
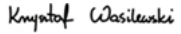




Test Report issued under the responsibility of:



<b>IEC 60601-1</b>	
<b>Medical electrical equipment</b>	
<b>Part 1: General requirements for basic safety and essential performance</b>	
<b>Report Number</b> .....	E349607-D1107-1/A0/C0-CB
<b>Date of issue</b> .....	2023-12-07
<b>Total number of pages</b> .....	175
<b>Name of Testing Laboratory preparing the Report</b> .....	UL International Polska Sp. z o.o. Równoległa 4, 02-235 Warsaw, Poland
<b>Applicant's name</b> .....	TDK-LAMBDA UK LTD
<b>Address</b> .....	KINGSLEY AVE ILFRACOMBE, DEVON EX34 8ES UNITED KINGDOM
<b>Test specification:</b>	
<b>Standard</b> .....	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
<b>Test procedure</b> .....	CB Scheme
<b>Non-standard test method</b> .....	N/A
<b>TRF template used</b> .....	IECEE OD-2020-F1:2020, Ed.1.3
<b>Test Report Form No.</b> .....	IEC60601_1U
<b>Test Report Form(s) Originator</b> .....	UL(US)
<b>Master TRF</b> .....	2022-05-13
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<b>This report is not valid as a CB Test Report unless signed by an approved IECEE Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.</b>	
<b>General disclaimer:</b>	
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 NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	

<b>Test item description</b> .....:	Medical Switch Mode Power Supply	
<b>Trade Mark(s)</b> .....	TDK-Lambda	
<b>Manufacturer</b> .....	Same as Applicant	
<b>Model/Type reference</b> .....:	NVM-175 or NVM175 (see Model Differences for details of models and nomenclature)	
<b>Ratings</b> .....:	100-240Vac nom, 3A rms max, 45-63Hz. (See Model Differences for details of ratings).	
<b>Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):</b>		
<input checked="" type="checkbox"/>	<b>CB Testing Laboratory:</b>	
<b>Testing location/ address</b> .....	UL International Polska Sp. z o.o. Równoległa 4, 02-235 Warsaw, Poland	
<b>Tested by (name, function, signature)</b> .....	Grzegorz Kowalski, Handler	
<b>Approved by (name, function, signature)</b> .. :	Krzysztof Wasilewski, Reviewer	
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 1:</b>	
<b>Testing location/ address</b> .....		
<b>Tested by (name, function, signature)</b> .....		
<b>Approved by (name, function, signature)</b> .. :		
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 2:</b>	
<b>Testing location/ address</b> .....		
<b>Tested by (name, function, signature)</b> .....		
<b>Witnessed by (name, function, signature)</b> .. :		
<b>Approved by (name, function, signature)</b> .. :		
<input checked="" type="checkbox"/>	<b>Testing procedure: CTF Stage 3:</b>	
<input type="checkbox"/>	<b>Testing procedure: CTF Stage 4:</b>	
<b>Testing location/ address</b> .....	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM	
<b>Tested by (name, function, signature)</b> .....	Nick S. Marsh, Steve Hirstwood, Testers	See the original CBTR for signature

<b>Witnessed by (name, function, signature) . :</b>	T. Burgess. Witness	See the original CBTR for signature
<b>Approved by (name, function, signature) .. :</b>	Krzysztof Wasilewski, Reviewer	See the original CBTR for signature
<b>Supervised by (name, function, signature) :</b>	Hubert Koszewski, Handler	See the original CBTR for signature

**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):**

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

**Testing location:**

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

**Summary of compliance with National Differences (List of countries addressed):**

List of countries addressed: United States of America, Canada, Japan

[X] The product fulfils the requirements of National standard AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14, National standard JIS T 0601-1:2023.

**Statement concerning the uncertainty of the measurement systems used for the tests**

(may be required by the product standard or client)

[ ] **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**

**Procedure number, issue date and title:**

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

[X] **Statement not required by the standard used for type testing**

(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

**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.*

<b>Test item particulars</b> .....	
Classification of Installation and Use:	For building in.
Supply Connection:	connection to the mains via host equipment
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
Accessories and detachable parts included:	None
Other Options Include:	None
<b>Possible test case verdicts:</b>	
- test case does not apply to the test object .....	N/A
- test object does meet the requirement .....	P (Pass)
- test object was not evaluated for the requirement.....	N/E (collateral standards only)
- test object does not meet the requirement .....	F (Fail)
<b>Abbreviations used in the report:</b>	
- normal condition .....	N.C.
- means of Operator protection .....	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection .....	MOPP
<b>Testing</b> .....	
<b>Date of receipt of test item</b> .....	2011-12-08, 2017-11-06
<b>Date(s) of performance of tests</b> .....	2011-12-08 to 2011-12-15, 2017-11-07 to 2017-11-09, 2017-12-07
<b>General remarks:</b>	
"(See Enclosure #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report.	
<b>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</b>	
<b>Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1:</b>	
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
<b>When differences exist; they shall be identified in the General product information section.</b>	
<b>Name and address of factory (ies)</b> .....	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  Trio-Tronics (Thailand) Ltd.

6 Map Yang Phon, Sub-District Pluak Daeng  
District  
7/295 Mu. , Rayong THAILAND

### General product information and other remarks:

#### Report Summary

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

Please refer to report modification summary table in GPI section for more details.

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).

May be prefixed by SP followed by / or - (SP represents a sales code)

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 -40°C - +85°C for deratings)

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 Instruction Manual/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):

IEC 60601-1:2005 + AMD1:2012 + AMD2:2020

From Country Differences:

- United States of America: AAMI ES60601-1:2005, ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021
- Canada: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14

Additional Standards:

National standard JIS T 0601-1:2023

- The following additional investigations were conducted:
- 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 (T<sub>ma</sub>) 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.

Multilayer PWB's accepted under CBTR Ref. No.: E349607-A23 dated 2014-07-31 and letter Report, Please see Enclosure of this report.

**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 instruction manual. 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
2023-12-07	<p>This report is a reissue of CBTR ref No: E349607-D1007-1/A1/C0-ULCB dated 2020-03-24 including CB Test Certificate Ref. No. DK-70495-A1-UL dated: 2020-04-06. 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. Based on the previously conducted testing it was determined that they are representative for compliance with the new edition of the standard.</p> <p>The reissue was done due to:</p> <ul style="list-style-type: none"> <li>- upgrade of the compliance with the latest standards: AAMI ES60601-1:2005, ES60601-1:2005/AMD1:2012, ES60601-1:2005/AMD2:2021, CSA-C22.2 No. 60601-1:14, Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14, IEC 60601-1:2005 + AMD1:2012 + AMD2:2020</li> <li>- change of the report number</li> <li>- addition of national differences for Japan</li> <li>- update of license numbers for capacitors, triple insulated wires optocouplers and thermistors.</li> <li>- addition of alternate J2 input connector, C1 and C4 X Capacitors, C8 Y Capacitor, C2, C3 Y Capacitors, C9, C14, C15, C16 Y Capacitors, C2, C3, C15, C16 Y Capacitors</li> </ul> <p>No changes to the construction and documentation of the device.</p>	Grzegorz Kowalski