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Revised: 2016-11-08

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: LCC600-28U-XX, LCC600-36U-XX, LCC600-48U-XX, LCC600-12U-

XX (where XX can 4P or 9P)

LCC600-28U-4XXX, LCC600-28U-9XXX, LCC600-36U-4XXX, LCC600-36U-9XXX, LCC600-48U-4XXX,LCC600-48U-9XXX, LCC600-12U-4XXX, LCC600-12U-9XXX (Where XXX can be any

alphanumeric character, symbol or blank that represents customer identity that do not affect safety)

Rating: LCC600-28U-XX (where XX can 4P or 9P)

LCC600-28U-4XXX,LCC600-28U-9XXX

(Where XXX can be any alphanumeric character, symbol or blank that represents customer identity that do not affect safety)

AC Input: 100-240Vac, 50/60Hz, 8A MAX

DC Output:

+28VDC, 25A MAX, +5Vsb, 1.5A MAX.

LCC600-36U-XX (where XX can be 4P or 9P)

LCC600-36U-4XXX,LCC600-36U-9XXX

(Where XXX can be any alphanumeric character, symbol or blank that represents customer identity that do not affect safety)AC

Input:

100-240Vac, 8A Max, 50/60Hz

DC Output: +36V, 16.7A Max +5Vsb, 1.5A Max

LCC600-48U-XX (where XX can be 4P or 9P)

LCC600-48U-4XXX,LCC600-48U-9XXX

(Where XXX can be any alphanumeric character, symbol or blank that represents customer identity that do not affect safety)AC

Input:

100-240Vac, **8A** Max, 50/60Hz

DC Output: +48V, 12.5A Max +5Vsb, 1.5A Max

LCC600-12U-XX (where XX can be 4P or 9P)

LCC600-12U-4XXX,LCC600-12U-9XXX

(Where XXX can be any alphanumeric character, symbol or blank that represents customer identity that do not affect safety)AC

Input:

100-240Vac, **8A** Max, 50/60Hz

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DC Output: +12V,50A Max +5Vsb ,1.5A Max

MAX. TOTAL OUTPUT POWER: 600W

Applicant Name and Address: ASTEC INTERNATIONAL LTD - FHILIPPINE 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: Eileen Hu / Cary Hu Reviewed by: Sammi Liang

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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 -
 - 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.

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Product Description

This unit is a medical switching mode 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.

Model Differences

Model LCC600-28U-4P is similar to LCC600-28U-9P except for the input connector is used on model LCC600-28U-9P instead of input cord used for LCC600-28U-4P, and the output connector is used on model LCC600-28U-9P instead of output cord used for LCC600-28U-4P.

Model LCC600-28U-XX is identical to Model LCC600-48U-XX except for the following safety controlled parameters.

- 1. Model name.
- 2. Ratings of DC Output, input connector
- 3. Power transformer (T204)

Model LCC600-28U-XX and LCC600-48U-XX is identical to Model LCC600-36U-XX except for the following safety controlled parameters.

- 1. Model name.
- 2. Ratings of DC Output
- 3. Power transformer (T204), alternate source of MOV101
- 4. LCC600, 9P version has two input connector option: Input Connector (J101) and Input cord with input connector (Optional).

Model LCC600-12U-XX is similar toLCC600-28U-XX, LCC600-48U-XX and LCC600-36U-XX except for the following safety controlled parameters.

- 1. Model name.
- 2. Ratings of DC output, Y-capacitors (C115, C105, C106), Power transformer (T204), and Auxiliary Transformer (T501).
- 3. Insulators, Dimension of Heatsink101 & Heatsink102, PFC Choke (L103), PWB and Output cord.
- 4. LCC60012U-4P and 9P is similar electrically and mechanically they just differ in input and output connections. For 4P it uses input cord and output cord, while 9P it uses input connector and output connector.

LCC600-28U-4XXX is identical to LCC600-28U-4P except for model name.

LCC600-28U-9XXX is identical to LCC600-28U-9P except for model name.

LCC600-36U-4XXX is identical to LCC600-36U-4P except for model name.

LCC600-36U-9XXX is identical to LCC600-36U-9P except for model name.

