

UL TEST REPORT AND PROCEDURE

Standard:	UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety) CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1: General Requirements for Safety)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Complementary CCN:	QQGQ2, QQGQ8 (Power Supplies for Information Technology Equipment Including Electrical Business Equipment)
Product:	Power Supply
Model:	Models 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>NOTE: Ratings in parentheses are for reference only. They are only included in the accompanying document and not on the device rating label.</p> <p>Outputs: HWS1000L-3, SWS1000L-3: 3.3Vdc, 200A HWS1000L-5, SWS1000L-5: 5Vdc, max. 200A (4~6 Vdc, max. 200A and 1000W) HWS1000L-12, SWS1000L-12: 12Vdc, max. 88A (9.6~14.4 Vdc, max. 88A and 1056W) HWS1000L-15, SWS1000L-15: 15Vdc, max. 70A (12~19.5 Vdc, max. 70A and 1050W) HWS1000L-24, SWS1000L-24: 24Vdc, max. 44A (19.2~28.8 Vdc, max. 44A and 1056W) HWS1000L-36, SWS1000L-36: 36Vdc, max. 29A (28.8~43.2 Vdc, max. 29A and 1044W) HWS1000L-48, SWS1000L-48: 48Vdc, max. 22A (38.4~56 Vdc, max. 22A and 1056W) HWS1000L-60, SWS1000L-60: 60Vdc, max. 17A (48~66 Vdc, max. 17A and 1020W)</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.

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

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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.

Product Description

The HWS1000L and SWS1000L series are Class I power supplies for building-in and intended for use in Medical Equipment. The metal enclosure is protectively earthed and provides partial protection to live parts. Fans of variable speed are provided.

Model Differences

All Models are similar to each other, except the following:

- a) Output rating; +3.3Vdc for HWS1000L-3 & SWS1000L-3; +5Vdc (4~6 Vdc) for HWS1000L-5 & SWS1000L-5; +12Vdc (9.6~14.4 Vdc) for HWS1000L-12 & SWS1000L-12; +15Vdc (12~19.5 Vdc) for HWS1000L-15 & SWS1000L-15; +24Vdc (19.2~28.8 Vdc) for HWS1000L-24 & SWS1000L-24; +36Vdc (28.8~43.2 Vdc) for HWS1000L-36 & SWS1000L-36; +48Vdc (38.4~56 Vdc) for HWS1000L-48 & SWS1000L-48; +60Vdc (48~66 Vdc) for HWS1000L-60 & SWS1000L-60; HWS1000L is identical to SWS1000L except for the model designation;
- b) Layout;
- c) Transformer (T2) secondary winding;
- d) Model designation (refer to Additional information more designation information);

Technical Considerations

- Classification of installation and use : NA. Built In Power Supply
- Supply connection : NA Built In Power Supply
- Accessories and detachable parts included in the evaluation : None
- Options included : None
- The product was investigated to the following additional standards:: CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada), UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA)(except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1, Programmable Electronic Systems, IEC 60601-1-4),
- The product was not investigated to the following standards or clauses:: Clause 52.1, Programmable Electronic Systems (IEC 601-1-4), Clause 48, Biocompatibility (ISO 10993-1), Clause 36, Electromagnetic Compatibility (IEC 601-1-2)
- The product is Classified only to the following hazards:: Casualty, Shock, Fire
- The degree of protection against harmful ingress of water is:: Ordinary
- The following accessories were investigated for use with the product:: N/A
- The mode of operation is:: Continuous
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock:: No
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen

or with nitrous oxide:: No,

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:

- Note: No default COAs exist for 60601: 1. CNR and USR: Product covered is Recognized Component and has been judged on the basis of the requirements for The Standard for Medical Electrical Equipment UL 60601-1, First Edition, dated April 25, 2003 and CAN/CSA-C22.2 No. 601.1-M90, Update No. 2, November 2003. 2. The device shall be installed in compliance with the enclosure, mounting, ventilation requirements, markings, symbols, spacing and segregation requirements of the end-use product. 3. The output connections are not suitable for current interruption. The acceptability of the mating connection relative to securedness, insulating material, leakage current and temperature shall be considered in the end-used equipment. 4. The suitability of the load and the isolation shall be investigated in the end-used equipment. 5. The product was considered as a Class I with no Applied Parts. 6. The Temperature Test was conducted with simulated load. The product was submitted and tested for use at the maximum ambient temperature (T_{ma}), permitted by the manufacturer's specification of: T_{ma} for Power Supply with Normal Fan Mode, configuration is 50degC; while T_{ma} for Power Supply with Reverse Fan Mode configuration is, 35degC. Temperature Test shall be considered when installed in the end-use equipment. 7. Leakage Current Tests (CL. 19) shall be considered on the end-use , equipment. 8. This equipment was not investigated for ingress of water (IPX0). 9. The unit must be installed as described in the Technical Specification. When installed in the end-used equipment, consideration shall be taken to ensure the openings, LEDs and wirings are enclosed. 10. The suitability of the mains power supply cord set and mating connector shall be considered in the end use application. 11. The transport and storage conditions (temperature, humidity, environmental, and pressure) shall be considered in the end use application. 12. The fuse markings shall be considered in end use product. 13. The technical specification, description and other information shall be included in the end use product accompanying documents. 14. Symbol 5041 from IEC 60417 shall be marked onto chassis for heat warning. 15. The power supply terminals and/or connectors are: Suitable for factory wiring only. 16. The maximum investigated branch circuit rating is: 20 A. 17. Proper bonding to the end-product main protective earthing termination is required., 18. The following end-product enclosures are required: Mechanical, Fire, Electrical. 19. The product shall be fully enclosed in the end product. 20. The Terminal Block (TB1) was not evaluated as terminal block for direct connecting of power supply cord.,
- The model "/BATz" is investigated as one output option, it needs to be considered in end-product..
- SWS1000L-X or HWS1000L-X (where X can be 3, 5, 12, 15, 24, 36, 48 or 60) has additional option where OCP can be adjusted. The suitable connection and the related test should be considered in end-product.

