

## Description

**UL TEST REPORT AND PROCEDURE**

<b>Standard:</b>	ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14
<b>Certification Type:</b>	Component Recognition
<b>CCN:</b>	QQHM2 / QQHM8
<b>Complementary CCNs:</b>	
<b>Product:</b>	Switching Power Supply
<b>Model:</b>	RWS1500B-12/ME, RWS1500B-15/ME, RWS1500B-24/ME, RWS1500B-36/ME, RWS1500B-48/ME, may be followed by suffix "abcd" (a is R, b is CO2, c is FO, d is RF; and "a", "b", "c" and "d" may be blank) (for details, see General Product Information)
	CME1500A-12, CME1500A-15, CME1500A-24, CME1500A-36, CME1500A-48, CUS1500M-12, CUS1500M-15, CUS1500M-24, CUS1500M-36, CUS1500M-48, may be followed by suffix "vwxy" (v is /, w is CO2, x is RF, y is SF; and "v", "w", "x", "y" may blank) (for details, see General Product Information)
<b>Rating:</b>	Input: 100-240 Vac, 19.0 A, 50-60 Hz Output: - RWS1500B-12/ME, CME1500A-12, CUS1500M-12: 12 Vdc, 125 A - RWS1500B-15/ME, CME1500A-15, CUS1500M-15: 15 Vdc, 100 A - RWS1500B-24/ME, CME1500A-24, CUS1500M-24: 24 Vdc, 63 A - RWS1500B-36/ME, CME1500A-36, CUS1500M-36: 36 Vdc, 42 A - RWS1500B-48/ME, CME1500A-48, CUS1500M-48: 48 Vdc, 32 A - AUX output for CME1500A, CUS1500M: 5 Vdc, 1 A
<b>Applicant Name and Address:</b>	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.

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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: Jun Orito, Project Handler    Reviewed by: Tsutomu Abe, 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 under tests is component type power supply for built-in type, model RWS1500B, CME1500A, and CUS1500M series, and intended for use in end-product equipment used in a hospital or related health care facility.

This equipment provides One Means Of Patient Protection (1MOPP) between Primary/Secondary and GND, and Two Means Of Patient Protection (2MOPP) between Primary and Secondary.

#### Output:

- RWS1500B-12/ME, CME1500A-12, CUS1500M-12: 12 Vdc (10.2 to 14.4 Vdc), maximum 125 A (maximum 1500 W),
- RWS1500B-15/ME, CME1500A-15, CUS1500M-15: 15 Vdc (12.75 to 18 Vdc), maximum 100 A (maximum 1500 W),
- RWS1500B-24/ME, CME1500A-24, CUS1500M-24: 24 Vdc (20.4 to 28.8 Vdc), maximum 63 A (maximum 1512 W),
- RWS1500B-36/ME, CME1500A-36, CUS1500M-36: 36 Vdc (30.6 to 43.2 Vdc), maximum 42 A (maximum 1512 W),
- RWS1500B-48/ME, CME1500A-48, CUS1500M-48: 48 Vdc (40.8 to 55.2 Vdc), maximum 32 A (maximum 1536 W)

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

### Model Differences

All RWS1500B models are identical except for model designation, output rating, T3 secondary windings and plates (material, thickness, turns), T3 internal construction (related to secondary windings and plates), and secondary components.

All CME1500A (or CUS1500M) models are identical except for model designation, output rating, T3 secondary windings and plates (material, thickness, turns), T3 internal construction (related to secondary windings and plates), secondary components, and primary to earth capacitor (C15) capacitance (for CME1500A only).

CME1500A and CUS1500M series are identical except for model designation, primary to earth capacitor (C15), and secondary to earth capacitor (C61).

For CME1500A-12 and -15, C15 capacitance is various from maximum 680 pF to no mount.

For CME1500A-12, -15, -24, -36, -48, C61 capacitance is maximum 0.01  $\mu$ F.

CME1500A (and/or CUS1500M) series are similar to RWS1500B series except for :

- Addition of AUX output with 5 Vdc, 1 A (for the additional models), This made changes to circuit diagram, silk/pattern trace layouts with additional transformer (T401) and insulation sheet to keep adequate spacing.
- Specification of noise filter coil (L1, 2),

- Speed-controllable fan motor,
- Addition of fuse (F4),
- Addition of suffix "SF" (for the additional models) meaning fuse (F4) is bypassed.
- Change of shape of fan flow barrier for suffix "RF"

Options "abcd" are defined as below.

- a: R (control on/off to output),
- b: CO2 (thin coating (QMJU2) on both sides of printed wiring board to prevent unintentional objectives from adhering),
- c: FO (remote sensing, parallel operation, low output voltage alarm),
- d: RF (DC fan with opposite direction and air flow, and different derating curve),

In addition, there is "RFO" combination "R" and "FO".

All the combinations using the options above are available except for "R"+"RFO" and "FO" + "RFO". For "FO" and "RFO" only, transformer (T1) is used.

Options "vwxy" are defined as below.

- v: / (separate),
- w: CO2 (thin coating (QMJU2) on both sides of printed wiring board to prevent unintentional objectives from adhering),
- x: RF (DC fan with opposite direction and air flow, and different derating curve),
- y: SF (F4 is bypassed, and F1 only left)

#### **Additional Information**

There are various conditions of output loads, and four patterns of installation conditions. For details, see Enclosure Miscellaneous-(01) for RWS1500B series, Miscellaneous-(05) for CME1500A series, Miscellaneous-(06) for CUS1500M series. (all same conditions)

Operating Condition: Unit was continuously operated with the rated output loads, considering derating curve and installation conditions.

Option "R", "CO2", "FO", and "RFO" would not give impact to product safety.

