





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.	4786814819
Date of issue	2015-04-02
Total number of pages	154 pages
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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If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.	
This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.	
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.	

<p>Test item description.....:</p>	<p>Medical Grade Power Supply</p>
<p>Trade Mark</p>	<p><i>TDK-Lambda</i></p>
<p>Manufacturer.....:</p>	<p>TDK-LAMBDA CORP NAGAOKA TECHNICAL CENTER R&D DIV 2704-1 SETTAYA-MACHI NAGAOKA-SHI NIIGATA 940-1195 JAPAN</p>
<p>Model/Type reference.....:</p>	<p>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.</p>
<p>Ratings</p>	<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 <Output> (1) HWS100A-5/ME, HWS100A-5/MEA, HWS100A-5/MER, and HWS100A-5/MERA: 5 V $\overline{\text{---}}$, 20 A (2) HWS100A-12/ME, HWS100A-12/MEA, HWS100A-12/MER, and HWS100A-12/MERA: 12 V $\overline{\text{---}}$, 8.5 A (3) HWS100A-15/ME, HWS100A-15/MEA, HWS100A-15/MER, and HWS100A-15/MERA: 15 V $\overline{\text{---}}$, 7.0 A (4) HWS100A-24/ME, HWS100A-24/MEA, HWS100A-24/MER, and HWS100A-24/MERA: 24 V $\overline{\text{---}}$, 4.5 A (5) HWS100A-48/ME, HWS100A-48/MEA, HWS100A-48/MER, and HWS100A-48/MERA: 48 V $\overline{\text{---}}$, 2.1 A</p>

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)		Tsutomu Abe 
Approved by (name + signature)		Katsuyuki Kusagawa 
<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)..... :		

<p>List of Attachments (including a total number of pages in each attachment): National Differences (7 pages) Enclosures (94 pages)</p>	
<p>Summary of testing</p>	
<p>Tests performed (name of test and test clause):</p> <ol style="list-style-type: none"> 1. Power Input Test (4.11) 2. Humidity Conditioning (5.7) 3. Working Voltage / Power Measurement (8.4.2) 4. Voltage or Charge Limitation (8.4.3) 5. Earthing and Potential Equalization Test (8.6.4a) 6. Leakage Current Tests (8.7) 7. Dielectric Voltage Withstand (8.8.3) 8. Ball Pressure (8.8.4.1) 9. Temperature (11) 10. Abnormal Operation Testing (13) 11. Transformer Overload and Short-Circuit Tests (15.5.1) 	<p>Testing location:</p> <p>UL Japan, Inc. 4383-326 Asama-cho, Ise-shi, Mie, 516-0021, Japan</p>
<p>Summary of compliance with National Differences List of countries addressed: AT, CA, GB, SE, US</p> <p><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.</p>	

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.



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)	2013-05-14, 2014-01-30
Dates tests performed	2013-06-11 to 2013-09-10, 2014-02-05 to 2014-02-17
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:	
<p>"(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.</p>	
<p>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</p>	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1:2012	
<p>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</p>	
<p><input checked="" type="checkbox"/> Yes <input type="checkbox"/> Not applicable</p>	
<p>When differences exist; they shall be identified in the General product information section.</p>	

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

General product information:**Report Summary**

All applicable tests according to the referenced standard(s) have been carried out.

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.

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-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.

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 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.

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 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.

IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

INSULATION DIAGRAM

