

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: | LPS58-M |
| Rating: | Rated Input: 100-240 V, 50/60 Hz, 2 A; Rated Output: 48 Vdc, 1.25 A, 60W |
| Applicant Name and Address: | ASTEC 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

Model LPS58-M is a component switching type power supply for building in which has been evaluated for use in Class I medical application. Unit provided with insulation transformers and all components are mounted on 94V-0 PWB without enclosure. The power supply was evaluated as 2 MOOP provided between Primary and Secondary, and 2MOPP provided between Primary and PE; Product have provided 1MOOP insulation between the polarity of mains parts. See insulation diagram for details.

Model Differences

N/A

Technical Considerations

- Classification of installation and use : Component, to be installed in end product
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : Recognized power supply for medical equipment usage
- Mode of operation : Continuous
- Supply connection : Appliance coupler, to be evaluated in end product.
- 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: Biocompatibility (ISO 10993-1), Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 60601-1-2)
- 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

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, ordinary Equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. An 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 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The power supply was evaluated as 2 MOOP between Primary to Secondary and 1 MOOP from Primary to Earth, Product have provided 1MOOP insulation between the polarity of mains parts ,see insulation diagram for details.
- Consideration should be given to measuring the temperatures on power electronic components and

transformer windings when the power supply is installed in the end use equipment. The primary transformer (T1) incorporates a Class 155 (F) insulation system.

- The secondary circuit of this power supply has not been evaluated for patient connected applications.
- The maximum ambient temperature is 50 degree C.
- The following tests shall be performed in the end-product evaluation: Earthing and Potential Equalization Test, Temperature Test, Dielectric Voltage Withstand Tests, Leakage Current Test.
- The maximum working voltage for T1 present is 307 Vrms, 595 Vpk. The electric strength tests in the end-product shall be based on this value.
- This power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings and segregation requirements of the end use application.
- "Voltage or charge limitation" may need to be reconsidered if additional EMC filter is provided between appliance inlet/ power cord to the product.
- A suitable Mechanical, Electrical and Fire enclosure shall be provided in the end-use product.
- This power supply is operated up to 3050m above sea level as declared by manufacturer.
- Separation from secondary to earth need to evaluated in end product.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply and the suitability of Fuse.
- The input and output connectors are not suitable for field connection.
- Proper bonding to the end-product main protective earthing termination is required.
- 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, moisture, and dielectric strength.
- End product to determine the acceptability of risk in conjunction to the movement of components and conductors 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 Arrangement of Indicators 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.

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-A105 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 |
| Supply Frequency | Rated frequency range in hertz |
| Alternating current |  |
| Power Input | Amps, VA, or Watts |
| Output | Rated output voltage, power |

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 |
|---------|----------------------|------------------------------|--|
| LPS58-M | NO EXEMPTION | NO EXEMPTION | EXEMPTION |

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 |
|-----------|
| N/A |

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 |
|---------------------------|------|-----------|----------------|
| N/A | -- | -- | -- |

TABLE: List of Critical Components

| Object/part or Description | Manufacturer/ trademark | type/model | technical data | CCN /Standard | Marks of Conformity |
|--|----------------------------|-----------------------|---|----------------------------|---------------------|
| Marking plate | 3M | 7815 | 100 °C, for application to Polycarbonate. | PGJ12 UL969 | UL/cUL |
| Label Supplier | interchangeable | interchangeable | Various | PGAA | UL |
| PWB | interchangeable | interchangeable | V-0 or Better, 130°C | ZPMV2/8 UL 796, UL94 | UL/cUL |
| Connector (SK1) | MOLEX | 5414 (Marked 41790A) | 7A, 250V | ECBT2 UL1977 | UL |
| Connector (SK2) | interchangeable | interchangeable | 6 pins provided. Plastic minimum V-1 or better. | QMFZ2 UL746C, UL94 | UL |
| Fuse (F1, F2) | LITTELFUSE WICKMANN | 392 | T3.15 A, 250 V. Marked "F1 T3.15AL 250V" and "F2 T3.15AL 250V" on PWB respectively. | JDYX2 UL248-14 | UL/cUL |
| Fuse (F1, F2)-Alternate | interchangeable | interchangeable | Listed, 3.15 A, 250 V ac. Marked "F1 T3.15AL 250V" and "F2 T3.15AL 250V" on PWB | JDYX 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, FOWX2 UL60384-14 | UL/cUL |
| Y-Cap (C2, C3) | interchangeable | interchangeable | Max. 680 pF, Min. 250 V, Class Y1, provided with VDE or SEV marking. | FOKY2, FOWX2 UL60384-14 | UL/cUL |
| Bridge capacitor (C17) (Optional) | interchangeable | interchangeable | Max. 1000 pF, Min. 250 V, Class Y1, provided with VDE or SEV marking. | FOKY2 FOWX2 UL60384-14 | UL/cUL |
| Opto-coupler (IC2, IC3) | Lite-On Technology Corp. | LTV-817 | Double Protection, Viso; 5000 V ac. | FPQU2, FPQU8 UL1577 | UL/cUL |
| Opto-coupler (IC2, IC3) - Alternate | Vishay Infrared Components | System code H or J | Double Protection, Viso; 4420 Vac. | FPQU2, FPQU8 UL1577 | UL/cUL |
| Transformer (T1) | Astec/ARTESYN | Part No. 852-72000040 | (OBJY2), Astec, type 155-10C(E94225). Construction to be separately checked under E127000. See enclosure attachment for T1 spec. | XORU3 | UL |
| Insulating Tape wrapping on the Secondary Heatsink | P LEO & CO | 1K7170 | Rated 180°C. Wrap at the secondary heatsink, 2 layers and extended 28 mm from the edge of heat sink near to the primary side. | OANZ2 UL510 | UL |

Enclosures

| <u>Type</u> | <u>Supplement Id</u> | <u>Description</u> |
|----------------|----------------------|------------------------------------|
| Photographs | Fig.3-01 | Top View |
| Photographs | Fig.3-02 | Bottom/Solder-Side View |
| Photographs | Fig.3-03 | Side-View/Nameplate View |
| Diagrams | ILL.4-01 | T1 Power Transformer Specification |
| Diagrams | ILL.4-02 | L1 Common Mode Choke Specification |
| Diagrams | ILL.4-03 | L3 Specification |
| Schematics+PWB | ILL.5-01 | PCB layout |
| Manuals | ILL.6-01 | Operating Instruction |
| Miscellaneous | ILL.7-01 | Label Specification |
| Miscellaneous | ILL.7-02 | Client Declaration |