

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:	LCC250-12U-XXXX The first "X" may be "4" or "7", which stands for the top enclosure style; All other "Y" can be blank or any alphanumeric combinations, which are for marketing purposes only and have no impact on safety. LCC250-24U-XXXX The first "X" may be "4" or "7", which stands for the top enclosure style; All other "Y" can be blank or any alphanumeric combinations, which are for marketing purposes only and have no impact on safety. LCC250-48U-XXXX The first "X" may be "4" or "7", which stands for the top enclosure style; All other "Y" can be blank or any alphanumeric combinations, which are for marketing purposes only and have no impact on safety.
Rating:	Power Input: For model LCC250-12U-XXXX AC INPUT RATING: 100-240V, 50/60Hz, 3.5A DC OUTPUT RATING: Refer to Model Differences section for details. IP Rating: IP64 For model LCC250-24U-XXXX AC INPUT RATING: 100-240V, 50/60Hz, 3.5A DC OUTPUT RATING: Refer to Model Differences section for details. IP Rating: IP64 For model LCC250-48U-XXXX AC INPUT RATING: 100-240V, 50/60Hz, 3.5A DC OUTPUT RATING: Refer to Model Differences section for details. IP Rating: IP64
Applicant Name and Address:	ASTECH INTERNATIONAL LTD - PHILIPPINE BRANCH 16TH FL LU PLAZA

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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: Ricky Wang / Clare He

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

LCC250-12U-XXXX, LCC250-24U-XXXX and LCC250-48U-XXXX are a series of switching mode power supplies, designed to power medical electrical equipment.

Electronic components are mounted on its PWB, which is fitted in metal enclosure. Potting material fills the completed power supply.

Model Differences

The differences between LCC250-12U-4PYY and LCC250-12U-7PYY are as follows:

(1) Top enclosure style

LCC250-12U-7PYY has a top enclosure with integral heat sink;

LCC250-12U-4PYY hasn't heat sink, but use external heat sink(refer to enclosure 4-07) fixed to its top enclosure with screws for testing.

(2) Output Derating

LCC250-12U-4PYY can only operate with full load (12V, 20.8A, 250W) on external heat sink's temperature doesn't exceed 85 degree C.

LCC250-12U-7PYY can operate with full load (12V, 20.8A, 250W) at a maximum ambient of 55 degree C or operated with half load(12V, 10.4A, 250W) at a maximum ambient of 85 degree C.

(3) Forced Ventilation

LCC250-12U-7PYY requires forced ventilation (2m/s) in all conditions;

LCC250-12U-4PYY does not require forced ventilation.

- The differences between Models LCC250-24U-4YYY and LCC250-24U-7YYY are as follows:

(1) Top enclosure style

LCC250-24U-7YYY has a top enclosure with integral heat sink;

LCC250-24U-4YYY hasn't heat sink, but use external heat sink(refer to enclosure 4-08) fixed to its top enclosure with screws for testing.

(2) Output Derating

LCC250-24U-7YYY can operate with full load (24V, 10.4A, 250W) at a maximum ambient of 55 degree C or operated with half load (24V, 5.2A, 125W) at a maximum ambient of 85 degree C.

LCC250-24U-4YYY can only operate with full load (24V, 10.4A, 250W) on external heat sink's temperature doesn't exceed 85 degree C

(3) Forced Ventilation

LCC250-24U-7YYY requires forced ventilation (2m/s) in all conditions;

LCC250-24U-4YYY does not require forced ventilation.

- The Model LCC250-12U-XXXX is identical to Model LCC250-24U-XXXX except for output rating, power transformer (T1), current transformer (L4), Y-cap (C54), Opto-coupler Code (IC207 for Model LCC250-24U-XXXX and IC216 for LCC250-12U-XXXX)

- The differences between Models LCC250-48U-4YYY and LCC250-48U-7YYY are as follows:

(1) Top enclosure style

LCC250-48U-7YYY has a top enclosure with integral heat sink;

LCC250-48U-4YYY hasn't heat sink, but use external heat sink(refer to enclosure 4-08) fixed to its top enclosure with screws for testing.

