



Test Report issued under
the responsibility of:



TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1:General requirements for safety

Report Reference No : E349607-A6-CB-1

Date of issue :

Total number of pages : 74

CB Testing Laboratory : UL International Germany GmbH

Address : Admiral-Rosendahl-Strasse 23, 63263 Neu-Isenburg (Zeppelinheim),
Germany

Applicant's name : TDK-LAMBDA UK LTD

Address : KINGSLEY AVE
ILFRACOMBE
DEVON
EX34 8ES UNITED KINGDOM

Test specification:

Standard : IEC 60601-1:1988 + A1:1991 + A2:1995

Test procedure : CB Scheme

Non-standard test method : N/A

Test Report Form No. : IEC60601_1c/97-04

Test Report Form originator : UL LLC

Master TRF : dated 97-04

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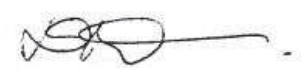
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General disclaimer

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	Component Power Supply
Trade Mark	TDK-Lambda 
Manufacturer	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Model/Type reference	NV350 , NF350 or NV3 Range (See enclosure 7-01 for details of model configurations)
Ratings	100-240Vac nominal (90-264V max. tolerance), 47-63Hz, 5.5A (See enclosure 7-01 for details of model ratings)

Testing procedure and testing location:		
<input type="checkbox"/>	CB Testing Laboratory	
	Testing location / address..... :	
<input type="checkbox"/>	Associated CB Test Laboratory	
	Testing location / address..... :	
	Tested by (name + signature)	_____
	Approved by (name + signature) ... :	_____
<input type="checkbox"/>	Testing Procedure: TMP/CTF Stage 1	
	Tested by (name + signature)	_____
	Approved by (+ signature)	_____
	Testing location / address..... :	_____
<input type="checkbox"/>	Testing Procedure: WMT/CTF Stage 2	
	Tested by (name + signature)	_____
	Witnessed by (+ signature)..... :	_____
	Approved by (+ signature)	_____
	Testing location / address..... :	_____
<input checked="" type="checkbox"/>	Testing Procedure: SMT/CTF Stage 3 or 4	
	Tested by (name + signature)	N. S. Marsh. S. Hirstwood 
	Approved by (+ signature)	K. P. Tizzard 
	Supervised by (+ signature)	Dennis Butcher 
	Testing location / address..... :	TDK-LAMBDA UK LTD, KINGSLEY AVE, ILFRACOMBE, DEVON, EX34 8ES UNITED KINGDOM
<input type="checkbox"/>	Testing Procedure: RMT	
	Tested by (name + signature)	_____
	Approved by (+ signature)	_____
	Supervised by (+ signature)	_____
	Testing location / address..... :	_____

List of Attachments
National Differences (7 pages)
Enclosures (183 pages)
Summary of Testing:
No tests were conducted

Summary of Compliance with National Differences:

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: CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)

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.


Refer to www.emea.tdk-lambda.com for installation manual.
 For Test Certificate: Refer to http://testcert.emea.tdk-lambda.com
 pl: uk@tdk-lambda.com/parts

610-1,
 IECEN/ULCSA6050-1 &
 47.40Hz For
 100-240Vac nom.
 Input



610-1,
 IECEN/ULCSA6050-1 &
 47.40Hz For
 100-240Vac nom.
 Input

5.5A rms max.
 IECEN/ULCSA6050-1 &
 47.40Hz For
 100-240Vac nom.
 Input



www.emea.tdk-lambda.com



NV-Power
NV-350 **TDK-Lambda**

Product Code : NV3Y072X

 Serial Number : 1111111111

 NV3VSS 12_5DB 24BH

Fan Type	V	Variable Speed	Made in the UK 16-Jan-14
Input Type	S	Screw	
Filter Type	S	Standard	

DB 12V 5V 13A 10A 	BH 24V 10A 
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Test item particulars :		
Classification of installation and use	Building into host equipment	
Supply connection	Units configured with an appliance inlet are suitable for connection to the mains supply via an appliance coupler; Units configured with a mains terminal block to be supplied by the host equipment (upon installation)	
Accessories and detachable parts included in the evaluation	None	
Options included	None	
Possible test case verdicts:		
- 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
Testing:		
Date(s) of receipt of test item	2014-05-19 to 2014-10-07	
Date(s) of Performance of tests	2014-05-20 to 2014-10-07	
General remarks:		
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.		
Manufacturer's Declaration per Sub Clause 4.2.5 of IEC60060-1:		
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.		
Name and address of Factory(ies):	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 2015-01-13 to include the following changes/additions:
The original report was modified to include the following changes/additions:
Range approval for a dual fused input connector (option J). This option has been used before as a non-standard. Thermal comparison with worst case configuration to allow use across the range.
Range approval for top fan (option T). This option has been used before as a non-standard. Thermal comparison with worst case configuration to allow use across the range.
NV3 FEP restored back to original value :11.5 - 15.5V
DB module, CH2 voltage range may be extended up to 6.0V (60W max) for some PSU configurations. Consultation with the factory is required. This is in line with the 61010-1 report No: E331788-A17-CB-1
L option added to nomenclature for fixed speed fan (Non-standard only)
Alternative fuse testing (not mains input fuse)
Alternative J1 connector to include Tianli B825 series (same ratings no testing required)

