Description

# UL TEST REPORT AND PROCEDURE

| | |
|---|---|
| **Standard:** | ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14 |
| **Certification Type:** | Component Recognition |
| **CCN:** | QQHM2 / QQHM8 |
| **Product:** | Component Power Supply |
| **Model:** | HWS1500-24/ME, HWS1500-36/ME and HWS1500-48/ME |
| **Rating:** | Input:<br>All models: 100-240Vac, 20A, 50/60Hz<br><br>Output:<br>Model HWS1500-24/ME: 24Vdc, 65A (100-180VAC) 70A (180-240VAC)<br>Model HWS1500-36/ME: 36Vdc, 42A (100-180VAC) 46.5A (180-240VAC)<br>Model HWS1500-36/ME: 48Vdc, 32A |
| **Applicant Name and Address:** | TDK-LAMBDA CORP<br>NAGAOKA TECHNICAL CENTER<br>R&D DIV<br>2704-1 SETTAYA-MACHI<br>NAGAOKA-SHI<br>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.

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

Prepared by: Katsuyuki Kusagawa Reviewed by: Tsutomu Abe

**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**

Products are component power supplies intended to be used as part of Medical Electrical Equipment.
This AC Input Power Supply provides 2MOOP isolation from Primary to Secondary and 1MOOP isolation from Primary to Earth. It contains the mains transformer with UL Recognized Insulation System.
Refer to the Report Modifications page for any modifications made to this report.

**Model Differences**

Models HWS1500-24/ME, HWS1500-36/ME and HWS1500-48/ME are identical, except for output rating, Transformer (T201), Inductor (L401) and some components on secondary circuit.

**Additional Information**

These products have been previously evaluated to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) as detailed in CBTR Ref. No E309264-A55-CB-1 and CB Test Certificate Ref No. US-21008-UL, and evaluated by UL to IEC 60601-1:1988+ A1:1991+ A2:1995 (2nd ed.), UL 60601-1: 1st ed., 2006-04-26 (includes National Differences for USA) and CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada) under Test Report No. E309264-A9 by UL, and also evaluated to IEC 60950-1:2005 under Test Report No. E122103- A37 by UL. All tests conducted per 2nd ed. of IEC 60601-1 and IEC 60950-1 were considered representative of the corresponding tests required by 3rd ed. of IEC 60601-1 as stated under Summary of Testing.

Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, it has been determined that the product continues to comply with the standard.
All required tests were carried out under the previously investigation.

The following test was conducted in this evaluation as the previously evaluated Test Report might have been insufficient.
- Cl. 5.7: Humidity Preconditioning
- Cl. 8.4.3: Voltage or Charge Limitation
- Cl. 8.7.3 e): Non-frequency-weighted Leakage Current
- Cl. 8.8.3: Dielectric Voltage Withstand

CB Test certificates for components are included in Licenses Enclosure. In accordance with the current rules of CB Scheme, CB Test certificate is effective for 3 years. Recognizing NCB may challenge the CBTC when certificates are more than 3 years.
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.

**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: Biocompatibility (ISO 10993-1), Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 60601-1-2)
- The following accessories were investigated for use with the product: N/A
- No Other Considerations.

**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:

- Considerations to the applied parts requirement, to be conducted as end-product
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end-use product shall ensure that the power supply is used within its ratings.
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF)
- The input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.
- The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
- The unit provides the following MOOP (means of operator protection): 2 MOOP based upon a working voltage 250Vrms, 420Vpk between input circuit of isolation transformer (T203); 267Vrms, 736Vpk between input circuit of isolation transformer (T201); 373Vrms, 656Vpk between input circuit of isolation transformer (T700). And the core of the transformer is treated as primary.
- Isolation transformer T203 employs a Class A (105 degree C) insulation system.
- Isolation transformer T201 employs a Class F (155 degree C) insulation system.
- Isolation transformer T700 employs a Class A (105 degree C) insulation system.
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- Proper bonding to the end-product main protective earthing termination is required.
- The product was tested for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification. See Enclosure "Manuals - (01)" for additional details regarding output derating depends on the product orientation.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- Additional fusing may be required in the end product to meet the requirement of Cl. 8.11.5, Mains fuses and Over Current Release. The product is only provided and tested with a single fuse.

- 
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- 
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No
- 
- The Clearances have additionally been assessed for suitability up to 3000 m elevation.
- 
- The risk management requirements of the standard were not addressed.
- 
- The investigated Pollution Degree is : 2

| **Markings and instructions** | |
|---|---|
| Clause Title | Marking or Instruction Details |
| Company identification | Classified or Recognized company's name, Trade name, Trademark or File |
| Model | Model number |

**Special Instructions to UL Representative**

Regarding TABLE: List of Critical Components, verify the information relating to UL and cUL or CSA only.
All Standard No. in critical components list is out of inspection.
Markings of conformity other than UL, cUL or CSA in critical components list are out of inspection.
They are related to CB test report only.

## Production-Line Testing Requirements

**Test Exemptions** - The following models are exempt from the indicated test

| Test | Exemption Specifics | Details |
|---|---|---|
| Grounding Continuity | The following models are exempt from the indicated test: | N/A |
| Dielectric Voltage Withstand | The following models are exempt from the indicated test: | All models |
| Patient Circuit Dielectric Voltage Withstand | The following models are exempt from the indicated test: | N/A |
| Solid-State Components | The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test: | N/A |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

**Sample and Test Specifics for Follow-Up Tests at UL**

The following tests shall be conducted in accordance with the Generic Inspection Instructions

| Plastic Enclosure or Part | Test | Sample(s) | Test Specifics |
|---|---|---|---|
| None | N/A | N/A | N/A |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |