

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10 + A1:12)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2014) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Medical Grade Power Supply
Model:	HWS100A-xx/ME, HWS100A-xx/MEA, HWS100A-xx/MER, and HWS100A-xx/MERA Where xx represents the output voltage rating, and can be one of the following: 5, 12, 15, 24, or 48.
Rating:	<p><Input> HWS100A-xx/ME, HWS100A-xx/MEA, HWS100A-xx/MER, and HWS100A-xx/MERA : 100 - 240 V ac, 50 - 60 Hz, 1.4 A</p> <p><Output> (1) HWS100A-5/ME, HWS100A-5/MEA, HWS100A-5/MER, and HWS100A-5/MERA: 5 V $\overline{=}$, 20 A</p> <p>(2) HWS100A-12/ME, HWS100A-12/MEA, HWS100A-12/MER, and HWS100A-12/MERA: 12 V $\overline{=}$, 8.5 A</p> <p>(3) HWS100A-15/ME, HWS100A-15/MEA, HWS100A-15/MER, and HWS100A-15/MERA: 15 V $\overline{=}$, 7.0 A</p> <p>(4) HWS100A-24/ME, HWS100A-24/MEA, HWS100A-24/MER, and HWS100A-24/MERA: 24 V $\overline{=}$, 4.5 A</p> <p>(5) HWS100A-48/ME, HWS100A-48/MEA, HWS100A-48/MER, and HWS100A-48/MERA: 48 V $\overline{=}$, 2.1 A</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.

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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Reviewed by: Katsuyuki Kusagawa

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 models HWS100A-xx/ME, HWS100A-xx/MEA, HWS100A-xx/MER and HWS100A-xx/MERA of Medical Grade Power Supplies are intended for building into end-product installations.

The power supply feature is intended to connect to UL recognized terminal block (TB1) by screws for input and output wiring.

2 Means Of Operator Protection (MOOP) are provided between Primary and Secondary on Transformer (T2) and Optocouplers (PC1, PC2 and PC3).

Model Differences

HWS100A-xx/ME: Standard Model (without both metal cover and ON/OFF control)

HWS100A-xx/MEA: with metal cover

HWS100A-xx/MER: with ON/OFF control function

HWS100A-xx/MERA: with metal cover and ON/OFF control function

Where xx denotes the output voltage ratings, 5, 12, 15, 24, or 48.

Output ratings:

Models HWS100A-5/ME, HWS100A-5/MEA, HWS100A-5/MER, and HWS100A-5/MERA: 4.0 - 6.0 V dc, max 20 A, max 100.0 W.

Models HWS100A-12/ME, HWS100A-12/MEA, HWS100A-12/MER, and HWS100A-12/MERA: 9.6 - 14.4 V dc, max 8.5 A, max 102.0 W.

Models HWS100A-15/ME, HWS100A-15/MEA, HWS100A-15/MER, and HWS100A-15/MERA: 12.0 - 18.0 V dc, max 7.0 A, max 105.0 W.

Models HWS100A-24/ME, HWS100A-24/MEA, HWS100A-24/MER, and HWS100A-24/MERA: 19.2 - 28.8 V dc, max 4.5 A, max 108.0 W.

Models HWS100A-48/ME, HWS100A-48/MEA, HWS100A-48/MER, and HWS100A-48/MERA: 38.4 - 52.8 V dc, max 2.1 A, max 100.8 W.

Technical Considerations

- The equipment was investigated to the following additional standards: IEC 60601-1: 2005 + CORR. 1: 2006 + CORR. 2: 2007 + AM1: 2012, ANSI/AAMI ES60601-1: 2005 + C1: 2009 + A2: 2010 + A1: 2012, CAN/CSA-C22.2 No. 60601-1: 14, EN60601-1: 2006 + CORR: 2010 + A11: 2011 + A1: 2013 + A12: 2014.
- The equipment was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14 Programmable Electronic Systems, Biocompatibility (ISO 10993-1), Usability (IEC 60601-1-6), Risk Management (ISO 14971)
- The degree of protection against harmful ingress of water is: Ordinary, IPX0
- The mode of operation is: Continuous
- The equipment 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:

