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2016-06-17

UL TEST REPORT AND PROCEDURE

Standard: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical

Equipment - Part 1: General Requirements for Basic Safety and

Essential Performance)

CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment -

Part 1: General Requirements for Basic Safety and Essential

Performance)

Certification Type: Component Recognition

CCN: QQHM2, QQHM8 (Power Supplies, Medical and Dental)

Product: Switching Power Supply

Model: LCM1500Q-T, LCM1500W-T, LCM1500U-T, LCM1500L-T,

LCM1000Q-T, LCM1500N-T, LCM1500R-T, LCM1000L-T,

LCM1000W-T, LCM1000N-T, LCM1000U-T

Rating: Input: 100-240Vac, 50/60Hz, 19A

DC Outputs:

+5Vsb, 2.0A Max (Optional); see below for additional output

For Model LCM1500Q-T

Output: +24.0V, 63.0A Max, 1500W Max;

(forward fan airflow only)

+24V, 31.25A Max, 750W Max; (reverse fan airflow only)

For Model LCM1500W-T

Output: +48.0V, 32.0A Max, 1500W Max;

(forward fan airflow only)

+48V, 20.83A Max, 1000W Max; (reverse fan airflow only)

For Model LCM1500U-T

Output: +36.0V, 42.0A Max, 1500W Max;

(forward fan airflow only)

For Model LCM1500L-T

Output: +12.0V, 125.0A Max, 1500W Max;

(forward fan airflow only)

For Model LCM1000Q-T

Output: 24V, 42Amax,1000 Watts

(forward fan airflow only)

+24V, 31.25A Max, 750W Max; (reverse fan airflow only)

For Model LCM1500N-T

Output: +15.0V, 100.0A Max, 1500W Max;

(forward fan airflow only)

For model: LCM1500R-T

DC outputs: +28V, 53.6A Max, 1500W Max;

(forward fan airflow only)

For Model LCM1000L-T

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Output: +12.0V, 84.0A Max, 1000W Max;

(forward fan airflow only)

For Model LCM1000W-T

Output: +48.0V, 21.0A Max, 1000W Max;

(forward fan airflow only)

+48V, 20.83A Max, 1000W Max; (reverse fan airflow only)

For model: LCM1000N-T

DC outputs: +15V, 67.0A Max, 1000W Max;

(forward fan airflow only)

For model: LCM1000U-T

DC outputs: +36V, 28.0A Max, 1000W Max;

(forward fan airflow only)

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: Eileen Hu/Clare He Reviewed by: Chenchen Lee

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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.

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Product Description

These units are 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 LCM1500W-T is identical to Model LCM1500Q-T excepted for:

- 1. Different output rating
- 2. Alternate T801 (801-006224-0001 or 006224-0001)
- 3. Little bigger size of Heatsink, HTSK1, HTSK3 and HTSK4

Model LCM1500U-T is identical to Model LCM1500W-T excepted for:

- 1. Different output rating
- 2. Alternate T801 (801-006713-0001 or 006713-0001)
- 3. Size of Heatsink HTSK3 and HTSK4

Model LCM1500L-T is identical to Model LCM1500Q-T excepted for:

- 1. Different output rating
- 2. Alternate T801 (801-006797-XXXX or 006797-XXXX)
- 3. Size of Heatsink, HTSK1, HTSK3 and HTSK4
- 4. Minor change in PCB layout
- 5. Overall mechanical dimension employing output busbars
- 6. Employment of discharge resistors and C1 before the fuse.

Model LCM1000Q-T, LCM1000W-T, LCM1000L-T, LCM1000U-T, LCM1000N-T are identical to Model LCM1500Q-T, LCM1500W-T, LCM1500U-T, LCM1500U-T, LCM1500N-T respectively excepted for:

1. Different output current rating and output power. See comparison list to Enclosure for details.

Model LCM1500N-T is similar to Model LCM1500L-T excepted for:

- 1. Different output rating
- 2. Alternate T801 (801-007009-XXXX or 007009-XXXX)
- 3. Alternate fan source by Nidec Taiwan Corp type H60T12BGA7 rated 12Vdc, 0.94A