LCC600-48U-4XXX is identical to LCC600-48U-4P except for model name except for rating of C105, C106 and C115, This change has no effect insulation requirements, After engineering evaluated, no additional testing to be considered.

LCC600-48U-9XXX is identical to LCC600-48U-9P except for model name except for rating of C105, C106 and C115 This change has no effect insulation requirements, After engineering evaluated, no additional testing to be considered.

LCC600-12U-4XXX is identical to LCC600-12U-4P except for model name.

LCC600-12U-9XXX is identical to LCC600-12U-9P except for model name.

Technical Considerations

- Classification of installation and use: For built-in
- Device type (component/sub-assembly/ equipment/ system) : Component

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 Intended use (Including type of patient, application location): Recognized power supply for medical equipment usage

- Mode of operation : Continuous
- Supply connection: Permanently installed for LCC600-28U-4P, LCC600-36U-4P, LCC600-48U-4P, LCC600-12U-4P / Input connector for LCC600-28U-9P, LCC600-36U-9P, LCC600-48U-9P and LCC600-12U-9P.
- 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:

- 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 /30A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The power supply was evaluated as 2 MOPP between Primary to Secondary and 1 MOPP 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 transformers (T204, T301, T501) incorporate a Class 155 (F) insulation system.
- The secondary circuit of this power supply has not been evaluated for patient connected applications.
- 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 with Normal MD, Non-frequency-weighted MD and Fuse Short Circuit Test.
- For Model LCC600-28U-XX, the maximum working voltage for T501 is 377 Vrms, 663 Vpk, for LCC600-48U-XX T501 is 391 Vrms, 681 Vpk for Model LCC600-36U-XX T501 is 382.8 Vrms, 660 Vpk. And for LCC600-12U-XX T501 is 389Vrms,641 VpK. The electric withstand test 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.
- A suitable Mechanical, Electrical and Fire enclosure shall be provided in the end-use product.
- This power supply is operated up to 5000m above sea level as declared by manufacturer.

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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 terminals and connectors have not been evaluated for field wiring.
- 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.
- 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.
- This power supply has two fuses (F101, F102) rated 12.5A, 250Vac connected in Live and Neutral.
- The power supply shall be properly bonded to the main earthing termination in end-use.
- * Maximum operation ambient temperature is 70 degree C for Model LCC600-28U-XX and LCC600-36U-XX, 76 deg. C for Model LCC600-48U-XX and 73 deg. C for Model LCC600-12U-XX (for reference only) with the temperature of baseplate at 85 degree C during temperature test.
- MOPP BF dielectric strength test (1500Vrms) was conducted between secondary and PE on the power supply.
- Additional evaluation has been considered on the +28V output with output voltage trimming range from minimum +24V output to maximum +30V output but limited to 600 W output power. For +48V output with output voltage trimming range from minimum +44V (limited to 550 W output power) output to maximum +54 output, but limited to 600 W. For +36V output with output voltage trimming range from minimum +32V (limited to 535 W output power) output to maximum +38 output, but limited to 600 W. For +12V output with output voltage trimming maximum +15V, but limited to 600W output power.
- Table represents the derating power and allowable baseplate temperature:
 Model LCC600-48-XX, Input 90-104 (Vac) Pout 600 (W) Base Plate Temp 70 (deg)
 Model LCC600-36-XX, Input 105-264 (Vac) Pout 600 (W) Base Plate Temp 85 (deg)

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Model LCC600-12-XX, Input 90-264 (Vac) Pout 535 (W) Base Plate Temp 85 (deg)Derating power and allowable baseplate temperature for Model LCC600-48U-XX, LCC600-36U-XX and LCC600-12U-XX, Input (Vac) Pout (W) Base Plate Temp (deg C): (90-104Vac, 600W, 70deg) (90-104Vac, 550W, 85deg) and (105-264Vac, 600W, 85deg). See Enclosure ILL 7-17 to get more information.

Hi-pot Voltage 1500Vac was performed between Secondary Circuit to Protective Earth.

- Built-in switching power supply. Applicability of the following is to be determined in end product evaluation: 8.4.2 – Limitation of Voltage Current Or Power
- End product to determine the acceptability of Clause 8.4.3 Power plug discharge test.