



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-A26-CB-1

Date of issue :

Total number of pages : 28

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 AVENUE
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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Test item description	Switch mode power supply
Trade Mark	TDK-Lambda 
Manufacturer	TDK-LAMBDA UK LTD KINGSLEY AVENUE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Model/Type reference	NV175 Series NV-175 Series NV1-1G000 (See Model Differences for details)
Ratings	NV175 Series; NV-175 Series: 100-240Vac (Nominal), 90-264V (Full Tolerance), 45-63Hz, 3Arms NV1-1G000 only: 88.9-240Vac (Nominal), 80-264V (Full Tolerance), 45-63Hz, 3Arms (See Model Differences for details)

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)	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 (3 pages)
Enclosures (144 pages)
Summary Of Testing
Unless otherwise indicated, all tests were conducted at TDK-LAMBDA UK LTD, KINGSLEY AVE, ILFRACOMBE, DEVON, EX34 8ES, UNITED KINGDOM.

Tests performed (name of test and test clause)	Testing location / Comments
<p>Temperature (42)</p> <p>Summary of Compliance with National Differences:</p> <p>Countries outside the CB Scheme membership may also accept this report.</p> <p>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</p> <p>The product fulfills the requirements of: IEC 60601-1, 2nd Edition, 1988 + A1:1991 + A2:1995 UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA) CAN/CSA-C22.2 No. 601.1-M90 EN 60601-1: 1990 + A1:1993 + A2:1995 (except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1, Programmable Electronic Systems, IEC 60601-1-4)</p>	

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

Test item particulars :	
Classification of installation and use	For building into host equipment
Supply connection	For building into 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	2014-08-22
Date(s) of Performance of tests	2014-09-01
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 IEC60061-1:	
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):	<p>TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM</p> <p>PANYU TRIO MICROTRONIC CO. LTD. SHIJI INDUSTRIAL ESTATE DONGYONG NANSHA CHINA</p>

GENERAL PRODUCT INFORMATION:**Report Summary**

The original report was modified on 2014-12-05 to include the following changes/additions:

Amendment 2:

The original Test Report Ref. No.: E349607-A26-CB-1-Original, dated 2012-06-12 was additionally modified on to include the following changes and/or additions, which were considered technical modifications:

1. Addition/deletion of multilayer PWBs to critical component list.
2. Critical component certificate updates.
3. Change factories.
4. Correction/Addition to CCL components.
5. Addition of 18V channel 1 with fan output. (thermal test carried out)

Product Description

Component Switch mode power supply NV175 or NV-175 series.
(see Model Differences for nomenclature and details)

Model Differences

NV175 or NV-175 models as described below:

Units may be marked with a Product Code: K1x or Q1x where x may be any number of letters and/or numbers 0 to 9.

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

Unit Configuration Code:

NVx-abcde-f-g-h-ijk

where:

x = 1 for 175

a = Number of Outputs : 1, 2, 3 or 4

b = Channel 1 Output Voltage†: 5, T, F, E or G

c = Channel 2 Output Voltage†: 1, 2, 3, 5, 5L, 7, F or 0

d = Channel 3 Output Voltage†: 3L, 5L, 7, TL, FL, T, F, G followed by Y for negative output or 0

e = Channel 4 Output Voltage†: 3H, 5H, 7, T, F, TH, FH, 0H (fan only channel 4 output) followed by V for variable output followed by P for positive output or 0

f = Global Option : N for 5V version, N1 for 12V version, N2 for 13.5V version, N3 for 5V version with ATX compatibility, N4 for 12V version with ATX compatibility, N5 for 13.5V version with ATX, N6 for 12-13.5V version, N7 for 12-13.5V version with ATX or nothing for no Global Option present

g = U for U chassis, C for U chassis and cover, F for U chassis and cover with fan, I for U chassis and cover with fan and IEC inlet or nothing for Open Frame

h = Blank is the standard upright output connector, R is for the right angle output connector, H is for high altitude, HR is for high altitude with right angle output connector, M is for IEC60601-1, MR is for IEC60601-1 spacings with right angle connector

ijk = Three numbers from 0 to 9 which denotes various output voltages and currents within the specified

ranges of each output for a particular unit or blank for standard output settings