Model LCM1500R-T is identical to previous tested model LCM1500Q-T except for Power transformer (T801), model number 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:: ANSI/AAMI ES60601-1 (2005/(R)2012 + C1:2009/(R)2012 + A2:2010/(R)2012) Revision Date 2012/01/17, CAN/CSA-C22.2 No.60601-1:08 Edition 2 (Incorporates Corrigendum 2) Revision Date 2011/06,
- The product was not investigated to the following standards or clauses:: Biocompatibility (ISO 10993-

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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
- The product was submitted and evaluated for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification of: 50°C at full load up to 70°C at derated output power for the main output (50%). Output power derates at 2.5% per °C from 50 °C to 70°C ambient temperature. Derated load upto 70deg C is applicable to forward fan airflow only.

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 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 primary transformer (T101, T801, 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, Leakage Current Test and Fuse Short Circuit Test, Legibility Test.
- For Model LCM1500Q-T, the maximum working voltage for T101 present is 391.0 Vrms; 716Vpk; 1130Vpk-pk. for T801 is 262.2 Vrms; 578Vpk; 955Vpk-pk. for T302 is 259.2 Vrms; 460Vpk; 796Vpk-pk. For Model LCM1500W-T, the maximum working voltage for T101 present is 394.6 Vrms; 689Vpk; 990Vpk-pk. for T801 is 252.6 Vrms; 504Vpk; 804Vpk-pk. for T302 is 259.4 Vrms; 486Vpk; 681Vpk-pk. For Model LCM1500U-T, the maximum working voltage for T101 present is 398.8 Vrms; 707Vpk; 1.18kVpk-pk. for T801 is 253.4 Vrms; 468Vpk; 902Vpk-pk. for T302 is 260.7 Vrms; 468Vpk; 796Vpk-pk. For Model LCM1500L-T, the maximum working voltage for T101 present is 396.2 Vrms; 716Vpk; 972Vpk-pk. for T801 is 255.5 Vrms; 513Vpk; 716Vpk-pk. for T302 is 254.9 Vrms; 451Vpk; 583Vpk-pk. For Model LCM1500N-T, the maximum working voltage for T101 present is 394.7 Vrms; 734Vpk; for T801 is 240.2 Vrms; 477Vpk; for T302 is 242.2 Vrms; 442Vpk; For Model LCM1500R-T, the maximum working voltage for T101 present is 391.0 Vrms; 716Vpk; for T801 is 248.8 Vrms; 460Vpk; for T302 is 259.2 Vrms; 460Vpk; 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.

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"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 with adequate breaking capacity shall be considered in end product investigation.
- For Model LCM1500Q-T: Additional evaluations have been considered for the +24V +/- 10% output voltage adjustability limited to the following combined conditions: Maximum allowed 63.0 A output current and 1500W output power.
- For model LCM1500W-T: Operating temperature up to 50°C, the +48V output of the equipment can be loaded full loading, and for operating temperature over 50°C and up to 70°C, the output loading should be decreased by 2.5% per 1 degree rise.
- The following are the output loading conditions used in the entire testing of model LCM1500W-T: , , Loading 1: +46.88V, 32.0A; +5Vsb, 2.0A , Loading 2: +52.80V, 28.41A; +5Vsb, 2.0A , Loading 3: +48.0V, 31.25A; +5Vsb, 2.0A , Loading 4: +46.88V, 24.0A; +5Vsb, 2.0A (75% load of Loading 1 at ambient temp 60°C) , Loading 5: +46.88V, 16.0A; +5Vsb, 2.0A (50% load of Loading 1 at ambient

