
	Test Report issued under the responsibility of:	
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**TEST REPORT  
IEC 60601-1  
Medical Electrical Equipment  
Part 1: General requirements for safety**

<b>Report Reference No</b> .....	E349607-A15-CB-1
<b>Date of issue</b> .....	2011-12-05
<b>Total number of pages</b> .....	28
<b>CB Testing Laboratory</b> .....	UL International Polska Sp. z o.o.
<b>Address</b> .....	Aleja Krakowska 81, 05-090 Sekocin Nowy, Poland
<b>Applicant's name</b> .....	TDK-LAMBDA UK LTD
<b>Address</b> .....	KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
<b>Test specification:</b>	
Standard .....	IEC 60601-1:1988 + A1:1991 + A2:1995
Test procedure .....	CB Scheme
Non-standard test method .....	N/A
<b>Test Report Form No.</b> .....	IEC60601_1c/97-04
Test Report Form originator .....	UL LLC
Master TRF .....	dated 97-04
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<b>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.</b>	
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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 .....	Power Supply Unit
Trade Mark .....	TDK-LAMBDA <b><i>TDK-Lambda</i></b>
Manufacturer .....	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Model/Type reference .....	NV700 or NV-700  (See enclosure 7-01 for model configuration)
Ratings .....	100-240 Vac (90-264V max tolerance) 47-63 Hz, 11 A rms max.  (See enclosure 7-01 for details of outputs)

<b>Testing procedure and testing location:</b>	
<input checked="" type="checkbox"/> <b>CB Testing Laboratory</b>	
Testing location / address..... :	UL International Polska Sp. z o.o. Aleja Krakowska 81, 05-090 Sekocin Nowy, Poland
<input type="checkbox"/> <b>Associated CB Test Laboratory</b>	
Testing location / address..... :	
Tested by (name + signature) ..... :	Wojciech Czerniak (Project Handler) <i>W. Czerniak</i>
Approved by (name + signature) ... :	Dennis Butcher (Reviewer) <i>[Signature]</i>
<input type="checkbox"/> <b>Testing Procedure: TMP/CTF Stage 1</b>	
Tested by (name + signature) ..... :	_____
Approved by (+ signature) ..... :	_____
Testing location / address..... :	_____
<input type="checkbox"/> <b>Testing Procedure: WMT/CTF Stage 2</b>	
Tested by (name + signature) ..... :	_____
Witnessed by (+ signature)..... :	_____
Approved by (+ signature) ..... :	_____
Testing location / address..... :	_____
<input type="checkbox"/> <b>Testing Procedure: SMT/CTF Stage 3 or 4</b>	
Tested by (name + signature) ..... :	_____
Approved by (+ signature) ..... :	_____
Supervised by (+ signature) ..... :	_____
Testing location / address..... :	_____
<input type="checkbox"/> <b>Testing Procedure: RMT</b>	
Tested by (name + signature) ..... :	_____
Approved by (+ signature) ..... :	_____
Supervised by (+ signature) ..... :	_____
Testing location / address..... :	_____

<b>List of Attachments</b>
National Differences (0 pages)
Enclosures (3 pages)
<b>Summary of Testing:</b>
No tests were conducted
<b>Summary of Compliance with National Differences:</b>

Issue Date: 2011-12-05  
Amendment 2 2017-05-11

Page 4 of 28

Report Reference #

E349607-A15-CB-1

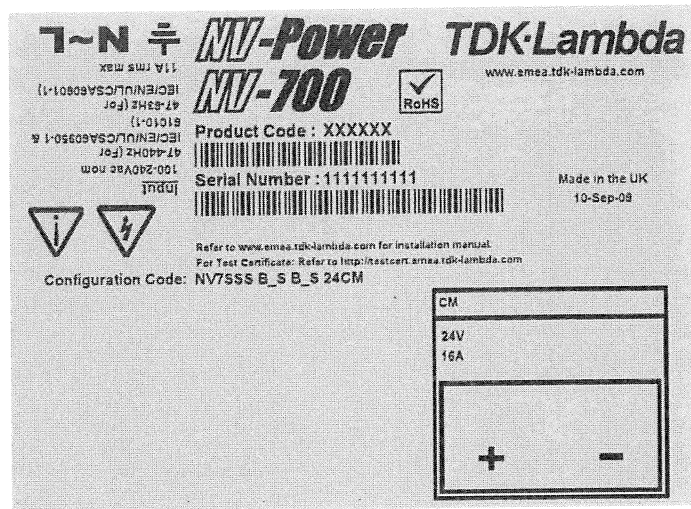
Countries outside the CB Scheme membership may also accept this report.

List of countries addressed: AT, AU, BE, BR, CA, CH, CZ, DE, DK, FI, FR, GB, GR, HU, IL, IN, IT, JP, KR, NL, NO, PL, RU, SE, SI, SK, UA, US