Alternative/second source fan testing
Model: NV3 KISE5V 12/12DB 5B (X00004#) should have been : NV3 KISE5V 12/12DB 5B (X00004#)
Removed Avnet and Arrow from the manufacturers list.
Updated handbook
Addition/deletion of multilayer PWBs to critical component list
Correction/addition to the critical component list
Updated licenses
Updated drawings

Product Description

Component Power Supplies

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 customer air cooled versions (with and without a cover) 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 installers responsibility to ensure that the final installation is in accordance with the NV350 handbook and that it is in compliance with IEC60601-1.

Model Differences

Model NV3 is identical to the NV350 .
Models NV350FEP and NF3 are identical to the NF350.

All models use a common front end supply and fan assembly. The NV350FEP can only use the FE module due to the shorter case size whereas the NV350 can use any module with the exception of the FE module.

Cooling option U has a chassis, no fans and no cover and is therefore dependant on customer air.
(Temperatures to be re-evaluated in the end equipment evaluation).

See enclosure 7-01 for details of models.

Additional Information

This report is a reissue of CBTR Ref. No.: E349607-A6-CB-1, dated 2011-12-01, CB Test Certificate Ref. No. DK-5219 dated 2011-12-01. Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard.

The original report was modified to include the following changes/additions:

Range approval for a dual fused input connector (option J). This option has been used before as a non-standard. Thermal comparison with worst case configuration to allow use across the range.

Range approval for top fan (option T). This option has been used before as a non-standard. Thermal comparison with worst case configuration to allow use across the range.

NV3 FEP restored back to original value :11.5 - 15.5V

DB module, CH2 voltage range may be extended up to 6.0V (60W max) for some PSU configurations.

Consultation with the factory is required. This is in line with the 61010-1 report No: E331788-A17-CB-1

L option added to nomenclature for fixed speed fan (Non-standard only)

Alternative fuse testing (not mains input fuse)

Alternative J1 connector to include Tianli B825 series (same ratings no testing required)

Alternative/second source fan testing

Model: NV3 KISE5V 12/12DB 5B (X00004#) should have been : NV3 KISE5V 12/12DB 5B (X00004#)

Removed Avnet and Arrow from the manufacturers list.

Updated handbook

Addition/deletion of multilayer PWBs to critical component list

Correction/addition to the critical component list

Updated licenses

Updated drawings

Program updated from CBTL to SMT.

Technical Considerations

- The product was investigated to the following additional standards: IEC 60601-1, 2nd Edition: 1988, 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 36, Electromagnetic Compatibility (IEC 601-1-2), Clause 48, Biocompatibility (ISO 10993-1), Clause 52.1, Programmable Electronic Systems (IEC 601-1-4)
- The product is Classified only to the following hazards: Fire, Shock
- The degree of protection against harmful ingress of water is: 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). --
- The product was investigated by UL for compliance with IEC60601-1. Some test results have been accepted based on the CB Test Report previously issued by BSI, CB Test Report Ref. No. 222/7225854, 222/4612938, 22/4827813 & 222/7050418, CB Test Certificate Ref. No. GB784W & GB668W/M2 as identified in this report --
- Multi-layer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report, Enclosure 8-08 of this report --

Engineering Conditions of Acceptability

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

- Modules B, BH, DA, DB and Global Options (SIP/SOP module) have basic insulation between the mains input and DC outputs. --
- These power supplies have been assessed as a component part of a 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 customer air cooled versions (with and without a cover) 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 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. --
- Except for permanently installed equipment and IEC60320 dual fused inlet models, the overall equipment in which these products are installed must be fitted with double pole fusing. --
- 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). --
- Screw terminals are suitable for factory wiring only. For models with IEC60320 inlet connectors the IEC inlet face of the enclosure has been evaluated as operator accessible. --
- Electrical and fire enclosures are to be provided in the end-use application. --
- If outputs are connected in series and if the total voltage of the outputs connected in series exceeds the 60Vdc SELV limit, then all outputs must be considered non-SELV. --
- This product must be earthed (class I) --
- This equipment has been evaluated for Continuous Power. If intended for use with intermittent power where the average power is higher than the maximum continuous output power evaluated within this report (350W total at input voltages between 90-100Vac, or 664W total at input voltages between 90-100Vac), the Power Input, Normal Temperature and Abnormal Operation tests shall be re-considered. --
- Evaluation for compliance with 6.8.2c) shall be considered in the end use equipment. --
- Electrical and fire enclosures provided as part of end-installations --

- Consideration shall be given to the requirements of clause 57.5 when installed in the end equipment.
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