

Description**UL TEST REPORT AND PROCEDURE**

Standard:	ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2 / QQHM8
Complementary CCNs:	
Product:	Switching Power Supply
Model:	CME350A-zxxxxxxx; CUS350M-zxxxxxxx (z = 12, 18, 24, 36 or 48; xxxxxxx = /, A, F, FN, FET, FGE, PG, 2, F2, PG2, S**, LN (for z = 24 only), other alphanumeric character, symbol or blank)
Rating:	Refer to Enclosure ID Miscellaneous-(01) for details.
Applicant Name and Address:	TDK-LAMBDA CORP NAGAOKA TECHNICAL CENTER R&D DIV 2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA 940-1195, JAPAN

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 as applicable.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Atsushi Fuchita, Project
Handler

Reviewed by: Thorsten Creter, Reviewer

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

The equipment is a component type switching mode power supply series intended for use in class I construction of medical equipment.

Output Rating:

12 V (11.1 - 12.6 V), maximum 29.0 A (Maximum 348.0 W) (for CUS350M-12 and CME350A-12 for convection cooling)

12 V (11.1 - 12.6 V), maximum 34.5 A (Maximum 414.0 W) (for CUS350M-12 and CME350A-12 for forced air cooling)

18 V (16.6 - 18.9 V), maximum 19.4 A (Maximum 349.2 W) (for CUS350M-18 and CME350A-18 for convection cooling)

18 V (16.6 - 18.9 V), maximum 23.0 A (Maximum 414.0 W) (for CUS350M-18 and CME350A-18 for forced air cooling)

24 V (22.1 - 25.2 V), maximum 14.7 A (Maximum 352.8 W) (for CUS350M-24 and CME350A-24 for convection cooling)

24 V (22.1 - 25.2 V), maximum 17.5 A (Maximum 420.0 W) (for CUS350M-24 and CME350A-24 for forced air cooling)

36 V (33.1 - 37.8 V), maximum 9.7 A (Maximum 349.2 W) (for CUS350M-36 and CME350A-36 for convection cooling)

36 V (33.1 - 37.8 V), maximum 11.5 A (Maximum 414.0 W) (for CUS350M-36 and CME350A-36 for forced air cooling)

48 V (44.2 - 50.4 V), maximum 7.3 A (Maximum 350.4 W) (for CUS350M-48 and CME350A-48 for convection cooling)

48 V (44.2 - 50.4 V), maximum 8.7 A (Maximum 417.6 W) (for CUS350M-48 and CME350A-48 for forced air cooling)

Modified O/P Output range:

Modified O/P Range is similar with original O/P Range except for adding Maximum output value(V_{o_max2}), the details refer to Miscellaneous - (01) 01-Electrical Ratings for all models.

Refer to the Report Modifications page for any modifications made to this report.

Model Differences

Model CUS350M-zxxxxxxx is basic model.

Model CME350A-zxxxxxxx is identical to Model CUS350M-zxxxxxxx except for model name.

Suffix "z" of all models denotes output voltage. (z = 12, 18, 24, 36 or 48)

Suffix "xxxxxxx" of all models denotes as follows. (xxxxxxx = /, A, F, FN, FET, FGE, PG, 2, F2, PG2, S**, LN

(for z = 24 only), other alphanumeric character, symbol or blank)
 /: Separator of model name letters, not related specification of equipment
 A: Add the cover on the top
 F: Full function
 FN: Provided with Fan Power Terminal
 FET: Full function and add M3 mounting holes on chassis
 FGE: Full function and Voltage Dip Improvement
 PG: Power good
 2: Provided with PWB coating
 F2: Full function and provided with PWB coating
 PG2: Power good and provided with PWB coating
 S**: Special modified model without affect to safety requirements
 LN: Reduce audio noise
 Other alphanumeric character, symbol: For market purposes, no construction differences and no safety impact.
 Brank: Standard type

Models suffix "A" for CUS350M and CME350A series are similar with original models except for adding the cover on the top and the temperature derating is less than the original. Miscellaneous - (02) for details.

Additional Information

This Test Report was based on the CB Test Certificates (Ref. Certif. Nos. DE 2-019004 dated 2015-06-11 and DE 2-019004-M1 dated 2016-01-04) and Test Reports (Ref. Nos. 15077101 001 dated 2015-06-09 and 15077101 002 dated 2015-12-29), which were prepared by TÜV Rheinland LGA Products GmbH and submitted by the CB Scheme.