(2) Output Derating

LCC250-48U-7YYY can operate with full load (48V, 5.2A, 250W) at a maximum ambient of 55 degree C or operated with half load (48V, 2.6A, 125W) at a maximum ambient of 85 degree C.

LCC250-48U-4YYY can only operate with full load (48V, 5.2A, 250W) on external heat sink's temperature doesn't exceed 85 degree C

(3) Forced Ventilation

LCC250-48U-7YYY requires forced ventilation (2m/s) in all conditions;

LCC250-48U-4YYY does not require forced ventilation.

- The Model LCC250-24U-XXXX is identical to Model LCC250-48U-XXXX excepted for output rating, power transformer (T1).

Technical Considerations

- Classification of installation and use : For built-in
- 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 : Primary connector - 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: AAMI ES60601-1 AMD 1 MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE, AMENDMENTS - Edition 1 - Issue Date 2012/08/20.CSA C22.2 NO. 60601-1:14 MEDICAL ELECTRICAL EQUIPMENTS. PT. 1, GENERAL REQUIREMENTS FOR BASIC SAFETY AND ESSENTIAL PERFORMANCE - Edition 3 - Issue Date 2014/01/01.
- 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:: IP64
- 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.

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 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/Core to Secondary of transformer (T1, T3 and L4). 2 MOOP provided between Primary to Secondary and 1MOOP provided between Primary and Enclosure, This product have been provided 1MOOP insulation between the polarity of mains parts; 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. Transformer T1, T3 and L4 employ a Class F (155°C) insulation system.
- The secondary output circuit of the product is SELV.
- For Model LCC250-12U-XXXX series, when loaded with full load (12V, 20.8A), all models in this series are designed to operate at an ambient temperature of 55 degree C. In addition, when LCC250-12U-7PYY models are loaded with half load (12V, 10.4A), they can operate at an ambient of 85 degree C. For Model LCC250-24U-XXXX series, when loaded with full load (24V, 10.4A), all models in this series are designed to operate at an ambient temperature of 55 degree C. In addition, when Model LCC250-24U-7PYY models are loaded with half load (24V, 5.2A), they can operate at an ambient of 85 degree C. For Model LCC250-48U-XXXX series, when loaded with full load (48V, 5.2A), all models in this series are designed to operate at an ambient temperature of 55 degree C. In addition, when Model LCC250-48U-7PYY models are loaded with half load (48V, 2.6A), they can operate at an ambient of 85 degree C.
- The following tests shall be performed in the end-product evaluation: Temperature Test, Dielectric Voltage Withstand Tests, and Leakage Current Test.
- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-SELV: 304.1 Vrms, 442 Vpk, Primary-Earthed Dead Metal: 246.2 Vrms, 451 Vpk.
- Forced air cooling required for LCC250-12U-7PYY, LCC250-24U-7PYY and LCC250-48U-7PYY models, should refer to Accompanying Document for the methods and details of connection, setup, orientation and ventilation.
- A suitable Mechanical, Electrical and Fire enclosure shall be provided in the end-use product.
- This power supply is operated up to 4000m above sea level as declared by manufacturer.
- The disconnection from the mains must be considered in the end product.
- This power supply has not been evaluated for patient connected applications.
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment.
- Transformers T1, T3 and L4 all employ a Class F (155°C) insulation system.
- Instructions and equipment marking shall be provided in a language, which is acceptable in the country in which the equipment is to be installed.
- Earthing test need to be conducted in end-product investigation.
- Cleaning, sterilization or disinfection should be, considered in the end use application.
- The necessity to conduct cord bending test to the AC input strain relief must be considered in end product investigation.
- For Models LCC250-12U-4PYY, LCC250-24U-4PYY and LCC250-48U-4PYY, a heat sink specified in Enclosure ID 4-08 or other similar means must be considered to ensure no hazard can arise from excessive temperature.
- The fuse employed didn't fractured and remained intact during the single fault condition testing and short circuit testing performed in client's facility.
- End product need to be evaluate the serial number or lot or batch identifier and date of manufacture.