

UL TEST REPORT AND PROCEDURE

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| Standard: | ANSI/AAMI ES60601-1 AMD1 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance, Amendments – Edition1 –Issue Date 2012/08/20 CAN/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 |
| Certification Type: | Component Recognition |
| CCN: | QQHM2, QQHM8 (Power Supplies, Medical and Dental) |
| Product: | Switching Power Supply |
| Model: | LCM600Q, LCM600Q-N, LCM600W, LCM600Q-T-401, LCM600L, LCM600L-N, LCM600U, LCM600W-T-401, LCM600N and LCM600U-T-404 |
| Rating: | <p>Power Input: 100-240VAC, 8.5A max, 50/60Hz</p> <p>Output (For Model LCM600Q and Model LCM600Q-N): +24VDC, 27.0A max, 600W max, +5Vsb, 2.0A max(Optional) Output power derates at 2.5% per degree C from 50 degree C to 70 degree C ambient</p> <p>Output (For Model LCM600W and LCM600W-T-401): +48VDC, 13.0A max, 600W max, +5.0Vsb, 2.0A max(Optional) Output power derates at 2.5% per degree C from 50 degree C to 70 degree C ambient</p> <p>Output (For Model LCM600Q-T-401): +24VDC, 18.75A max, 450W max, +5.0Vsb, 2.0A max(Optional) Output power derates at 2.5% per degree C from 50 degree C to 70 degree C ambient</p> <p>Output (For Model LCM600L and LCM600L-N): +12.0Vdc, 52.0A max, 600W max, +5.0Vsb, 2.0A max(Optional) Output power derates at 2.5% per degree C from 50 degree C to 70 degree C ambient</p> <p>Output (For Model LCM600U): +36.0Vdc, 18.0A max, 600W max, +5.0Vsb, 2.0A max(Optional) Output power derates at 2.5% per degree C from 50 degree C to 70 degree C ambient</p> <p>Output (For Model LCM600N): +15Vdc, 44.0A max, 600W max +5.0Vsb, 2.0A(Optional) Output power derates at 2.5% per degree C from 50 degree C to 70</p> |

degree C ambient

Output (For Model LCM600U-T-404):

+40Vdc, 15.0A max, 600W max

Output power derates at 2.5% per degree C from 50 degree C to 70 degree C ambient

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.

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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 -
 - 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 an insulation transformer and all components are mounted on 94V-0 PWB.

Model Differences

Model LCM600W is similar to Model LCM600Q excepted for the different output voltage, power transformer and minor change of PCB layout (not affecting insulation).

Model LCM600Q-T-401 is similar to Model LCM600Q excepted for the output rating.

Model LCM600L is similar to Model LCM600Q excepted for the different output voltage, power transformer T801, turns of secondary winding of auxiliary transformer T101, output choke L302.

Model LCM600L-N is similar to model LCM600L except for the DC fan.

Model LCM600U is identical to Model LCM600L excepted for different T801 and secondary output (T101 is same as LCM600Q).

Model LCM600W-T-401 is identical to Model LCM600W excepted for the number of output terminals. LCM600W have 2 while LCM600W-T-401 have 4.

Model LCM600Q-N is similar to Model LCM600Q excepted for the fan and cover.

Model LCM600N is similar to Model LCM600Q excepted for the different output voltage, power transformer T801 and the Insulator between T801 core and HTSK_ PRI (option).

Model LCM600U-T-404 is identical to Model LCM600U except for model designation, output rating, input wiring assembly and PCB lay-out to meet the new creepage and clearance required by the customer which are higher than the medical requirement. Between Primary and Secondary (except for optocouplers): Minimum 12 mm. creepage and minimum 7 mm. clearance. Between Secondary and PE: Minimum 5.0 mm. creepage and minimum 2.28 mm. clearance. Between Line and Neutral: Minimum 4.0 mm. creepage.

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: 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

- LCM600Q was also tested at inhibit mode (fan off/ stop condition) at 50°C ambient temperature.

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 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 primary transformer (T101, T801 and T302) 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 need to refer to enclosure 6-01 for details.
- The following tests shall be performed in the end-product evaluation: Earthing and Potential Equalization Test, Temperature Test, Dielectric Voltage Withstand Tests, and Leakage Current Test.
- The maximum working voltage present is 422.7 V rms; 681Vpk; 1122Vpk-pk. (Refer to report E182560-A25) 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.
- 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 LCM600Q, LCM600Q-T-401 and LCM600Q-N: Additional evaluation has been considered for the +24V +/- 20% Output voltage adjustability limited to the following combined conditions: maximum allowed 27A output current and 600W output power. For Model LCM600W and LCM600W-T-401: Additional evaluation has been considered for the +48V +/- 20% Output voltage adjustability limited to the following combined conditions: maximum allowed 13A output current and 600W output power. For Model LCM600L and LCM600L-N: Additional evaluation has been considered for the +12V +/- 20% Output voltage adjustability limited to the following combined conditions: maximum allowed 52A output current and 600W output power. For Model LCM600U: Additional evaluation has been considered for the +36V +/- 20% Output voltage adjustability limited to the following combined conditions: maximum allowed 18A output current and 600W output power. For Model LCM600N: Additional evaluation has been considered for the +15V +30% - 20% Output voltage adjustability limited to the following combined conditions: maximum allowed 44A output current and 600W output power.
- The touch time for external enclosure isn't determined by the client, end product shall consider it according to client's definition.
- The leakage current test was performed with non-frequency-weighted in model LCM600U-T-404. For other models, the leakage current test was performed without non-frequency-weighted MD, it shall be considered in End-product.
- MOPP Isolation requirement (dielectric strength) between Secondary and PE has been considered for model LCM600U-T-404.