






Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.....:	4787342581
Date of issue	2016-03-03
Total number of pages.....:	12
CB Testing Laboratory.....:	UL Japan, Inc.
Address	4383-326 Asama-cho, Ise-shi, Mie, 516-0021, Japan
Applicant's name.....:	TDK-LAMBDA CORP
Address	NAGAOKA TECHNICAL CENTER R&D DIV 2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA 940-1195 JAPAN
Test specification:	
Standard	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	CB Scheme
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_1J
Test Report Form Originator	UL(US)
Master TRF	2014-07
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General disclaimer: The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	

Test item description	Medical Grade Power Supply
Trade Mark	
Manufacturer	TDK-LAMBDA CORP NAGAOKA TECHNICAL CENTER R&D DIV 2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA 940-1195 JAPAN
Model/Type reference.....	HWS50A-xx/ME, HWS50A-xx/MEA, HWS50A-xx/MER, and HWS50A-xx/MERA Where xx represents the output voltage rating, and can be one of the following: 5, 12, 15, 24, or 48.
Ratings.....	<Input> HWS50A-xx/ME, HWS50A-xx/MEA, HWS50A-xx/MER and HWS50A-xx/MERA: 100 - 240 V ac, 50 - 60 Hz, 0.7 A <Output> (1) HWS50A-5/ME, HWS50A-5/MEA, HWS50A-5/MER and HWS50A-5/MERA: 5 V --- , 10 A (2) HWS50A-12/ME, HWS50A-12/MEA, HWS50A-12/MER and HWS50A-12/MERA: 12 V --- , 4.3 A (3) HWS50A-15/ME, HWS50A-15/MEA, HWS50A-15/MER and HWS50A-15/MERA: 15 V --- , 3.5 A (4) HWS50A-24/ME, HWS50A-24/MEA, HWS50A-24/MER and HWS50A-24/MERA: 24 V --- , 2.2 A (5) HWS50A-48/ME, HWS50A-48/MEA, HWS50A-48/MER and HWS50A-48/MERA: 48 V --- , 1.1 A

Testing procedure and testing location:		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	UL Japan, Inc.
Testing location/ address		4383-326 Asama-cho, Ise-shi, Mie, 516-0021, Japan
<input type="checkbox"/>	Associated CB Testing Laboratory:	
Testing location/ address		
Tested by (name + signature).....		Atsushi Fuchita 
Approved by (name + signature)		Jun Orito 
<hr/>		
<input type="checkbox"/>	Testing procedure: TMP/CTF Stage 1:	
Testing location/ address		
Tested by (name + signature).....		
Approved by (name + signature)		
<hr/>		
<input type="checkbox"/>	Testing procedure: WMT/CTF Stage 2:	
Testing location/ address		
Tested by (name + signature).....		
Witnessed by (name + signature)		
Approved by (name + signature)		
<hr/>		
<input type="checkbox"/>	Testing procedure: SMT/CTF Stage 3 or 4:	
Testing location/ address		
Tested by (name + signature).....		
Witnessed by (name + signature)		
Approved by (name + signature)		
Supervised by (name + signature).....		
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List of Attachments (including a total number of pages in each attachment): Enclosures (2 pages)	
Summary of testing	
Tests performed (name of test and test clause):	Testing location:
No tests were conducted.	
Summary of compliance with National Differences List of countries addressed: AT, CA, GB, SE, US	
<input checked="" type="checkbox"/> The product fulfils the requirements of 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.	

Copy of marking plate



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use	Component for building-in
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location) :	To supply regulated power, no patient connection
Mode of operation	Continuous
Supply connection	N/A (to be considered in end-use product)
Accessories and detachable parts included.....	None
Other options include	None
Testing	
Date of receipt of test item(s)	N/A
Dates tests performed	N/A
Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement.....	Pass (P)
- test object was not evaluated for the requirement	N/E (collateral standards only)
- test object does not meet the requirement.....	Fail (F)
Abbreviations used in the report:	
- normal condition	N.C.
- means of Operator protection	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection	MOPP
General remarks:	
"(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.	
Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	

Manufacturer's Declaration per sub-clause 4.2.5 of IEC60060-1:2012

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided..... : Yes Not applicable