Additional Information

Under SR2237442.532077- Report Transfer (Project #4786791333; Feb 2015)

E252373 X3 A3 is transferred to E309264 X5 A69. The applicant and listee details (name and addresses) are changed from the release site to the intended applicant.

HWS1000L-X /YYYYYYY, SWS1000L-X /YYYYYYY, where X can be 3, 5, 12, 15, 24, 36, 48, or 60. And, /YYYYYYY can be /RF, /RFHC, /RFCO2, /HC, /HCCO2, /CO2, /RFHCCO2, /LLF, /LLFCO2, /BATz or blank.

1) /RF Reverse Fan

2) /HC Hiccup mode

3) /CO2 Carbon coating

- Power supply is evaluated at 100% loading (declared by manufacturer) at ambient up to and including 50°C.

- Power supply is evaluated at 100% loading (declared by manufacturer) at ambient up to and including 35degC for reverse fan mode.

Amendment 1: (08CA30820): Addition of models SWS1000L-3, SWS1000L-15, SWS1000L-36, SWS1000L-

48, SWS1000L-60

Amendment 2: (08CA54968): Update of trademark and addition of HWS1000L-X series. HWS1000L is identical to SWS1000L except for the model designation.

SR4837614-T001 Correction Report

No Test is considered necessary.

(1) Critical component table 1.5.1, Insulation sheet (Between main board and metal enclosure), manufacturer change from GE to Sabic Innovative Plastics for material type FR60

Reissue E252373-A3-UL-2 (10CA28238): Change manufacturer from "Nemic Lambda" to "TDK-Lambda".

Addition of the following alternate components:

- (a) Varistor, Manufacturer: Thinking Corp, type: TVR10471V
- (b) Varistor, Manufacturer: Nipponchemicon, type: TND10V471
- (c) Varistor, Manufacturer: Epcos, type: S10K300E2
- (d) Dummy tape (margin tape) in transformer T4, manufacturer: 3M, type: 69

E252373-A3-UL (10CA54562) : Addition of the following alternate components:

- (a) supplementary fuse, F2 (manufacturer: Daito, type: D51, rated: DC450V 10A)
- (b) X-capacitor, C1 & C4
 - (i) manufacturer: EPCOS, type: B3293 and B3292 series, rated: 1uF, 250Vac, X2;
 - (ii) manufacturer: Xiamen Faratronic, type: MKP62 series, rated: 1uF, 250Vac, X2;
 - (iii) manufacturer: Europtronic, type: MPX series, rated: 1uF, 250Vac, X2

E252373-A3-UL: 11CA55000: Testing is not required for this project since it is addition of capacitor C13 in the critical component table that was missed out in previous investigation.

E252373-A3-UL (13CA16959): Construction review and testing is unnecessary due to update the special instructions only.

E252373-A3-UL (13CA35432):

Alternate Fan (Type 109L0612G4) from Sanyo Denki with the same rating as type D041(original one), Heatsink1 ((For D1, D12, TH2, Q1, Q2, Q4, D4, D5, SR1) , Insulation sheet with little change. The humidity test and dielectric voltage withstand test were performed.

Alternate similar model "LLF" which is for the new alternate Fan (Type 109L0612G4) from Sanyo Denki. No test required for this alternate.

Alternate similar model "/LLFCO2"which is the combination for model "LLF" and model "CO2"for alternative fan & coated PCB.

Alternate Model "/BATz", Construction review and testing is unnecessary due to Models with suffix "/BATz" are identical to the basic model . and the only difference from model HWS1000L-36 and HWS1000L-60 with suffix /BATz to the others is the OCP settings can be changed by user skilled person and PCB may be additionally coated.

User skilled person can adjust the OCP range within 55%~100% rating in the normal condition.

And SWS1000L-X or HWS1000L-X (where X can be 3, 5, 12, 15, 24, 36, 48 or 60) has additional option where OCP can be adjusted to minimum 30% rating in the normal condition by factory personnel only.

Where OCP setting can be adjusted to minimum 30% rating in normal condition, the PCB of these models may also be additionally coated.


Report revision (2014, Sep., project number: 4786529829)

Expanding output voltage from single value to a range and with max. output power. NOTE: Ratings in parentheses are for reference only. They are only included in the accompanying document and not on the device rating label.

Additional Standards

The product fulfills the requirements of: CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)

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
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Marking of hot parts	Parts inside the equipment that are hot and may be touched are marked with 60417-2-IEC-5041 symbol adjacent to the part.