



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-A31-CB-1

Date of issue :

Total number of pages : 10

CB Testing Laboratory : UL International Demko A/S

Address : Borupvang 5A, 2750 Ballerup, Denmark

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

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| | |
|------------------------------------|--|
| 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 | NV300 and NV-300 Series (See model differences for details of models and nomenclature). |
| Ratings | 100-240Vac nom, 5Arms max, 45-63Hz. |

| | |
|---|---|
| Testing procedure and testing location: | |
| <input checked="" type="checkbox"/> CB Testing Laboratory | Testing location / address..... : UL International Demko A/S Borupvang 5A, 2750 Ballerup, Denmark |
| <input type="checkbox"/> Associated CB Test Laboratory | Testing location / address..... : |
| | Tested by (name + signature) : Ermanno Rebecchi  |
| | Approved by (name + signature) ... : Dennis Butcher  |
| <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 type="checkbox"/> Testing Procedure: SMT/CTF Stage 3 or 4 | Tested by (name + signature) : _____ |
| | Approved by (+ signature) : _____ |
| | Supervised by (+ signature) : _____ |
| | Testing location / address..... : _____ |
| <input type="checkbox"/> Testing Procedure: RMT | Tested by (name + signature) : _____ |
| | Approved by (+ signature) : _____ |
| | Supervised by (+ signature) : _____ |
| | Testing location / address..... : _____ |

| |
|---|
| List of Attachments |
| National Differences (0 pages) |
| Enclosures (3 pages) |
| Summary of Testing: |
| No tests were conducted |
| 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, JP, KR, NL, NO, PL, RU, SE, SI, SK, UA, US

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)

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.

T T~ N

22-Jul-14

Made in the UK

INPUT: 100-240 Vac nom. 45-440Hz (for IEC/EN/UL/CSA60950-1)
 5A rms max.
 100-240Vac nom. 45-63Hz (for IEC/EN/UL/CSA60601-1)

TDK-Lambda NV-300


www.emea.tdk-lambda.com

Product Code : NVA30114H

Serial Number : 8142020153

Description : NVA3-4G5FHFH-C

Customer Data :



8142020153

UL **CE**

| | | |
|------|-----------|---|
| CH 1 | 24V_12.5A | Refer to www.emea.tdk-lambda.com for installation manual. For Test Certificate: Refer to http://testcert.emea.tdk-lambda.com pat: uk.tdk-lambda.com/patents |
| CH 2 | 5V_8A | |
| CH 3 | 15V_8A | |
| CH 4 | -15V_2A | |
| AUX | | |

| | |
|--|--|
| 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 | N/A |
| Date(s) of Performance of tests | N/A |
| 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: | |
| | 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 MICROTRNIC CO. LTD. SHIJI INDUSTRIAL ESTATE DONGYONG NANSHA GUANGZHOU GUANGDONG CHINA |

GENERAL PRODUCT INFORMATION:**Report Summary**

The original report was modified on 2015-07-27 to include the following changes/additions:
CORRECTION to add to the Report Summary the following reason:
PANYU TRIO MICROTRNIC CO. LTD added as additional factory.

Product Description

NV300 or NV-300 series. Switch mode power supplies for building into end equipment.

Model Differences

Input Parameters

| | |
|-----------------------------|---------------|
| NOMINAL INPUT VOLTAGE RANGE | 100 - 240V AC |
| INPUT FREQUENCY | 45 - 63 Hz |
| MAXIMUM INPUT CURRENT | 5A rms |
| INRUSH CURRENT | <15A AT 25°C |

All ratings apply for ambient temperatures up to 50°C. From 50 to 65°C the total output power and the module current ratings are both derated at 2.5% per deg C.

Output Parameters

NV300 or NV-300 models as described below:

Unit Configuration Code:

NVx-abcde-f-g-ijk

(may be prefixed by NS # followed by / or- where # may be any characters indicating non safety related model differences)

where:

| | | |
|---|---|---|
| x | = | A3 for 300 or -300 |
| a | = | Number of Outputs : 1, 2, 3 or 4 |
| b | = | Channel 1 Output Voltage†: 5, T or G |
| c | = | Channel 2 Output Voltage†: 1, 2, 2H 3, 3H, 5, 5H, T, F or 0 |
| d | = | Channel 3 Output Voltage†: T, F, TH, FH, G or 0 |
| e | = | Channel 4 Output Voltage†: 3H, 5H, T, F, TH, FH, 0H (fan only channel 4 output) |

followed by P for positive output or 0

| | | |
|-----|---|---|
| f | = | Global Option : N3 for 5V version with ATX compatibility, N4 for 12V version with ATX, N5 for 13.5V version ATX compatibility 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 |
| 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 |

Output Voltage Cross Reference

| Designation | Output Voltage |
|-------------|----------------|
| 0 | Omit output |
| A | 1.5 |