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies)..... : WUXI TDK-LAMBDA ELECTRONICS CO LTD
NO 6
XING CHUANG ER LU
WUXI
JIANGSU 214028 CHINA

TDK-LAMBDA MALAYSIA SDN BHD
PLO33 KAWASAN PERINDUSTRIAN SENAI
81400 SENAI MALAYSIA

TDK-LAMBDA CORP
2704-1 SETTAYA-MACHI
NAGAOKA-SHI
NIIGATA-KEN 940-1195 JAPAN

ALPS LOGISTICS FACILITIES CO LTD
593-1 NISHI-OHASHI
TSUKUBA-SHI
IBARAKI-KEN 305-0831 JAPAN

SENDAN ELECTRONICS MFG CO LTD
1010 HABUSHIN
NANTO-SHI
TOYAMA-KEN 939-1756 JAPAN

TDK-LAMBDA MALAYSIA SDN BHD
LOT 2 & 3, BATU 9 3/4 KAWASAN
PERINDUSTRIAN BANDAR BARU JAYA GADING
26070 KUANTAN MALAYSIA

General product information:

Report Summary

The original report was modified on 2016-03-03 to include the following changes/additions:

- Addition of factory, TDK-LAMBDA MALAYSIA SDN BHD, LOT 2 & 3 BATU 9 3/4 KAWASAN PERINDUSTRIAN BANDAR BARU JAYA GADING 26070 KUANTAN MALAYSIA

See Enclosure-Miscellaneous ID 7-06 for Manufacturer`s Declaration.

No tests were considered necessary as this modification would not affect safety.

This Test Report is only valid in conjunction with Test Report Ref. No. 4786814808, Cert. No. US-25009-UL at 2015-04-16.

Product Description

The models HWS50A-xx/ME, HWS50A-xx/MEA, HWS50A-xx/MER, and HWS50A-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 (T1) and Optocouplers (PC101, PC102, and PC103).

Model Differences

HWS50A-xx/ME: Standard Model (without both metal cover and ON/OFF control)

HWS50A-xx/MEA: with metal cover

HWS50A-xx/MER: with ON/OFF control function

HWS50A-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 HWS50A-5/ME, HWS50A-5/MEA, HWS50A-5/MER, and HWS50A-5/MERA: 4.0 - 6.0 V dc, max 10 A, max 50.0 W.

Models HWS50A-12/ME, HWS50A-12/MEA, HWS50A-12/MER, and HWS50A-12/MERA: 9.6 - 14.4 V dc, max 4.3 A, max 51.6 W.

Models HWS50A-15/ME, HWS50A-15/MEA, HWS50A-15/MER, and HWS50A-15/MERA: 12.0 - 18.0 V dc, max 3.5 A, max 52.5 W.

Models HWS50A-24/ME, HWS50A-24/MEA, HWS50A-24/MER, and HWS50A-24/MERA: 19.2 - 28.8 V dc, max 2.2 A, max 52.8 W.

Models HWS50A-48/ME, HWS50A-48/MEA, HWS50A-48/MER, and HWS50A-48/MERA: 38.4 - 52.8 V dc, max 1.1 A, max 52.8 W.

General product information (continued):

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-A57-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 HWS50A-xx (xx: denotes output voltage, 5, 12, 15, 24 and 48) under maximum normal load condition described in General Product Information at input voltage, 90-264 Vac.

Difference between Models HWS50A-xx and Models HWS50A-xx/ME was only capacitance of Y-Capacitor (C2, C3). Model HWS50A-xx: maximum 2200 pF, Model HWS50A-xx/ME: 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 HWS50A-48/ME.

The similar products, HWS50A-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-A133-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 HWS50A-xx and Model HWS50A-xx/ME in this report was only capacitance of Y-Capacitor (C2, C3). Model HWS50A-xx: maximum 2200 pF, Model HWS50A-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.

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

When installed in end products, 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 399 V rms, 532 V pk between input circuit of isolation transformer (T1) and transformer output circuit. The core of the transformer is treated as secondary.
- Isolation transformer T1 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.

General product information (continued):

- 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 energy 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.