The product fulfills the requirements of: N/A

### 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.



<b>Test item particulars :</b>		
Classification of installation and use .....	Dependent on final installation	
Supply connection .....	Dependent on final installation	
Accessories and detachable parts included in the evaluation .....	None	
Options included .....	None	
<b>Possible test case verdicts:</b>		
- test case does not apply to the test object .....	N / A	
- test object does meet the requirement .....	P(Pass)	
- test object does not meet the requirement .....	F(Fail)	
Abbreviations used in the report:		
- normal condition .....	N.C. - single fault condition .....	S.F.C.
- operational insulation .....	OP - basic insulation .....	BI
- basic insulation between parts of opposite polarity:	BOP - supplementary insulation .....	SI
- double insulation .....	DI - reinforced insulation .....	RI
<b>Testing:</b>		
Date(s) of receipt of test item .....	N/A	
Date(s) of Performance of tests .....	N/A	
<b>General remarks:</b>		
List of test equipment must be kept on file and be available for review.		
"(see Enclosure #)" refers to additional information appended to the report.		
"(see appended table)" refers to a table appended to the report.		
Throughout this report a point is used as the decimal separator.		
<b>Manufacturer's Declaration per Sub Clause 4.2.5 of IEC60060-2:</b>		
Yes		
The application for obtaining a CB Test Certificate includes more than one factory 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 .....		
When differences exist, they shall be identified in the General Product Information section.		
<b>Name and address of Factory(ies):</b>	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM	
	PANYU TRIO MICROTRONIC CO. LTD SHIJI INDUSTRIAL ESTATE DONGYONG NANSHA GUANGZHOU GUANGDONG CHINA	

## GENERAL PRODUCT INFORMATION:

### Report Summary

The original report was modified on 2017-05-11 to include the following changes/additions:

Alternate Y1 capacitors (C5, C6, C7) added to the critical components list. Their licences added to the enclosures.  
CBTL changed to UL International Polska.

### Product Description

The NV700 series are switch mode power supplies for building into host equipment.

This product range is available as a forced air cooled version (in-built fan) with screw terminal input connections or an IEC 60320 Inlet. It is also available as a customer air cooled version where the end cap is not fitted and the customer must provide an air flow and measure appropriate temperatures of components within the product.

It should be noted that the power supplies have been assessed as a component part. It is the installer's responsibility to ensure that the final installation is in accordance with the NV700 Handbook and that it is in compliance with IEC60601-1.

### Model Differences

See enclosure 7-01

### Additional Information

Project 4787707401 information:

This is Amendment 1 to the CB Test Report E349607-A15-CB-1-Original dated 2011-12-04 with CB Test Certificate DK-5300 and with Amendment 1 dated 2015-02-10 with CB Test Certificate DK-5300-A1-UL. This Amendment is published due to changes provided in Report Summary.

No additional testing has been done.

This amendment shall be read in conjunction with Original Test Report and Test Certificate and with previous Amendment 1.

### Technical Considerations

- The product was investigated to the following additional standards: UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada).
- 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: Shock, Fire, Casualty
- The degree of protection against harmful ingress of water is: Ordinary (IPX0)
- The following accessories were investigated for use with the product: None
- 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
- Product evaluated for an operating temperature of 50°C (Full load), to 65°C maximum (See enclosure 7-01 for models and conditions to which the extended ambient applies) --
- Some test results have been accepted based on the CB Test Report previously issued by BSI, CB Test Report Ref. No. 222/4933585/2, CB Test Certificate Ref. No. GB750W/A1/M1 as identified in this report. --
- Multilayer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report, in enclosure 8-07 of this report. --

#### **Engineering Conditions of Acceptability**

When installed in an end-product, consideration must be given to the following:

- With the exception of the units utilising 'C' output modules, the Power Supplies detailed in this Report were rated, by the Client, for Basic insulation requirements between the mains input and DC outputs, with respect to UL 60601-1 2nd Edition. --
- It should be noted that the power supplies have been assessed as a component part. It is the installer's responsibility to ensure that the final installation is in accordance with the NV700 Handbook and that it is in compliance with IEC60601-1. , --
- Except for permanently installed equipment, the overall equipment in which these products are installed must be fitted with double pole fusing as detailed in the Special Instructions section of the NV700 Handbook. , --
- This product range is available as a forced air cooled version (in-built fan) with screw terminal input connections (suitable for factory wiring only), or an IEC 60320 Inlet. It is also available as a customer air cooled version where the end cap is not fitted and the customer must provide an air flow and measure appropriate temperatures of components within the product. --
- Units utilising 'C' and/or 'CM' output modules have Reinforced insulation requirements between the mains input and DC outputs. The requirements of clauses 17. a and 17. g shall be considered in the end use application. Refer to the isolation diagram and associated table for further guidance. --
- Insulation between the secondary (PSU output) and earthed chassis is 'functional only' except for units utilising 'CM' output modules only, which have Basic insulation, at the Working Voltage only. Provided that no part of the module is fitted in slot location 1 (left hand side looking from module end of PSU). See table to insulation diagram for details. --
- The following outputs are considered SELV: All outputs are SELV except under the following circumstance:- outputs connected in series are non-SELV if the total output voltage + 30% of the max. rated output voltage of the output with the highest rated voltage exceeds 60Vdc (the 30% addition allows for a single fault in any one individual channel.) --
- It should be noted that the power supply has been assessed as a component part of an end equipment. It is the installer's responsibility to ensure that the final installation is in accordance with the NV700 handbook and that it is in compliance with the 60601-1 standards. --
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end use equipment. --
- The products were tested on a 16A (20A for North America and Canada) branch circuit. --
- Modules B, BH, DA, DB and global options (SIP/SOP module) have basic insulation between the mains input and DC outputs. --
- The component shall be installed in compliance with enclosure, mounting, marking, spacing and



separation requirements of the end use application. --

- For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. --
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF) --
- Proper bonding to the end product main protective earthing termination is required. --
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C at full load and 65°C maximum (see enclosure 7-01 for model configuration and output details for models and conditions to which the extended ambient applies). --
- Consideration should be given to repeating the earth leakage tests in the end use equipment. --
- No external surfaces of the power supply are allowed to be operator accessible, including the inlet face of the PSU fitted with an IEC60320 inlet. --
- The following outputs are considered an energy hazard and must not be accessible to an end user:- 12BH, 24BH, 12C, 16C, 24C, 30C, 12CM, 16CM, 24CM and 30CM. --