Correction 1 2015-07-27

| | |
|---|-----|
| 1 | 1.8 |
| B | 2 |
| 2 | 2.7 |
| 3 | 3.3 |
| 5 | 5 |
| 7 | 7 |
| T | 12 |
| F | 15 |
| G | 24 |

All channels are adjustable except for Channel 4 and Global Options in accordance with the following table:

| O/P Channel | Designation | Vout (V) | Range (V) | I out (A) | Max Power (W) |
|------------------|-------------|----------------|-----------|-----------|---------------|
| CH1 | 5 | 5 | 5 - 5.5 | 40A | 200 |
| | T | 12 | 12 - 13.2 | 25A | 300 |
| | G | 24 | 24 - 28.5 | 12.5A | 300 |
| CH2 (CH1 5V) | 1 | 1.8 | 0.9 - 2.5 | 15A | 37.5 |
| | 2 | 2.7 | 2.5 - 3.8 | 15A | 50 |
| | 2H | 2.7 | 2.5 - 3.8 | 24A | 80 |
| | 3 | 3.3 | 2.5 - 3.8 | 15A | 50 |
| | 3H | 3.3 | 2.5 - 3.8 | 24A | 80 |
| CH2 (CH1 12V) | 5 | 5 | 3.3 - 5.5 | 10A | 50 |
| | 5H | 5 | 3.3 - 5.5 | 16A | 80 |
| CH2 (CH1 24V) | 5 | 5 | 5 - 5.5 | 8A | 40 |
| | 5H | 5 | 5 - 5.5 | 12.5A | 62.5 |
| | T | 12 | 12 - 15.5 | 10A | 150 |
| CH3 | F | 15 | 12 - 15.5 | 10A | 150 |
| | T | 12 | 12 - 15 | 5A | 60 |
| | F | 15 | 12 - 15 | 5A | 60 |
| | TH | 12 | 12 - 15 | 8A | 96 |
| | FH | 15 | 12 - 15 | 8A | 96 |
| | G | 24 | 18 - 24.5 | 2.5A | 60 |
| CH4 | 3H | +/-3.3 | Fixed | 2A | 6.6 |
| | 5H | +/-5 | Fixed | 2A | 10 |
| | T | +/-12 | Fixed | 1A | 12 |
| | F | +/-15 | Fixed | 1A | 15 |
| | TH | +/-12 | Fixed | 2A | 24 |
| | FH | +/-15 | Fixed | 2A | 30 |
| CH4 (fan output) | OH | - | - | - | - |
| Global Option | N3 | 5 (ATX) | Fixed | 2A | 10 |
| | N4 | 12-13.5* (ATX) | Fixed | 1A | 12-13.5 |
| | N5 | 12-13.5* (ATX) | Fixed | 1A | 12-13.5 |

*12-13.5 is the range. Nomenclature kept for legacy purposes.

Variations and limitations of use:

Maximum 300W power output. With 180Vac and greater input voltage, output power 300W plus global option (max 313.5W)

Channels 1 and 2 combined output currents must not exceed 40A.

Channel 1 with G output, 25V max with 5V channel 2 fitted.

Additional variations and limitations of use for fan version with 5V channel 1:

Output power de-rated 3W per volt from 100Vac to 90Vac (at 90Vac input, 270W output)

Unit with global option, high current channel 2 de-rated to 21A

Unit without global option, high current channel 2 de-rated to 19A

Unit without global option, low current channel 2 de-rated to 13A

Additional variations and limitations of use for all fan version:

Channel 4 3H, 5H, TH and FH max output current 1.5A.

The products listed in the following table are typical examples:

| Model | CH1 | CH2 | CH3 | CH4 | Global Option |
|---------------|-----------|----------|----------|---------|---------------|
| NVA3-453FFH | 5V/40A | 3.3V/15A | 15V/5A | -15V/2A | - |
| NV3A-453HFHFH | | | | | |
| -N3 | 5V/40A | 3.3V/24A | 15V/8A | -15V/2A | 5V/2A |
| NV3A-4GFGT-N5 | 24V/12.5A | 15V/10A | 24V/2.5A | -12V/1A | 13.5V/1A |

Output Limitations

All outputs have functional spacing to earth, and due consideration must be given to this in the end product design.

Adjusting output voltage beyond the stated range may cause overvoltage protection (OVP) to operate. To reset for normal operation simply adjust the potentiometer to reduce the output voltage to within its range or cycle the input off then on if the unit has latched off after adjusting the potentiometer.

Seriesing of outputs is not allowed.

Products may additionally be marked with Product Code NVA3x or Y3x where x may be up to any six letters and/or numbers 0 to 9 indicating non-safety related model differences.

Additional Information

This report is a re-issue of CBTR ref No: E349607-A31-CB-1 dated 2012-10-04 including CB Test Certificate Ref. No. DK-27462-UL dated 2012-08-07. Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, it has been determined that the product continues to comply with the standard. Only the tests listed below were deemed necessary, including the following changes/additions:

F2, alternative fuse testing (not mains input fuse)

Added Trio to the manufacturers list.

Re-assessed for hazardous energy outputs.

Updated handbook

Addition/deletion of multilayer PWBs to critical component list

Correction/addition to the critical component list

Updated licenses

Updated drawings

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 222/7112462/ 1 of 2 dated 2008-04-21 and 222/4933584/ 2 of 2 dated 2007-03-29. --
- Multi-layer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report, enclosure 8-05 of this report. --

Engineering Conditions of Acceptability

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

- When installed in an end-product, consideration must be given to the following: --
- All 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 NV300 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 NV300 handbook. --
- This product range is available as 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 , --
- 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 at full load, 65°C maximum at reduced load. --
- 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 following secondary output voltages are at hazardous energy levels: CH1. --
- The following secondary voltages are at non-hazardous energy levels: CH2, CH3, CH4 and option. --