† Table1: Output Voltage Cross Reference

Designation	Output Voltage
0	Omit output
A	1.5
1	1.8
B	2
2	2.7
3	3.3
5	5
7	7
T	12
F	15
E	18
G	24

Output channels and Global Options ratings are in accordance with the following table subject to variations and limitations of use below:

Output Channel	Designation	Vout	Adj. Range	Output Current	
CH1	5	5	5 - 5.5	25A	
	T	12	12 - 15.5	15A	
	F	15	12 - 15.5	15A	
	E	18	16 - 20	10A	
	G	24	24 - 28.5	7.5A	
CH2	1	1.8	0.9 - 3.8	15A	
	2	2.7	2.5 - 3.8	15A	
	3	3.3	2.5 - 3.8	15A	
CH2 (CH1 12V)	5	5	3.3 - 5.5	10A	
CH2 (CH1 15V)	5	5	3.3 - 5.5	10A	
CH2 (CH1 24V)	5L	5	Fixed	2A	
	5	5	3.3 - 5.5	8A	
	7	7	5.5 - 8	5.5A	
	F	15	12-15.5	6A	
	CH3	7	+/-7	7 - 8	5A
	T	+/-12	12 - 15	5A	
	F	+/-15	12 - 15	5A	
CH3	G	+/-24	18 - 24.5	2.5A	
	3L	+/-3.3	Fixed	2A	
	5L	+/-5	Fixed	2A	
	TL	+/-12	Fixed	2A	
	FL	+/-15	Fixed	2A	
	CH4	3H	+/-3.3	Fixed	2A
		5H	+/-5	Fixed	2A
		7	+/-7	7 - 8	1A
		T	+/-12	Fixed	1A
		F	+/-15	Fixed	1A
TH		+/-12	Fixed	2A	
FH		+/-15	Fixed	2A	
THV		+/-12	12 - 15	2A	
FHV	+/-15	12 - 15	2A		
CH4 (fan output)	OH	-	-	-	

Amendment 2 2014-12-05

Global Option	N	5	Fixed	2A
	N1	12	Fixed	1A
	N2	13.5	Fixed	1A
	N3	5(ATX)	Fixed	2A
	N4	12(ATX)	Fixed	1A
	N5	13.5(ATX)	Fixed	1A
	N6	12	12-13.5*	1A
	N7	12(ATX)	12-13.5*	1A

Channels 1 and 2 combined output currents must not exceed 25A

*Can only be set at the factory.

Variations and limitations of use:

All NV175 or NV-175 PSUs can output 180W except 5V channel 1 models which can output 175W. These power ratings are for channels 1 to 4. The global option output can be run in addition to the channel 1 to 4 maximum power outputs.

Units with channel 1 T and G outputs (no other channels fitted) have a peak power output of 200W including the global option with the following duty cycles:

In any 5 minutes 30% at 200W followed by 70% at 171W (average 180W)

In any 5 minutes 20% at 200W followed by 80% at 175W (average 180W)

Options -H and -HR meet spacings for 5000m.

Options -M and -MR meet IEC60601-1 Edition 2 Reinforced spacing's with the following limitations (interpolated creepage spacings):

Channel 1 cannot be 5V model (T1 and T2 with foils)

Channel 2 cannot be fitted

Cannot be global option variants

Fan versions:

Channel 1 with G output, 25V maximum with 5V channel 2 maximum output current of 7A.

Channel 1 with G output, 25V maximum with 7V channel 2 maximum output current of 5.5A.

Channel 1 with G output, 5L channel 2 maximum output current 1.8A.

Channel 2 with T and F outputs, channel 2 maximum output current of 9A.

Channel 4 maximum output current of 1.5A

Model NV1-1G000 (with or without global option or -M/-MR option) may also be run with Channel 1 output voltage range 22.5V to 28V with maximum current of 7.5A and maximum power of 180W

Model NV1-1G000 (with or without -M option) may also be run at 80Vac to 264Vac input, output: 24V to 28V at 6.25A maximum current and 150W maximum power.

