Test Report issued under the responsibility of:

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

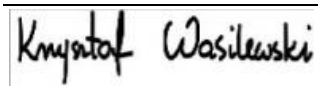
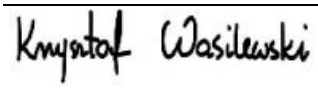
Report Reference No ..... :	E349607-A9-CB-2
Date of issue ..... :	2018-02-08
Total number of pages ..... :	83
CB Testing Laboratory ..... :	UL International Polska Sp. z o.o.
Address ..... :	Aleja Krakowska 81, 05-090 Sekocin Nowy, Poland
Applicant's name ..... :	TDK-LAMBDA UK LTD
Address ..... :	KINGSLEY 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

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:			
[ ]	**CB Testing Laboratory**		
	Testing location / address..... :		
[ ]	**Associated CB Test Laboratory**		
	Testing location / address..... :		
	Tested by (name + signature) ..... :		
	Approved by (name + signature) ... :		
[ ]	**Testing Procedure: TMP/CTF Stage 1**		
	Tested by (name + signature) ..... :		
	Approved by (+ signature) ..... :		
	Testing location / address..... :		
[ ]	**Testing Procedure: WMT/CTF Stage 2**		
	Tested by (name + signature) ..... :		
	Witnessed by (+ signature)..... :		
	Approved by (+ signature) ..... :		
	Testing location / address..... :		
[x]	**Testing Procedure: SMT/CTF Stage 3 or 4**		
	Tested by (name + signature) ..... :	N. Marsh & S.Hirstwood (Testers)	
	Approved by (+ signature) ..... :	Krzysztof Wasilewski (Approver)	
	Supervised by (+ signature) ..... :	Krzysztof Wasilewski (Reviewer)	
	Testing location / address..... :	TDK-Lambda UK, Kingsley Avenue, Ilfracombe, EX34 8ES, UK	
[ ]	**Testing Procedure: RMT**		
	Tested by (name + signature) ..... :		
	Approved by (+ signature) ..... :		
	Supervised by (+ signature) ..... :		
	Testing location / address..... :		

List of Attachments

National Differences (13 pages)

Enclosures (72 pages)

Summary Of Testing

Unless otherwise indicated, all tests were conducted at TDK-Lambda UK, Kingsley Avenue, Ilfracombe, EX34 8ES, UK.

Tests performed (name of test and test clause)	Testing location / Comments
Earthing and Potential Equalization (18F)	
Leakage Current (19)	
Dielectric Voltage Withstand (20.4)	
Humidity Preconditioning Treatment (44.5)	
Abnormal Operation and Fault Conditions (52)	

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 ..... :	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 ..... :	2017-11-06			
Date(s) of Performance of tests ..... :	2017-11-07 to 2017-12-07			
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 IECEE 02:				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

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

Product Description

The NVM-175 Series are switched mode power supplies for building into host equipment.

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 = blank for Open Frame or '-' followed by U for U chassis, C for U chassis with cover, K for custom chassis with cover and IEC inlet.
h = Blank is the standard upright output connector or '-' followed by R is for the right angle output connector, S is for the screw terminal.
i = Blank for standard leakage or '-' followed by 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

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:

X50015# (where # can be any letter except A, B, C, D, E or F)
Factory fitted output loom
Earth connection made via ring tag and screw

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.

Marking label in Enclosures is representative for both models in this Test Report.

Reissue 1
This report is reissue to CBTR Ref. No. E349607-A9-CB-1 dated 2011-11-29 including amendments 1 to 3 and CB Test Certificate Ref. No. DK-5244 dated 2011-12-02.

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

1. Addition of Non-standard model X50015#, output loom Photograph added to Enclosures.
2. Non-standard Earth connection made via ring tag and screw (X50015#). Photograph added to Enclosures.
3. Critical component certificate reference numbers updated in the CCL.
4. Addition of alternate and corrections to CCL components.
5. Corrections to the Insulation Table and changing from MOOP to MOPP for primary to earth.
6. Removal of X50001# and X50005# from Model Differences.
7. CBTL changed to UL Poland

Tests were completed according to IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint) / ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012 and found to be representative for this evaluation.

Based on previously conducted testing and the review of product construction it has been determined that the product continues to comply with the standard and only limited testing was required.

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 (Tma) 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. --