

	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-A9-CB-1
Date of issue: 2011-11-29
Total number of pages: 10

CB Testing Laboratory: UL International Demko A/S
Address: Borupvang 5A, 2750 Ballerup, Denmark

Applicant's name: TDK-LAMBDA UK LTD
KINGSLEY AVE
Address: 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

Copyright © 2008 IEC System for Conformity Testing and Certification of Electrical Equipment (IECEE), Geneva, Switzerland. All rights reserved.


This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.



If this test Report 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.

Test item description	Switch mode power supply
Trade Mark	TDK-Lambda 
Manufacturer	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Model/Type reference	NVM175 or NVM-175 models Units may be marked with a Product Code: X5x or NVM1x where x may be any number of characters. (see Model Differences for details)
Ratings	Input: 100-240 Vac nom, 45-63Hz, 3 A rms max Outputs: (see Model Differences for details)

Testing procedure and testing location:	
<input checked="" type="checkbox"/> CB Testing Laboratory	
Testing location / address..... :	UL International Demko A/S Borupvang 5A, 2750 Ballerup, Denmark
<input type="checkbox"/> Associated CB Test Laboratory	
Testing location / address..... :	
Tested by (name + signature)	Ermanno Rebecchi 
Approved by (name + signature) ... :	Dennis Butcher 
<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 type="checkbox"/> Testing Procedure: SMT/CTF Stage 3 or 4	
Tested by (name + signature)	_____
Approved by (+ signature)	_____
Supervised by (+ signature)	_____
Testing location / address..... :	_____
<input type="checkbox"/> Testing Procedure: RMT	
Tested by (name + signature)	_____
Approved by (+ signature)	_____
Supervised by (+ signature)	_____
Testing location / address..... :	_____

List of Attachments
National Differences (0 pages)
Enclosures (0 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, NL, NO, PL, RU, SE, SI, SK, UA, US

The product fulfills the requirements of: EN 60601-1: 1990 + A1:1993 + A2:1995 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)

Copy of Marking Plate - Refer to Enclosure titled Marking Plate for copy.

Test item particulars :	
Classification of installation and use	The NVM-175 Series is a range of switched mode power supplies for building into host equipment
Supply connection	Connection to mains via host equipment
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
- operational insulation	OP - basic insulation
- basic insulation between parts of opposite polarity:	BOP - supplementary insulation
- double insulation	DI - reinforced insulation
Testing:	
Date(s) of receipt of test item	N/A
Date(s) of Performance of tests	N/A
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 IEC60060-2:	
	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.	
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 2014-08-01 to include the following changes/additions:
Correcting the CB Testing Location entered by mistake.

Product Description

The NVM-175 Series are switched mode power supplies for building into host equipment. Both supply lines are fused (except -FL option). Appropriate cooling conditions must be fulfilled by the end-use product.

Storage temperature is -40 to 85°C (except NVM1D models as stated below)

No applied parts.

Marking label attached as Enclosure to this report is representative of all models.

Model Differences

NVM175 or NVM-175 models as described below:

Units may be marked with a Product Code: X5x or NVM1x where x may be any number of characters.

Unit Configuration Code (Description): may be prefixed by NS # followed by / or - (where # may be any number of characters indicating non- safety related model differences).

Unit Configuration Code:
NVMxy-abcdefghijklm

Where:

x = 1 for 175 or 1D (1D for Double insulated or Class II unit)

y = Blank for Y2 capacitors from output to earth (except 1D models)

P for Y1 capacitors from output to earth (except 1D models)

a = Number of Outputs: 1.

b = Channel 1 Output Voltage where: T is for 12V, F is for 15V and G is for 24V.

c = O (for omit).

d = O (for omit).

e = O (for omit).

f = Standby supply:

Blank for no standby and no remote on/off (enable) or '-' followed by

S for 12V version with power good, logic level high enables main output.

S1 for 12V version with power good, logic level low enables main output.

S2 for 12V version with Channel 1 good, logic level high enables main output.