The products listed in the following table are typical examples:

Model	CH1	CH2	CH3	CH4	Global Option
NV1-453FF	5V/25A	3.3V/15A	15V/5A	15V/1A	-
NV1-4G5FFH-N3	24V/7.5A	5V/8A	15V/5A	15V/2A	5V/2A
NV1-350TT-N	5V/25A	-	12V/5A	12V/1A	5V/2A
NV1-453TT-N1	5V/25A	3.3V/15A	12V/5A	12V/1A	12V/1A

NV1-250T0-N2 5V/25A - 12V/5A - 13.5V/1A

Custom Models:

All ratings as per standard models unless otherwise stated.

Model: NS-LAM/NV1-453TTH-N2-H-C (K10035)
Rated to 4600m altitude
Input voltage range from 90Vac to 264Vac

Model: NS-LAMF/NV1-4G5TTH-F (K10066)
5L low current channel 2 fitted.
Channel 2 rated: 5V, 1.4A

Additional Information

The original report was modified on 2014-09-30 to include the following changes/additions:

1. Addition/deletion of multilayer PWBs to critical component list.
2. Critical component certificate updates.
3. Change factories.
4. Correction/Addition to CCL components. (transformer 33489 left out of previous report by error)
5. Addition of 18V channel 1 with fan output (transformer 230089). (thermal test carried out)

Cooling for units with customer supplied air (open frame, U and C options)

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.

Circuit Ref.	Description	Max. Temperature (°C)
L3, L7	Common mode choke winding	140
C1, C4	X capacitors	100
C6, C12	Capacitor	105
L2	Boost choke winding	130
C7	Electrolytic capacitor	70 (105)
T1, T2	Transformer winding	130
XU3	Control board optocoupler	100
TX701	Global option transformer	90
L5	Channel 1 Output choke	125
XL401	Channel 2 Output choke	125
XL601	5L channel 2 output choke	125
XU601	5L channel 2 IC	115

XL501 or XL601	Channel 3 and 4 output choke	125
IC1*	Channel 4 Voltage regulator	110
XQ406	Ch2 highside FET (SMA 2)	115
XV504	Ch3 highside FET (SMA 3)	115
XU601	Ch4 IC (SMA 4)	115
Various	All other electrolytic capacitors	90 (105)

* 1A channel 4 only

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

Technical Considerations

- The product was investigated to the following additional standards: IEC 60601-1, 2nd Edition, 1988 + A1:1991 + A2:1995, UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA) CAN/CSA-C22.2 No. 601.1-M90, EN 60601-1: 1990 + A1:1993 + A2:1995, (except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1, Programmable Electronic Systems, IEC 60601-1-4)
- 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
- 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 IEC inlet and the fan assembly enclosure face must not be made accessible within the host equipment without further evaluation during installation. --
- For voltages above 250Vac, interpolations of spacings have been used. This rationale is based on sub-clause 3.4 for alternative forms of construction having equivalent levels of safety. Reference BSI report 222/7020084/2 of 2 dated 2007-05-15 and 222/7150346/1 of 2 dated 2008-05-14. --

Engineering Conditions of Acceptability

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

- Reinforced insulation between primary and secondary circuits applies only to NV175 narrow version - M and -MR options with the following limitations --
- All other power supplies detailed in this report are rated for Basic insulation between primary and secondary circuits. --
- The power supplies have been assessed as component parts. It is the installers responsibility to ensure that the final installation is in accordance with the NV175 Handbook and that it is in compliance with IEC60601-1 & EN60601-1. --
- 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 NV175 handbook. --
- This product range is available as a forced air-cooled version with a 3 pin input connector (Molex type) or an IEC60320 Inlet. It is also available as a customer air-cooled version where the end cap is not fitted and the customer must provide airflow and measure appropriate temperatures of

components within the product. There are three versions of customer airflow, these being : Open frame, fitted with a "U" chassis, fitted with a "U" chassis and cover. --

- Although the standard only requires testing for a 40°C ambient temperature the equipment has been rated and therefore tested for an operation at 50°C ambient temperature. --
- A suitable fire and electrical enclosure must be provided by the end product. --
- Connection to the protective conductor terminal within the end product must be ensured. --
- Overcurrent protection must be provided by the end equipment to the neutral supply connection --
- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-SELV Reinforced: 278 Vrms, 542 Vpk. Primary-SELV Basic: 337 Vrms, 616 Vpk. , Primary-Earthed Dead Metal: 337 Vrms, 608 Vpk. --