

UL TEST REPORT AND PROCEDURE

Standard:	UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety) CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1: General Requirements for Safety)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Power Supply Unit
Model:	NV700 or NV-700
Rating:	(See enclosure 7-01 for model configuration) 100-240 Vac (90-264V max tolerance) 47-63 Hz, 11 A rms max. (See enclosure 7-01 for details of outputs)
Applicant Name and Address:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON 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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Reviewed by: Dennis Butcher

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

The NV700 series are switch mode power supplies for building into host equipment.

This product range is available as a forced air cooled version (in-built fan) with screw terminal input connections or an IEC 60320 Inlet. It is also available as a customer air cooled version where the end cap is not fitted and the customer must provide an air flow and measure appropriate temperatures of components within the product.

It should be noted that the power supplies have been assessed as a component part. It is the installer's responsibility to ensure that the final installation is in accordance with the NV700 Handbook and that it is in compliance with IEC60601-1.

Model Differences

See enclosure 7-01

Technical Considerations

- Classification of installation and use : Dependent on final installation
- Supply connection : Dependent on final installation
- Accessories and detachable parts included in the evaluation : None
- Options included : None
- The product was investigated to the following additional standards:: UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada).
- 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 (IPX0)
- 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
- Product evaluated for an operating temperature of 50°C (Full load), to 65°C maximum (See enclosure 7-01 for models and conditions to which the extended ambient applies)
- Some test results have been accepted based on the CB Test Report previously issued by BSI, CB Test Report Ref. No. 222/4933585/2, CB Test Certificate Ref. No. GB750W/A1/M1 as identified in this report.
- Multilayer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report, in enclosure 8-07 of this report.

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:

- With the exception of the units utilising 'C' output modules, the Power Supplies detailed in this Report were rated, by the Client, for Basic insulation requirements between the mains input and DC outputs,

with respect to UL 60601-1 2nd Edition.

- It should be noted that the power supplies have been assessed as a component part. It is the installer's responsibility to ensure that the final installation is in accordance with the NV700 Handbook and that it is in compliance with IEC60601-1. ,
- 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 NV700 Handbook. ,
- This product range is available as a forced air cooled version (in-built fan) with screw terminal input connections (suitable for factory wiring only), or an IEC 60320 Inlet. It is also available as a customer air cooled version where the end cap is not fitted and the customer must provide an air flow and measure appropriate temperatures of components within the product.
- Units utilising 'C' and/or 'CM' output modules have Reinforced insulation requirements between the mains input and DC outputs. The requirements of clauses 17. a and 17. g shall be considered in the end use application. Refer to the isolation diagram and associated table for further guidance.
- Insulation between the secondary (PSU output) and earthed chassis is 'functional only' except for units utilising 'CM' output modules only, which have Basic insulation, at the Working Voltage only. Provided that no part of the module is fitted in slot location 1 (left hand side looking from module end of PSU). See table to insulation diagram for details.
- The following outputs are considered SELV: All outputs are SELV except under the following circumstance:- outputs connected in series are non-SELV if the total output voltage + 30% of the max. rated output voltage of the output with the highest rated voltage exceeds 60Vdc (the 30% addition allows for a single fault in any one individual channel.)
- It should be noted that the power supply has been assessed as a component part of an end equipment. It is the installer's responsibility to ensure that the final installation is in accordance with the NV700 handbook and that it is in compliance with the 60601-1 standards.
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end use equipment.
- The products were tested on a 16A (20A for North America and Canada) branch circuit.
- Modules B, BH, DA, DB and global options (SIP/SOP module) have basic insulation between the mains input and DC outputs.
- The component shall be installed in compliance with enclosure, mounting, marking, spacing and separation requirements of the end use application.
- For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc.
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF)
- Proper bonding to the end product main protective earthing termination is required.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C at full load and 65°C maximum (see enclosure 7-01 for model configuration and output details for models and conditions to which the extended ambient applies).
- Consideration should be given to repeating the earth leakage tests in the end use equipment.
- No external surfaces of the power supply are allowed to be operator accessible, including the inlet face of the PSU fitted with an IEC60320 inlet.
- The following outputs are considered an energy hazard and must not be accessible to an end user:- 12BH, 24BH, 12C, 16C, 24C, 30C, 12CM, 16CM, 24CM and 30CM.