S3 for 12V version with Channel 1 good, logic level low enables main output.

S4 for 12V 0.8A version with power good, logic level low enables main output.

S5 for 5V 0.5A version with power good, logic level low enables main output.

S6 for 5V 0.5A version with power good, logic level high enables main output.

0 for no standby and no remote on/off (enable).

g = U for U chassis, C for U chassis with cover, K for custom chassis with cover and IEC inlet or blank for Open Frame.

h = Blank is the standard upright output connector, R is for the right angle output connector, S is for the screw terminal.

i = Blank for standard leakage, L for low leakage, Zx is for custom leakage which is less than standard leakage and x is a number between 1 and 9 for different custom leakage current options.

jkl = Blank for standard output setting or '-' followed by three numbers from 0 to 9 which denotes various output voltages and currents within the specified range of channel 1 output for a particular unit.

m = Blank for dual fuse input or -FL for single fuse input in the Live line

Output Parameters

There are three NVM1 standard models with various options, and 3 non-standard models with output parameters shown in the tables below:

Output Channel	Voltage Designation	Vout Nom.	Adjustment Range (V)	Output Current (A)	Maximum Power (W)
Channel 1	T	12	12 - 15.5	15	180
	F	15	12 - 15.5	15	180
	G	24	24 - 28.5	7.5	180
Standby output	S	12	Fixed	0.2	2.4
	S1	12	Fixed	0.2	2.4
	S2	12	Fixed	0.2	2.4
	S3	12	Fixed	0.2	2.4
	S4	12	12 - 13	0.8	10.4
	S5	5	Fixed	0.5	2.5
	S6	5	Fixed	0.5	2.5

Variations and limitations of use:

NVM175 PSUs can output 180W from channel 1 plus 10.4W maximum from the standby output.

Component temperatures must be monitored in the end use application as described in the "COOLING FOR UNIT" section.

All ratings apply for ambient temperatures up to 50°C. From 50 to 70°C the total output power and current ratings are both derated at 2.5% per deg C.

Non-Standard Model:

Non- Standard model: X50001# (# can be any letter), (modified NVM1-1T000-S1-K-R-L)

Output Channel	Voltage Designation	Vout Nom.	Adjustment Range (V)	Output Current (A)	Maximum Power(W)
Channel 1	T	12	12 - 15.5	15	180
Standby output	S1	12	Fixed	0.2	2.4

Additional Variations and limitations of use for Non- Standard model X50001#:

Ratings apply for ambient temperatures up to 60°C. From 60 to 65°C the total output power and current ratings are both derated at 2.5% per deg C.

Component temperatures must be monitored in the end use application as described in the "COOLING FOR UNIT" section.

X50005# - (# can be any letter), (modified NVM1-1T model) with 5V 0.5A standby option.

X50007# - NVM1D - 1G-f-g-h-j

may be any letter where this indicates any of the options described in the nomenclature table above for f, g, h and j and where g will always be blank (open frame). D indicates that the product is double insulated (no earth connections). This product has 18-way output connector.
Maximum storage temperature 65°C.

For ambient temperature requirements see Conditions of Acceptability and user manual (Enclosure 6-01).

Input Parameters

Parameter	60601-1
Nominal input voltage	100 - 240 Vac
Input voltage range	90 - 264Vac
Input frequency range	45 - 63Hz
Maximum input current	3A rms

Environmental Specifications:

Description	Operation	Storage & Transportation
Use	Indoor	-
Temperature	0°C - +70°C (See O/P tables for deratings)	-40°C - +85°C
Humidity	5 - 95% RH, non-condensing	5 - 95% RH, non-condensing
Altitude	-200m - 4000m	-200m - 5000m
Pressure	63kPa - 106kPa	54kPa - 106kPa

Orientation	The unit may be mounted on either side, vertical with input lowest and horizontal. (Customer Air versions can be mounted in any orientation).
Material Group	IIIb
Pollution Degree	2
Overvoltage Category	II
Class	I or II (depending on model)
Weight	1 Kg max
IP Rating	IPX0

