



Test Report issued under the responsibility of:



IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No.: E349607-D1007-1/A0/C0-ULCB

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CB Testing Laboratory: UL International Polska Sp. z o.o.

Address: Aleja Krakowska 81, 05-090 Sekocin Nowy k./Warszawy, POLAND

Applicant's name: TDK-LAMBDA UK LTD

Address: KINGSLEY AVE
ILFRACOMBE, DEVON EX34 8ES UNITED KINGDOM

Test specification:

Standard: IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007
+ A1:2012
(or IEC 60601-1: 2012 reprint)

Test procedure: CB Scheme

Non-standard test method.....: N/A

Test Report Form No.....: IEC60601_1K

Test Report Form Originator: UL(US)

Master TRF: 2015-11

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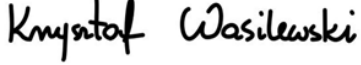

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This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.

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Test item description:	Medical Switch Mode Power Supply	
Trade Mark:	TDK-Lambda	
Manufacturer:	Same as Applicant	
Model/Type reference:	NVM-175 or NVM175 (see Model Differences for details of models and nomenclature)	
Ratings:	100-240Vac nom, 3A rms max, 45-63Hz. (See Model Differences for details of ratings).	
Testing procedure and testing location:		
<input checked="" type="checkbox"/> CB Testing Laboratory:		
Testing location/ address:	UL International Polska Sp. z o.o. Aleja Krakowska 81, 05-090 Sekocin Nowy k./Warszawy, POLAND	
<input type="checkbox"/> Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name, function, signature):	Hubert Koszewski, Handler	
Approved by (name, function, signature):	Krzysztof Wasilewski, Reviewer	
Testing procedure: CTF Stage 1:		
Testing location/ address:		
Tested by (name, function, signature):		
Approved by (name, function, signature):		
Testing procedure: CTF Stage 2		
Testing location/ address:		
Tested by (name, function, signature):		
Witnessed by (name, function, signature):		
Approved by (name, function, signature):		
Testing procedure: CTF Stage 3:		
Testing procedure: CTF Stage 4:		
Testing location/ address:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM	
Tested by (name, function, signature):	Nick S. Marsh, Steve Hirstwood, Testers	
Witnessed by (name, function, signature):		

Approved by (name, function, signature):	Krzysztof Wasilewski, Reviewer	
Supervised by (name, function, signature):	Hubert Koszewski, Handler	

List of Attachments (including a total number of pages in each attachment):

Refer to Appendix A of this report. All attachments are included within this report.

Summary of testing

Tests performed (name of test and test clause):

Testing location:

Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.

Summary of compliance with National Differences

List of countries addressed: Austria, Korea, Republic of, USA, Canada, United Kingdom, Sweden

[X] The product fulfils the requirements of IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012

(or IEC 60601-1: 2012 reprint).

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 the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of Installation and Use:	For building in.
Device type (component/sub-assembly/ equipment/ system):	Component Switched Mode Power Supply
Intended use (Including type of patient, application location):	To provide DC power for electronic circuits within medical equipment.
Mode of Operation:	Continuous
Supply Connection:	connection to the mains via host equipment
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s)	2011-12-08, 2017-11-06
Dates tests performed	2011-12-08 to 2011-12-15, 2017-11-07 to 2017-11-09, 2017-12-07
Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement.....	Pass (P)
- test object was not evaluated for the requirement	N/E
- test object does not meet the requirement.....	Fail (F)
Abbreviations used in the report:	
- normal condition: N.C.	- single fault condition: S.F.C.
- means of Operator protection: MOOP	- means of Patient protection: MOPP
General remarks:	
<p>Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "K" of TRF for IEC for 60601-1 3rd edition with Amendment 1.</p> <p>"(See Attachment #)" refers to additional information appended to the report.</p> <p>"(See appended table)" refers to a table appended to the report.</p> <p>The tests results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced except in full without the written approval of the testing laboratory.</p> <p>List of test equipment must be kept on file and available for review.</p> <p>Additional test data and/or information provided in the attachments to this report.</p>	
Throughout this report a point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC 60601-1:2012	
The application for obtaining a CB Test Certificate includes more than one factory location 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	Yes
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 511453 CHINA

GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.
 Refer to the Report Modifications for any modifications made to this report.

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.

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:

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 attached in Enclosures is representative for both models.

Technical Considerations

- The product was investigated to the following standards:

Main Standard(s):

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CAN/CSA C22.2 No. 60601-1:14, IEC 60601-1 :2005 +A1 :2012

From Country Differences:

- Austria: EN 60601-1:2006/A1:2013
- Korea, Republic of: KS C IEC 60601-1
- USA: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
- United Kingdom: BS EN 60601:2006 A1
- Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

Additional Standards:

CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada)

ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)

- The following additional investigations were conducted: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)
- CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada)
- EN 60601-1: 2006.10.01 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2)
- Clause 14, Programmable Electronic Systems
- Biocompatibility (ISO 10993-1)
- The following accessories were investigated for use with the product: None
- The degree of protection against harmful ingress of water is: Ordinary
- The mode of operation is: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No
- Tests previously conducted for a strictly similar construction for the same applicant, covered in CBTR Ref. No.: E349607-A23-CB-1, E349607-A9-CB-1 including Correction 1 and Amendment-1, CB Test Certificates Ref. No. DK-25447-UL, DK-5244-A1-UL were considered representative of the tests required for this report.
- 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 products covered section Enclosure 6-01 for model difference

- An optional Appliance Coupler is used on some models. This has not been evaluated for Pluggable Type A in this product.

-

Engineering Conditions of Acceptability

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

Insulation (Separation) between primary - secondary output circuits: 2MOPPs.

Insulation (Separation) between primary - earth: 1MOOP

Insulation (Separation) between secondary circuits - earth:1MOPP (at mains), except NVM1D - which has no earth.

Branch circuit protection required: 20A

All outputs are considered non-hazardous and meet the requirements of clause 8.4.2

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 degree C

X50015# 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 by the end use product.

The maximum working voltage of isolation transformers T1, T2 is 275V and T3 is 410V.

Transformers providing insulation barrier T1, T2 and T3 are built in class F insulation system.

NVM1D max storage temp is 65C

Report Modifications

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By
2018-02-06	<p>This report is a reissue of CBTR ref No: E349607-A23-CB-1 dated 2012-03-20 including CB Test Certificate Ref. No. DK-25447-UL dated: 2012-03-21. 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. Only the tests listed below was deemed necessary.</p> <p>The original report was reissued to include the following changes/additions:</p> <ol style="list-style-type: none"> 1. Standard updated to the latest edition. 2. Addition of Non standard model X50015#, output loom Photograph added to Enclosures. 3. Non standard Earth connection made via ring tag and screw 	Hubert Koszewski

	(X50015#). Photograph added to Enclosures. 4. Critical component certificate reference numbers updated in the CCL. 5. Addition of alternate and corrections to CCL components. 6. Corrections to the Insulation Table and changing from MOOP to MOPP for primary to earth. 7. Removal of X50001# and X50005# from Model Differences. CBTL changed to UL International Polska.	