Option "RF" was applied for test in addition to a standard model.

In case of maximum output voltage, load current is equivalent to maximum output power.

In case of minimum output voltage, load current is equivalent to maximum output current.

Based on the simple difference between CME1500A and CUS1500M series, tests were conducted on CME1500A series.

CME1500A and CUS1500M series has speed-controllable fan motor. Speed pattern is low and high. The condition for fan speed is referred to Enclosure Miscellaneous-(07). This condition is common in all outputs, suffix (including "RF"), and installation conditions.

The similar model to RWS1500B series was evaluated in E122103-A211-CB-1 (2016-12-19) with A1 (2017-01-23) and A2 (2017-02-06) under IEC 60950-1: 2005 (Second Edition) + Am1: 2009 + Am2: 2013. The difference in the model specification of IEC 60950 and 60601 is the capacitance and type of capacitors (C3, 4, 5, 6, 15, 20, 60, 61) with suffix "/ME" which indicates medical use, and noise filter coil (L1, 2). For details, see Enclosure Miscellaneous-(04).

Some test results were derived from E122103-A211-CB-1 due to the equivalent requirements to IEC 60601-1. For details, see Appended Tables.

Also, the following test data was used from E122103-A211-CB-2 (2018-06-06). For details, see Appended Tables.

- Cl. 13.2: Abnormal Operation Testing (PC1001 Pin 1 to 3, S/c) due to the same AUX sub board except for speed control circuit.

For RWS1500B series, the following tests were conducted on the equipment with the alternate L1, 2 (type DN-DL3514-2) to verify almost no impact against the main L1 (type CV1A0045SAA), L2 (type

CV190070SAA).

- Cl. 5.7: Humidity Conditioning (following earth leakage current),
- Cl. 8.7.4.5: Earth Leakage Current

Unless otherwise stated, the models subject to tests in Appended Tables were provided with the main L1, 2 (type CV1A0045SAA), L2 (type CV190070SAA).

#### Technical Considerations

- The product was investigated to the following additional standards: EN 60601-1:2006/A1:2013/A12:2014
- The following additional investigations were conducted: N/A
- 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), Risk Management (ISO 14971)
- The following accessories were investigated for use with the product: N/A
- There is no speed control in cooling fans for RWS1500B series.
- There is speed control in cooling fans for CME1500A and CUS1500M series.
- For some of critical components, EN standards were used to verify the compliance. The EN standards were harmonized to IEC standard, and technically equivalent.
- CB Test certificates for components are included in Licenses Enclosure.
- When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.
- The maximum specified operational ambient temperature is 50 °C at 100 % load, and 60 °C at 60 % for standard model, and 50 °C at 100 % load, 60 °C at 75 % load and 70 °C at 50 % load for suffix "RF" model.
- 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.
- Input voltage deviation is +/-10 %. 85 Vac (-15 %) was excluded from this evaluation by the applicant's request.
- Output voltage deviation is -15 % and +20 % for 12, 15, 24, 36 Vdc models, and +/- 15 % for 48 Vdc model.
- In temperature test for CME1500A and CUS1500M series, the condition for low fan speed was applied. As shown in Enclosure Miscellaneous-(07), the worst condition should be 80 % load in Tma 30 °C. However, test was conducted in 80 % load in Tma 40 °C by the applicant's request.
- In temperature test and abnormal test for CME1500A and CUS1500M series, clearances from the surroundings were required. For details, see Enclosure Miscellaneous-(08).

#### 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 cl. 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.
- - Dielectric Strength Test in the end product is to be based upon the maximum working voltage of: For RWS1500B-12/ME, PRI-GND 240 Vrms, 422 Vpk, PRI-SEC 240 Vrms, 462 Vpk. For RWS1500B-15/ME, PRI-GND 240 Vrms, 446 Vpk, PRI-SEC 240 Vrms, 472 Vpk. For RWS1500B-24/ME, PRI-GND 240 Vrms, 414 Vpk, PRI-SEC 240 Vrms, 488 Vpk. For RWS1500B-36/ME, PRI-GND 240 Vrms, 406 Vpk, PRI-SEC 264 Vrms, 636 Vpk. For RWS1500B-48/ME, PRI-GND 240 Vrms, 408 Vpk, PRI-SEC 262 Vrms, 700 Vpk. For CME1500A and CUS1500M series (T401 common), PRI-GND 384 Vrms, 584 Vpk, PRI-SEC 386 Vrms, 592 Vpk.
- - 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, Mechanical.

- - All main output circuits are non-hazardous voltage, but all at hazardous energy level (240 VA) in accordance with cl. 8.4.2 c).
- - AUX output circuit is non-hazardous and energy level (240 VA) in accordance with cl. 8.4.2 c).
- - AUX output circuit complies with power availability (15 W) in accordance with cl. 13.1.2.
- - The maximum investigated branch circuit rating is 20 A. If used on a branch circuit greater than this, additional testing may be necessary.
- - 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.
- - The equipment has been evaluated for use under Pollution degree 2, and at altitude up to 4000 m.
- - 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.
- - 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.
- - Final installation of this equipment should comply with the enclosure, mounting, marking, spacing and separation requirements. In addition, Temperature, Leakage Current, Dielectric Voltage Withstand and Interruption of this equipment tests should be considered as part of the end product evaluation.
- - Risk Management Process in accordance with cl. 4.2 shall be evaluated in the end product.
- - The equipment has been judged on the basis of the required creepage and clearance according to cl. 8.9 in IEC 60601-1 Edition 3.1 (2012) that covers the end application for which the component was designed.
- - 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 OBJY2 insulation system with the indicated rating greater than Class A (105 °C): T1, T2, T401 (Class B), T3, T401 (Class F)