The test results and clause verdicts of the above noted report were reviewed and found to comply with the applicable Standard IEC 60601-1:2005 (Third Edition) + Am 1:2012. As a result the clause verdicts and test results for this report were noted as N/A and have been referred to the TÜV Rheinland LGA Products GmbH. Test Reports for details. All test data have been retained in UL's files.

Project scope of 4788445507:

1. Change lower and upper limit of output voltage. Details including: Adjust the minimum O/P range and add one maximum output range column. The total output power remained less than the original. Refer to Miscellaneous - (01) for details.
2. Add modified models suffix "A" for CUS350M and CME350A series.
3. Add alternate silicon cap: PIONEER MATERIAL PRECISION TECH; Type: PMP-P-100

Technical Considerations

- The product was investigated to the following additional standards: N/A
- The following additional investigations were conducted: N/A
- The product was not investigated to the following standards or clauses: Clause 17: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1), Risk Management (ISO 14971), Usability (IEC 60601-1-6)
- The following accessories were investigated for use with the product: N/A
- The degree of protection against harmful ingress of water is ordinary, IPX0.

The mode of operation is continuous.

The product is not suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide.

Although product specification says 85-265 Vac for input voltage range, test was conducted at 90-

264 Vac (+/- 10 %) by the applicant's request.

The maximum specified operational ambient temperature is 70 °C. For derating curve, see Enclosure ID Miscellaneous-(02)

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:

- - Overcurrent protection in accordance with clause 8.11.5 shall be prepared in the end product. Also, opposite polarities between live and neutral (1MOOP) shall be evaluated in the end product.
- The equipment has been evaluated for use at altitudes up to 4,000m and pollution degree 2.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (T_{ma}). See Enclosure ID Miscellaneous-(02) for additional details regarding out derating depending on ambient temperature or input voltage.
- This power supply has been judged on the basis of the required creepage and clearances in the Standard for Medical Electrical Equipment, AAMI ES / CSA 60601-1, sub-clause 8.9.
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the equipment is used with the end product. The end product shall ensure that the equipment is used within its ratings.
- Instructions for use shall be checked in the end product.
- This unit is a power supply intended for building in. Final installation should comply with the enclosure, mounting, marking, spacing and separation requirements. In addition, Temperature, Leakage Current, Dielectric Voltage Withstand and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- The output circuit has not evaluated for connecting to Applied Parts. For end products intended to connect the output circuit to Applied Parts, suitable evaluation of the separation, leakage current, dielectric voltage withstand and related requirements should be conducted.
- Proper bonding to protective earthing terminal of end product shall be provided.
- Input and output connectors are not intended for field-wiring connection. They are only intended for factory-wiring inside the end product.
- Dielectric Strength Test in the end product is to be based upon the maximum working voltage of: T1: 340 V_{rms}, 590 V_{pk}; T2: 250 V_{rms}, 528 V_{pk}.
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF). Additional requirements may be required if used for connection to applied parts.
- The following end-product enclosures are required: Electrical, Fire
- All secondary output circuits are non-hazardous voltage, and hazardous energy level (240 VA) in accordance with sub-clause 8.4.2 c).
- The maximum investigated branch circuit rating is 20 A. If used on a branch circuit greater than this, additional testing may be necessary.
- Temperature Test was conducted without test corner. The acceptability of risk in conjunction to temperature testing with test corner shall be considered in the end product.

- Risk Management Process in accordance with clause 4.2 shall be evaluated in the end product.
- The equipment has been evaluated as a Class I, continuous operation, IPX0, and not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. Additional evaluations shall be considered if the equipment is intended for classifications other than these.
- The following magnetic devices (e.g. transformers or inductor) are provided with an UL1446 insulation system with the indicated rating greater than Class A (105°C): T1 (Class B), T2 (Class F), L1, L2 (120°C), L3, L4 (130°C)
- The maximum continuous power supply output (Watts) relied on forced air cooling from: See Enclosure ID Miscellaneous-(02) for details.
- X-Capacitors (C1, C4) may have variation in capacitance up to 2.2 μ F (C1), 0.68 μ F (C4). Therefore, consideration shall be given in controlling the capacitance value in the end-product application with respect to capacitance discharge issue.
- Y-Capacitors (C2, C3, C6, C53, C54) may have variations in capacitance up to 1000 pF (C2, C3, C6), and 4700 pF (C53, C54) respectively. Therefore, consideration shall be given in controlling the capacitance values in end product application with respect to touch Current issue.