

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: | LCM300Q, LCM300U, LCM300L, LCM300W, LCM300N |
| Rating: | <p>Model LCM300Q: Input: 100-240Vac, 50/60Hz, 5Amax Output: +24.0V, 14.5A Max, 350W Max; +5.0Vsb, 2.0A (Optional). Output power derates at 2.5% per °C from 50 °C to 70°C ambient temperature.</p> <p>Model LCM300U: Input: 100-240Vac, 50/60Hz, 5Amax Output: +36.0V, 9.73A Max, 350W Max; +5.0Vsb, 2.0A (Optional). Output power derates at 2.5% per °C from 50 °C to 70°C ambient temperature.</p> <p>Model LCM300L: Input: 100-240Vac, 50/60Hz, 5Amax Output: +12.0V, 25.0A Max, 300W Max; +5.0Vsb, 2.0A (Optional). Output power derates at 2.5% per °C from 50 °C to 70°C ambient temperature.</p> <p>Model LCM300W: Input: 100-240VAC, 50/60Hz, 5.0A max. Output: +48VDC, 6.25A max., 300W max. +5Vsb, 2.0A max. (optional) Output power derates at 2.5% per °C from 50 °C to 70°C ambient temperature.</p> <p>Model LCM300N: Input: 100-240Vac, 50/60Hz, 5Amax Output: +15.0V, 20.0A Max, 300W Max;+5.0Vsb, 2.0A (Optional). Output power derates at 2.5% per °C from 50 °C to 70°C ambient temperature.</p> |
| Applicant Name and Address: | ASTEC INTERNATIONAL LTD - PHILIPPINE BRANCH |

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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.

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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

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

LCM300U is similar to LCM300Q except for T4 power transformer and output ratings.

LCM300L is similar to LCM300Q except for T4 power transformer, T2 gate drive transformer, PCB layout and output ratings.

LCM300W is similar to LCM300Q except for T4 power transformer, T2 gate drive transformer and output ratings.

LCM300N is similar to LCM300L except for T4 power transformer, and output ratings.

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 : 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 EQUIPMENT. 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:: 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 is a built-in device as parts of medical equipment. The date of manufacture & S/N number marked needs to be evaluated in the end-product
- Leakage current test, Temperature test, marking test, and earth impedance test need to be repeated / considered in end-product investigation.
- 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 primary transformer (T4, T2 and 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 as per indicated in enclosure ID 6-03.
- 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 and Fuse Short Circuit Test.
- The maximum working voltage for T4 present is 268.9 Vrms; -663Vpk. for T2 is 267.1 Vrms; 468Vpk. for T1 is 400.5 Vrms; 712Vpk. 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 3000m 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.
- 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.
- A suitable fuse shall be considered in end product investigation.
- For Model LCM300Q: Additional evaluations have been considered for the +24V +/- 20% output voltage adjustability limited to the following combined conditions: maximum allowed 12.5 A output current and 300W output power at 50°C ambient; and maximum allowed 14.5A output current and 350W output power at 45°C ambient. Additional evaluations have also been considered for Reversed Airflow condition with maximum output power of 300W at 50°C ambient.
- For Model LCM300Q: Maximum ambient of 50°C at full load for +24V output at 300W Max; and Maximum ambient of 45°C at full load for +24V output at 350W Max.
- This power supply was tested on a 20A branch circuit at the client's facility. If used on a branch circuit greater than this, additional testing in the end system and under end system power branch is necessary. The fuse employed didn't fractured and remained intact during the single fault condition testing and short circuit testing performed in client's facility.
- For Model LCM300U: Additional evaluations have been considered for the +36V +/- 20% output voltage adjustability limited to the following combined conditions: maximum allowed 8.35 A output current and 300W output power at 50°C ambient; and maximum allowed 9.73 A output current and 350W output power at 45°C ambient.
- For Model LCM300U: Maximum ambient of 50°C at full load for +36V output at 300W Max; and Maximum ambient of 45°C at full load for +36V output at 350W Max.
- For Model LCM300L: Additional evaluations have been considered for the +12V +/- 20% output voltage adjustability limited to the following combined conditions: maximum allowed 25.0 A output current and 300W output power at 50°C ambient.
- For Model LCM300L: Maximum ambient of 50°C at full load for +12V output at 300W Max.
- Power supplies also conform to IEC60601-1 2nd Ed:1988 + A1:1991 + A2:1995.
- For Model LCM300W: Additional evaluations have been considered for the +48V +/- 20% output voltage adjustability limited to the following combined conditions: maximum allowed 6.25A output current and 300W output power at 50°C ambient.
- For Model LCM300W: Maximum ambient of 50°C at full load for +48V output at 300W Max.
- For Model LCM300W: The maximum working voltage for T4 present is 279 Vrms; 681Vpk. for T2 is 261 Vrms; 495Vpk. The electric strength tests in the end-product shall be based on this value.
- For Model LCM300N: Additional evaluations have been considered for the +15V +/- 20% output voltage adjustability limited to the following combined conditions: maximum allowed 20.0A output current and 300W output power at 50°C ambient.
- For Model LCM300N: Maximum ambient of 50°C at full load for +15V output at 300W Max.
- Built-in switching power supply. Applicability of the following is to be determined in End Product Evaluation: 8.4.2 - Accessible Parts Including Applied Parts.
- Only Nidec type U40G12BHA is allowed to be used for Reversed fan condition of LCM300Q.