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temp 70°C),

- For Model LCM1500W-T: Additional evaluations have been considered for the +48V -12.5% to +10% output voltage adjustability limited to the following combined conditions: Maximum allowed 32.0A output current and 1500W output power.
- For model LCM1500U-T: Additional evaluations have been considered for the +36V +/- 10% output voltage adjustability limited to the following combined conditions: Maximum allowed 42.0A output current and 1500W output power.
- For model LCM1500U-T: Operating temperature up to 50°C, the +36V output of the equipment can be loaded full loading, and for operating temperature over 50°C and up to 70°C, the output loading should be decreased by 2.5% per 1 degree rise.
- The following are the output loading conditions used in the entire testing of model LCM1500U-T: , , Loading 1: +35.72V, 42.0A; +5Vsb, 2.0A , Loading 2: +39.6V, 37.88A; +5Vsb, 2.0A , Loading 3: +36.0V, 41.67A; +5Vsb, 2.0A , Loading 4: +35.72V, 31.5A; +5Vsb, 2.0A (75% load of Loading 1 at ambient temp 60°C) , Loading 5: +35.72V, 21.0A; +5Vsb, 2.0A (50% load of Loading 1 at ambient temp 70°C)
- For model LCM1500L-T: Additional evaluations have been considered for the +12V output voltage adjustability from 10V to 13.2V limited to the following combined conditions: Maximum allowed 125.0A output current and 1500W output power.
- For model LCM1500L-T: Operating temperature up to 50°C, the +12V output of the equipment can be loaded full loading, and for operating temperature over 50°C and up to 70°C, the output loading should be decreased by 2.5% per 1 degree rise.
- The following are the output loading conditions used in the entire testing of model LCM1500L-T: , , Loading 1: +12.0V, 125.0A; +5Vsb, 2.0A , Loading 2: +13.2V, 113.64A; +5Vsb, 2.0A , Loading 3: +12.0V, 93.75A; +5Vsb, 2.0A (75% load of Loading 1 at ambient temp 60°C) , Loading 4: +12.0V, 62.5A; +5Vsb, 2.0A (50% load of Loading 1 at ambient temp 70°C).
- For Model LCM1000Q-T: Additional evaluations have been considered for the +24V +/- 10% output voltage adjustability limited to the following combined conditions: Maximum allowed 42.0 A output current and 1000W output power.
- For model LCM1500N-T: Additional evaluations have been considered for the +15V +/-10% output voltage adjustability limited to the following combined conditions: Maximum allowed 100.0A output current and 1500W output power.
- For model LCM1500N-T: Operating temperature up to 50°C, the +15V output of the equipment can be loaded full loading, and for operating temperature over 50°C and up to 70°C, the output loading should be decreased by 2.5% per 1 degree rise.
- The following are the output loading conditions used in the entire testing of model LCM1500N-T: Loading 1: +15V, 100A; +5Vsb, 2.0A, Loading 2: +16.5V, 90.91A; +5Vsb, 2.0A, Loading 3: +15V, 75A; +5Vsb, 2.0A (75% load of Loading 1 at ambient temp 60°C), Loading 4: +15V, 50A; +5Vsb, 2.0A (50% load of Loading 1 at ambient temp 70°C), Loading 5: +15V, 0A; +5Vsb, 2.0A.
- For Model LCM1500R-T: Additional evaluations have been considered for the +28V +/- 10% output voltage adjustability limited to the following combined conditions: maximum allowed 53.6 A output current and 1500W output power.
- The following are the output loading conditions used in the entire testing of model LCM1500R-T: , Loading 1: +25.2V, 53.6A; +5Vsb, 2.0A, Loading 2: +28.0V, 53.6A; +5Vsb, 2.0A, Loading 3: +30.8V, 48.71A; +5Vsb, 2.0A, Loading 4: +28.0V, 40.2A; +5Vsb, 2.0A (75% load of Loading 2 at ambient temp 60°C), Loading 5: +28.0V, 26.8A; +5Vsb, 2.0A (50% load of Loading 2 at ambient temp 70°C), Loading 6: +28.0V, 0A; +5Vsb, 2.0A.
- The output power and stored energy under Normal and Single Fault Condition shall be evaluated in end application to determine the accessible parts.

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 Additional evaluation has been considered for adding reverse fan airflow direction (use Fan rating: 32.23CFM, air from input/output side going out towards the fan side) at specific loading condition applicable for models LCM1500Q-T, LCM1500W-T, LCM1000Q-T, LCM1000W-T

Reverse fan airflow was evaluated at the following limited loading conditions: for model LCM1500Q-T and LCM1000Q-T: +24V, 31.25A max; 5Vsb, 2A, 750W max output power at AC 90 – 264V at 70 degC max ambient temperature; for model LCM1500W-T and LCM1000W-T: +48V, 20.83A max; 5Vsb, 2A, 1000W max output power at AC 100 – 264V at 50 degC ambient temperature, 900W max output power at AC 90 – 264V at 70 degC ambient temperature.