper magnet wire wound toroidal ferrite core and bobbin, (QMFZ2), E I Dupont , type FR50(+)(f1)V-0, min.0.75mm thick. Secured on PWB by soldering. | - | - |
| Y-Cap (C2, C3) | interchangeable | interchangeable | Max. 220 pF, Min. 250 V, Class Y1, provided with VDE or SEV marking. | FOKY2/8, FOWX2/8 UL60384-14, IEC60384-14 | UL/cUL |
| Common Mode Choke (L3) | Astec/ARTESYN | Part No. 85272000010 | 130°C. Consists of (OBMW2), copper magnet wire wound toroidal ferrite core and stand-base, (QMFZ2), Chang Chun Plastic, type T375J, V-0, min.0.79 mm thick. Secured on PWB by soldering. | - | - |
| Bridge Diode (DB1) | interchangeable | interchangeable | Min 600 V, 4 A. | - | - |
| Electrolytic Capacitor (C5, C32) | interchangeable | interchangeable | 68 µF, minimum 400 V, minimum 105 °C, provided with pressure relief. | - | - |
| Transistor (Q5) | interchangeable | interchangeable | Rated 500 V, 9 A. | - | - |
| Primary heatsink (Q5) | interchangeable | interchangeable | Metal, L-shaped, overall approximately 61.5 by | - | - |

| Object/part or Description | Manufacturer/ trademark | type/model | technical data | CCN /Standard | Marks of Conformity |
|--|------------------------------------|--|---|--|---------------------|
| | | | 20.5 mm by 8.4 mm, 1.1 mm thick | | |
| Secondary heatsink (D2) | interchangeable | interchangeable | Metal, L-shaped, overall approximately 65.0 mm by 32.5 by 22.8 by 32.5 mm, 1.1 mm thick. Wrapped by polyester film tape in primary components side. | - | - |
| Transformer (T1) | Astec/ARTESYN | Part No. 852-72000070 or 801-004177-XXXX | Class F (OBJY2), Astech, type 155-10C(E94225). Construction to be separately checked under E12700. See enclosures 4-01, 7-05 for T1 spec. | XORU3/9 | UL/cUL |
| Transformer (T2) | Astec/ARTESYN | 85270000720 | Consists of (OBMW2), copper magnet wire wound toroidal ferrite core and (QMFZ2), E I Dupont, type FR50(+)(f1)V-0, min.0.75mm thick. Secured on PWB by soldering. 130°C. | - | - |
| Photo Coupler (IC2, IC3) | Lite-On Technology Corp. (E113898) | LTV-817 | Double Protection, Viso; 5300 Vac. | FPQU2, FPQU8 UL60384-14, IEC60384-14 | UL/CUL |
| Photo Coupler (IC2, IC3) -Alternate | Vishay Infrared Components | System code H or J | Double Protection, Viso;4420 Vac. | FPQU2, FPQU8 UL60384-14, IEC60384-14 | UL/CUL |
| Bridge capacitor (C17) (Optional) | interchangeable | interchangeable | Max. 1000 pF, Min. 250 V, Class Y1. | FOKY2/8 FOWX2/8 UL60384-14, IEC60384-14 | UL/cUL |
| Output Choke (L2) | Astec/ARTESYN | Part No. 85220101290 | Secondary location. Enamelled copper wire wound on cylindrical ferrite core. | - | - |
| Connector (SK3) | interchangeable | interchangeable | 6 pins provided. Plastic minimum V-1 or better. | QMFZ2/8 UL746C, UL94 | UL/cUL |
| PWB | interchangeable | interchangeable | V-0 or Better, 130°C | ZPMV2/8 UL 796, UL94 | UL/cUL |

Enclosures

| <u>Type</u> | <u>Supplement Id</u> | <u>Description</u> |
|----------------|----------------------|---|
| Photographs | Fig.3-01 | Top view |
| Photographs | Fig.3-02 | Bottom view |
| Diagrams | ILL.4-01 | Choke Spec (L1) |
| Diagrams | ILL.4-02 | Transformer Spec (T1) |
| Diagrams | ILL.4-03 | Choke Spec (L2) |
| Diagrams | ILL.4-04 | Choke Spec (L3) |
| Diagrams | ILL.4-05 | Mylar Dimensions |
| Diagrams | ILL.4-06 | Transformer Spec (T2) |
| Diagrams | ILL.4-07 | T2 Stand-Base Drawing |
| Diagrams | ILL.4-08 | L1 Bobbin Drawing |
| Diagrams | ILL.4-09 | L3 Stand-Base Drawing |
| Diagrams | ILL.4-10 | Material list for T1 |
| Schematics+PWB | ILL.5-01 | PWB layout |
| Manuals | ILL.6-01 | Installation and Operating Instructions |
| Miscellaneous | ILL.7-01 | Marking plate |
| Miscellaneous | ILL.7-02 | Client declaration table |