- The equipment is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No
- The unit provides the following MOOP (means of operator protection): 2 MOOP based upon a working voltage 285 V rms, 620 V pk between input circuit of isolation transformer (T2) and transformer output circuit. The core of the transformer is treated as float.
- Isolation transformer T2 employs a Class F (155 °C) insulation system.
- The output circuit has not been evaluated for connection 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 considered.
- 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.
- This power supply was tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- Secondary outputs are SELV and non-hazardous every level for all models.
- 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.
- This power supply has been evaluated as Class I, altitude up to 4000 m (based on 62 kPa), 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.
- The equipment was submitted and tested for use at the manufacturer's recommended ambient temperature (T_{mra}). See Enclosure-Miscellaneous ID No. 7-01 "Output derating curve - for without cover (p.1), for with cover (p.2)" for additional details regarding output derating and the equipment orientation.
- The equipment incorporates a fuse with high-breaking capacity in the Line conductor only. Consideration shall be given in the end-use product regarding additional fuse having the same or better characteristics in order to comply with fusing requirements of Clause 8.11.5 of the Standard.
- Earth terminal provided on Terminal Block (TB1) has not been evaluated as protective earthing terminal. If the earth terminal is treated as protective earthing in the end product, Limited Short-Circuit Test per CSA C22.2 No.04 shall be conducted. This component is intended to be bonded to a protective earth of the end product via chassis. Protective bonding mark (60417-1-IEC-5017) is provided on terminal block, however, Limited Short-Circuit Test per CSA C22.2 No.04 has not been conducted.
- 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.
- Instructions for use shall be checked in the product.

Additional Information

Operating Condition: Unit was continuously operated with rated output load. The combination of output derating and the equipment orientation is specified in Enclosure-Miscellaneous ID No. 7-01 "Output derating curve - for without cover (p.1), for with cover (p.2)".

The product has been previously evaluated by UL according to CB Scheme to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) under CB Test Report No. E309264-A58-CB-1, Amendment 1 and Amendment 2. Test results were derived from the CB Test Reports. In addition, new factory, SENDAN ELECTRONICS MFG CO LTD was added.

Unless otherwise stated, all tests were conducted on Model HWS100A-xx/A (xx denotes output voltage; 5, 12, 15, 24, 48) under maximum normal load condition described in General Product Information at input voltage, 90-264 Vac.

Difference between Models HWS100A-xx/A and Models HWS100A-xx/MEA was only capacitance of Y-Capacitor (C2, C3). Model HWS100A-xx/A: maximum 2200 pF, Model HWS100A-xx/MEA: maximum 1500 pF. Voltage or Charge Limitation (clause 8.4.3), Earth leakage current (clause 8.7) and Dielectric strength test between Primary and GND (clause 8.8.3) were also conducted on Model HWS100A-48/ME.

The similar products, HWS100A-xx have been previously evaluated by UL according to CB Scheme to IEC 60950-1: 2005 (2nd Edition); Am 1:2009 under CB Test Report No. E122103-A138-CB-1 and Amendment 1. Test results for Limitation of voltage (clause 8.4.2) and Maximum voltage, current and power/energy (clause 8.4.2) were derived from the CB test reports. Model difference between Model HWS100A-xx and Model HWS100A-xx/ME in this report was only capacitance of Y-Capacitor (C2, C3). Model HWS100A-xx: maximum 2200 pF, Model HWS100A-xx/ME: maximum 1500 pF.

Because Dielectric Voltage Withstand (8.8.3) for some insulation tapes and Ball Pressure for terminal block material (TB1) have been previously evaluated by UL according to CB Scheme to IEC 60950-1:2005 (2nd Edition); Am 1:2009 under CB Test Report No. E122103-A138-CB-1 and Amendment 1, the test results were derived from the CB test reports.

Additional Standards

The product fulfills the requirements of: IEC 60601-1:2012 (AM1)

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
Fuses	Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure)