

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:	Built in Power Supply
Model:	HWS1000L-X /YYYYYYYY, SWS1000L-X /YYYYYYYY, where X can be 3, 5, 12, 15, 24, 36, 48, or 60; and /YYYYYYYY can be /RF, /RFHC, /RFCO2, /HC, /HCCO2, /CO2, /RFHCCO2, /LLF, /LLFCO2, /BATz (z = blank or 3 digit max which consist of 0 to 9 and/or A to Z) or blank.
Rating:	<p>Input: 100-240 VAC, 50/60 Hz, 13 A</p> <p>Outputs:</p> <ul style="list-style-type: none"> - HWS1000L-3, SWS1000L-3; 3.3 Vdc, 200 A - HWS1000L-5, SWS1000L-5; 5 Vdc, max. 200 A (4-6 Vdc, max. 200 A and 1000 W) - HWS1000L-12, SWS1000L-12; 12 Vdc, max. 88 A (9.6-14.4 Vdc, max. 88 A and 1056 W) - HWS1000L-15, SWS1000L-15; 15 Vdc, max. 70 A (12-19.5 Vdc, max. 70 A and 1050 W) - HWS1000L-24, SWS1000L-24; 24 Vdc, max. 44 A (19.2-28.8 Vdc, max. 44 A and 1056 W) - HWS1000L-36, SWS1000L-36; 36 Vdc, max. 29 A (28.8-43.2 Vdc, max. 29 A and 1044 W) - HWS1000L-48, SWS1000L-48; 48 Vdc, max. 22 A (38.4-56 Vdc, max. 22 A and 1056 W) - HWS1000L-60, SWS1000L-60; 60 Vdc, max. 17 A (48-66 Vdc, max. 17 A and 1020 W) <p>NOTE: Ratings in the parentheses are for reference only. These are not indicated on the device rating label.</p>
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: 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 is medical grade switching power supply, Model HWS1000L and SWS1000L series intended for building into end-product.

Two Means Of Patient Protection (2MOPP) are provided between Primary and Secondary. Refer to the Report Modifications page for any modifications made to this report.

Model Differences

Model differences are as follows.

1. Output Rating:

- HWS1000L-3, SWS1000L-3; 3.3 Vdc, 200 A
- HWS1000L-5, SWS1000L-5; 5 Vdc, max. 200 A (4-6 Vdc, max. 200 A and 1000 W)
- HWS1000L-12, SWS1000L-12; 12 Vdc, max. 88 A (9.6-14.4 Vdc, max. 88 A and 1056 W)
- HWS1000L-15, SWS1000L-15; 15 Vdc, max. 70 A (12-19.5 Vdc, max. 70 A and 1050 W)
- HWS1000L-24, SWS1000L-24; 24 Vdc, max. 44 A (19.2-28.8 Vdc, max. 44 A and 1056 W)
- HWS1000L-36, SWS1000L-36; 36 Vdc, max. 29 A (28.8-43.2 Vdc, max. 29 A and 1044 W)
- HWS1000L-48, SWS1000L-48; 48 Vdc, max. 22 A (38.4-56 Vdc, max. 22 A and 1056 W)
- HWS1000L-60, SWS1000L-60; 60 Vdc, max. 17 A (48-66 Vdc, max. 17 A and 1020 W)

2. Layout

3. Transformer (T2) Turns of Primary and Secondary Windings

4. Model Designation (including "HWS" and "SWS", which differ in model designation only)

Options "/YYYYYYY" are defined as follows.

1. /RF: Reversed Fan
2. /HC: Hiccup Mode
3. /CO2: Carbon Coating
4. /LLF: Alternate Fan (Type 109L0612G4)
5. /BATz (z = blank or 3 digit max which consist of 0 to 9 and/or A to Z): Applied to HWS1000L-36 and HWS1000L-60. Model HWS1000L-36 and HWS1000L-60 with suffix "/BATz" is that OCP (overcurrent protection) settings can be adjusted to within 55-100 % by user skilled persons in normal condition, and PWB may be additionally coated.
6. /RFHC: Combination of "/RF" and "/HC".
7. /RFCO2: Combination of "/RF" and "/CO2".
8. /HCCO2: Combination of "/HC" and "/CO2".
9. /RFHCCO2: Combination of "/RF", "/HC", and "/CO2".
10. /LLFCO2: Combination of "/LLF" and "/CO2".

Additional Information

For all the models, OCP (overcurrent protection) can be adjusted to within 30-100 % in normal condition by factory personnel only, and PWB may be additionally coated. The equipment is provided with fan with variable speed.

The equipment was previously evaluated under IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10), CAN/CSA-C22.2 No. 60601-1:2008 + C2:2011 on the CB Test Report Reference No. E309264-A67-CB-1 with Cert No. DK-44206-UL. Test results, except for Heating Test, Abnormal Test, Transformer Overload/Short test, and some of Dielectric Strength Test, were derived from the CB Test Report due to no change in specification.

For Heating Test, Abnormal Test, and Transformer Overload/Short Test, the test results were replaced with CB Test Report Reference No. E122103-A169-CB-1 with Cert No. DK-44280-UL. E122103-A169-CB-1 is subject to the same model under IEC 60950-1:2005 (2nd Edition), Am 1:2009, therefore the test data is effective.

In the previously evaluated Test Reports, two major amendments were conducted. In Heating Test, Abnormal Test, and Transformer Overload/Short Test, the test results were divided into three groups (incl. original specification) as follows, stating each condition.

A: Original Specification.

B: Addition of alternate T4 (Type 50T-6014E). Addition of alternate plastic material, FR530 from E I Dupont for L1, L4 core covers as well as T3 bobbin

C: Addition of /RF: Reversed Fan, /HC: Hiccup Mode, /CO2: Carbon Coating. Addition of SWS1000L-3.3, SWS1000L-15, SWS1000L-36, SWS1000L-48, and SWS1000L-60. Addition of alternate T4 (Type PA57805x).

The following test was conducted in this evaluation as the previously evaluated Test Report might have been insufficient.

- 5.7: Humidity Preconditioning
- 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: None
- 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: None
- 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:

- - The equipment provides the following MOPP (means of patient protection): based upon working voltage 413 Vrms, 558 Vpk between Primary to Secondary.
- T2 employs a Class F (155 °C) insulation system. T4 employs a Class B (130 °C) or Class F (155 °C).
- The equipment was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The output circuit has not been evaluated for connection to applied parts (Type B, BF or CF).

- This unit is a power supply intended for building in. Final installation should comply with the enclosure, mounting, marking, spacing, and separation requirements.
- Temperature, Leakage Current, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- The end-use product shall ensure that the power supply is used within its ratings.
- The input/output terminals are not intended for field connections, they are only intended for factory wiring inside the end-use product.
- The equipment has been evaluated as Class I, altitude up to 3000 m, pollution degree 2, overvoltage category II, 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. Additional evaluation shall be considered if the power supply is intended to be classified as the other conditions.
- 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.
- Risk management process has not been conducted in this evaluation. Risk management process shall be conducted in the end product, including the evaluation of requirements related to the power supply.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- This equipment is intended to be bonded to protective earth of the end product via chassis.
- The equipment was submitted and tested for use at the manufacturer's recommended ambient temperature (T_{mra}) of 50 °C at Normal Fan Mode and 35 °C at Reverse Fan Mode at 100 % loading. See Product Specification incl. Derating Curve in Enclosure Miscellaneous-(001).
- The equipment was not evaluated for SELV or energy hazard in cl. 8.4.2. They are to be considered in the end product, if applicable.

