# UL TEST REPORT AND PROCEDURE

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|---|---|
| **Standard:** | ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)<br>CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) |
| **Certification Type:** | Component Recognition |
| **CCN:** | QQHM2, QQHM8 (Power Supplies, Medical and Dental) |
| **Complementary CCN:** | QQGQ2, QQGQ8 (Power Supplies for Information Technology Equipment Including Electrical Business Equipment) |
| **Product:** | Switch mode power supply |
| **Model:** | NV175 Series<br>NV-175 Series<br>NV1-1G000<br><br>(See Model Differences for details) |
| **Rating:** | NV175 Series; NV-175 Series:<br>100-240Vac (Nominal), 90-264V (Full Tolerance), 45-440Hz, 3Arms<br><br>NV1-1G000 only:<br>88.9-240Vac (Nominal), 80-264V (Full Tolerance), 45-440Hz, 3Arms<br><br>(See Model Differences for details) |
| **Applicant Name and Address:** | TDK-LAMBDA UK LTD<br>KINGSLEY AVENUE<br>ILFRACOMBE<br>DEVON<br>EX34 8ES UNITED KINGDOM |

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

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**Supporting Documentation**

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

A. Authorization - The Authorization page may include additional Factory Identification Code markings.

B. Generic Inspection Instructions -

i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.

ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.

iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

**Product Description**

Component Switch mode power supply NV175 or NV-175 series.

**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 |
| | 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 | - | - | - |
| 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, except model K10142x where x may be any letter not affecting Safety.
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.

Model NV1-1G000-M operation to 4000m.

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

**Technical Considerations**

- Classification of installation and use : For building into host equipment
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : For building into host equipment
- Mode of operation : Continuous
- Supply connection : For building into host equipment
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: IEC 60601-1:2005 + CORR1 2006 + CORR2: 2007 , EN 60601-1:2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance), 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/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012. (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)
- 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 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
- The IEC inlet and the fan assembly enclosure face must not be made accessible within the host equipment without further evaluation during installation.

**Engineering Conditions of Acceptability**

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. When installed in an end-product, consideration must be given to the following:

- Insulation (Separation) between primary - secondary output circuits: 2 MOPPs for the -M and -MR models and 2 MOOPs for all other models.
- Power Supply tested in 25°C, 95%RH. End product Risk Management Process to determine risk acceptability criteria.
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply.
- Insulation (Separation) between primary - earth: 1 MOOP.
- The power supplies have been assessed as component parts. It is the installer’s responsibility to ensure that the final installation is in accordance with the NV175, NV-175 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.

**Additional Information**

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.

Project 4786603042:
This report is a reissue of CBTR Ref. No. E349607-A27-CB-1, CB Test Certificate Ref. No. DK-26606-UL to update standard to IEC60601-1 3rd edition + Am1. Based on previously conducted testing and the review of product construction, no tests were deemed necessary".

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Project 4787416539 (May-2016)

In this project, revision of the only E349607-A27 UL Test Report was performed.
CB Test Report was revised by Amendment to E349607-D13.

Revision to the E349607-A27-UL is published to include the following changes/additions:

1. New model NV1-1G000-M with operation up to 4000 m added to Test Report.
2. Revision of Insulation Table.
3. Update of the Manual.
4. Optional PCB support spacer added to CCL.

Testing was not considered necessary based on the results of previous investigation.

**Additional Standards**

The product fulfills the requirements of: IEC 60601-1:2005 + CORR1 2006 + CORR2: 2007 EN 60601-1:2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance) 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/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)

**Production-Line Testing Requirements**

**Test Exemptions** - The following models are exempt from the indicated test

| Model | Grounding Continuity | Dielectric Voltage Withstand | Patient Circuit Dielectric Voltage Withstand |
|---|---|---|---|
| All models | Not exempted | Not exempted | Exempted |

**Solid-State Component Test Exemptions** - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:

| Component |
|---|
| N/A |

**Sample and Test Specifics for Follow-Up Tests at UL**

The following tests shall be conducted in accordance with the Generic Inspection Instructions

| Plastic Enclosure or Part | Test | Sample(s) | Test Specifics |
|---|---|---|---|
| N/A | | | |