Additional Information

Cooling for units:

The following method must be used for determining the safe operation of PSUs. The components listed in the following table must not exceed the temperatures given. To determine the component temperatures the heating tests must be conducted in accordance with the requirements of the standard in question. Consideration should also be given to the requirements of other safety standards. Test requirements include: PSU to be fitted in its end-use equipment and operated under the most adverse conditions permitted in the end-use equipment handbook/specification and which will result in the highest temperatures in the PSU. To determine the most adverse conditions consideration should be given to the end use equipment maximum operating ambient, the PSU loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers, etc. Temperatures should be monitored using type K fine wire thermocouples (secured with cyanoacrylate adhesive or similar) placed on the hottest part of the component (out of any direct airflow) and the equipment should be run until all temperatures have stabilised.

Cooling for unit temperature table:

Circuit Ref.	Description	Max. Temperature (°C)
L3, L7	Common mode choke winding	115 (155)
C1, C4	X capacitors	100
C6	Capacitor	105
C12	Resonant capacitor	105
T3	Aux trx windings	130
L2	Boost choke winding	120 (155)
C7	Electrolytic capacitor	70 (105)
T1, T2	Transformer winding 130	
L1	Primary choke (24V channel 1 only)	140
XU3, XU4, XU106	Opto-couplers on control board	100
U1, U2	Opto-couplers on base board	100
L5	Channel 1 output choke	125 (140)
L4	Standby output choke	85
J2	Input connector	105
J1	Output connector	105
Various	All other electrolytic capacitors 90 (105)	

Higher temperature limits (in brackets) may be used but product life may be reduced.

Technical Considerations

- The product was investigated to the following additional standards: EN 60601-1: 1990 + A1:1993 + A2:1995, 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
- 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
- The product was submitted and tested for use at the maximum ambient temperature (T_{ma}) permitted by the manufacturer's specification of: 50°C (full load); 70°C (output power decreasing linearly by 2.5%/°C above 50°C), see Model Differences. --

Engineering Conditions of Acceptability

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

- Insulation (Separation) between primary - secondary output circuits: Double/Reinforced. --
- Insulation (Separation) between primary - earth: BASIC (except for NVM1D - class II) --
- Insulation (Separation) between secondary circuits - earth: BASIC (at mains). --
- Branch circuit protection required: 20A --

- All outputs are considered SELV --
- Some PWB mounted components are rated at the minimum coating rating of 130°C. --
- NVM175 PSUs can output 180W from channel 1 plus 10.4W maximum from the standby output. --
- Component temperatures must be monitored in the end use application as described in , the COOLING FOR UNIT section of the handbook. 1 m/s blown air was used for temperature test. --
- NVM175 ratings apply for ambient temperatures up to 50°C. From 50 to 70°C the total output power and current ratings are both derated at 2.5% per deg C. --
- X50001# ratings apply for ambient temperatures up to 60°C. From 60 to 65°C the total output power and current ratings are both derated at 2.5% per deg C. --
- This power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings and segregation requirements of the end use application. --
- The need for Enclosure and Patient leakage current tests should be considered as part of the end product evaluation. --
- A suitable Electrical and Fire enclosure shall be provided in the end use product. --
- The maximum working voltage of isolation transformers T1, T2 is 275Vrms, 697Vpk and T3 is 410Vrms, 648Vpk. --
- Transformers providing insulation barrier T1, T2 and T3 are built in class F insulation system. --
- NVM1D max storage temp is 65C --
- For all non-earthed models, Supplementary Insulation shall be provided in the End Product to the metal chassis. --
- Assessed for operation at 4000m. Clearance spacings multiplied by 1.14 as in IEC60601-1 3rd edition for MOPPs --
- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-Secondary: 410 Vrms, 697 Vpk, Primary-Earthed Dead Metal: 398 Vrms, 662 Vpk, Secondary-Earthed Dead Metal: 240 Vrms, 340 Vpk. --