UL TEST REPORT AND PROCEDURE

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:	LPS52-M
Rating:	Rated Input: 100-240 V, 50/60 Hz, 2 A; Rated Output: 5 Vdc, 11 A, 55W
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 LPS52-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..

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 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 291Vrms, 641Vpk. 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 reconsider 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 Leakage of Liquids 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.
- 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 related to Accompanying Documents, Clause 7.9 are met.
- 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.

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-A104 for details.
The risk management requirements of the standard were not addressed.

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

- Changed all “various” to “interchangeable” in CCL.
- 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
LPS52-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
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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
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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.	PGJI2/8 UL969	UL/CUL
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 WERKE (E67006)	392	T3.15 A, 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, 3.15 A, 250 V ac. Marked "F1 T3.15AL 250V" and "F2 T3.15AL 250V" on PWB. 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
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
Electrolytic Capacitor (C5, C32)	Interchangeable	Interchangeable	68 µF, minimum 400 V, minimum 105 °C, provided with pressure relief.	-	-
Bridge capacitor (C17) (Optional)	Interchangeable	Interchangeable	Max. 1000 pF, Min. 250 V, Class Y1, 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	-	-
Bridge Diode (DB1)	Interchangeable	Interchangeable	Min 600 V, 4 A.	-	-
Transistor (Q5)	Interchangeable	Interchangeable	Rated 500 V, 9 A.	-	-
Discharging resistor (R4, R5)	Interchangeable	Interchangeable	1.5 Mohm, 1/4 W respectively.	-	-

Object/part or Description	Manufacturer/ trademark	type/model	technical data	CCN /Standard	Marks of Conformity
Opto-coupler (IC2, IC3)	Lite-On Technology Corp.	LTV-817	Double Protection, Viso; 5000 V ac.	FPQU2/8 UL1577	UL/CUL
Opto-coupler (IC2, IC3) - Alternate	Vishay Infrared Components	System code H or J	Double Protection, Viso; 4420 Vac.	FPQU2/8 UL1577	UL/CUL
Transformer (T1)	Astec/Artesyn	Part No. 85272000050	(OBJY2), Astec, type 155-10C (E94225). Construction to be separately checked under E127000. See enclosure attachment for T1 spec.	XORU3	UL
Common Mode Choke (L1)	Astec/Artesyn	Part No. 852-00037410	Consists of (OBMW2), copper magnet wire wound toroidal ferrite core and bobbin, (QMFZ2), E I Dupont, FR50, V-0, min. 0.75 mm thick, 130°C Secured on PWB by soldering.	-	-
Common Mode Choke (L2)	Astec/Artesyn	Part No. 852-20101330	Secondary location. Enameled copper wire wound on cylindrical ferrite core.	-	-
Common Mode Choke (L3)	Astec/Artesyn	Part No. 852-72000010	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.	-	-
Primary heatsink (Q5)	Interchangeable	Interchangeable	Metal, L-shaped, overall approximately 55.5 by 8.5 by 20.5 mm, 1.0 mm thick	-	-
Secondary heatsink (D2)	Interchangeable	Interchangeable	Metal, L-shaped, overall approximately 51 by 32.5 by 25.5 mm, 1.0 mm thick.	-	-
Insulating Tape wrapping on the Secondary Heatsink	P LEO & CO	1K170	Rated 180°C. Wrap at the secondary heatsink, 2 layers and extended 25 mm from the edge of heat sink near to the primary side.	OANZ2 UL510	UL

Enclosures

Type	Supplement Id	Description
Photographs	Fig.3-01	Overall View
Photographs	Fig.3-02	Bottom View
Photographs	Fig.3-03	Overall View (Label shown)
Diagrams	ILL.4-01	T1 Spec
Diagrams	ILL.4-02	L1 Spec
Diagrams	ILL.4-03	L3 Spec
Diagrams	ILL.4-04	L2 Spec
Diagrams	ILL.4-05	Q5 Dimension
Diagrams	ILL.4-06	D2 Dimension
Schematics+PWB	ILL.5-01	PCB layout of main board
Manuals	ILL.6-01	Operating Instruction
Miscellaneous	ILL.7-01	Label Artwork
Miscellaneous	ILL.7-02	Client Declaration Table