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:	Component Power Supply
Model:	NV700 Series (See enclosure 7-01 for model configuration)
Rating:	100-240V AC 11A Max 47-63Hz (See enclosure 7-01 for details of outputs)
Applicant Name and Address:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE 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.

Prepared by: Wojciech Czerniak 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

Component Power Supplies

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 : Dependant on final installation
- Supply connection : Dependant on final installation
- Accessories and detachable parts included in the evaluation : None
- Options included : None
- The product was investigated to the following additional standards:: 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
- 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)

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 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' output modules were rated, by the Client, for Reinforced insulation requirements between the mains input and DC outputs, with respect to UL 60601-1 2nd Edition.
- Insulation between the intermediate circuits and earthed chassis was considered 'functional only'.

Additional Information

N/A

Additional Standards

The product fulfills the requirements of: CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)

Markings and instructions

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts

Special Instructions to UL Representative

Individual sub-assemblies of the NV700 may be made at either TDK-Lambda UK Ltd, Kingsley Avenue, Ilfracombe, Devon, EX34 8ES or by Trio Engineering Co. Ltd.

Sub-assemblies built as above are to be constructed in accordance with this Follow-Up Service Procedure. Each sub-assembly built by Trio Engineering Co. Ltd. is to be marked with a yellow dot. This identification code is to indicate to the field representative at the final assembly locations that the sub-assemblies were subject to inspection at Trio Engineering Co. Ltd.

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
N/A			

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:

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

Model	Samples	Test	Test Details
N/A			