Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CAN/CSA C22.2 No. 60601-1:14	
Certification Type:	Component Recognition	
CCN:	QQHM2, QQHM8	
Complementary CCNs:		
Product:	Medical Switch Mode Power Supply	
Model:	NV350, NV-350, NF350, NV350FEP, NF3, and NV3 Series (See model differences)	
Rating:	100-240Vac nominal (85-264V max. tolerance), 47-63Hz, 5.5A	
	(See model differences)	
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 as applicable.

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

Prepared by: Mona H. Nielsen (Project Reviewed by: Lars Groennegaard (reviewer) Handler)

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 -

- 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 NV350 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.

Refer to the Report Modifications page for any modifications made to this report.

Model Differences

Series NV3 is identical to the NV350.

Series NV350FEP and NF3 are identical to the NF350.

All models use a common front end supply and fan assembly. The NV350FEP can only use the FE module due to the shorter case size whereas the NV350 can use any module with the exception of the FE module.

Cooling option U has a chassis, no fans and no cover and is therefore dependent on customer air. (Temperatures to be re-evaluated in the end equipment evaluation).

Unit Configuration Code:

NV350 or NV3 or NV-350 (these models are identical)

followed by: S, R, Q, P, V, C, U or K where:

Option Letter Airflow Option

- S Forward airflow, standard fan
- R Reverse airflow, standard fan
- Q Forward airflow, quiet fan
- P Reverse airflow, quiet fan
- V Forward airflow, temperature controlled fan
- C Customer air, fan not fitted
- T Forward airflow, top fan
- U Customer air, fan not fitted, cover not fitted
- K Custom fan/chassis assembly
- Fixed speed fan (Non-standards only)

followed by: S, J or I, where:

Option Letter Input Option S Screw input terminals

IEC input IEC dual fused input J followed by: S, M, L, R, or T, where: Option Letter Leakage Option Standard Leakage (Class B Filter) S Μ Medium Leakage Low Leakage L R **Reduced Leakage** т Tiny Leakage Unit configuration may be given using the above code and/or by the option description. The input terminal type (screw or IEC) may alternatively be determined by examination of the unit. optionally followed by: EN#V, EN12V, EN13.5V, IN#V, IN12V, IN13.5V, ES#V, ES12V, ES13.5V, IS#V, IS12V or IS13.5V. Where: Option Letter Global Option EN#V AC good, global module good, PSU enable, 5-5.5V, 2A standby output EN12V AC good, global module good, PSU enable, 12V, 1A standby output EN13.5V AC good, global module good, PSU enable, 13.5V, 1A standby output IN#V AC good, global module good, PSU inhibit, 5-5.5V, 2A standby output IN12V AC good, global module good, PSU inhibit, 12V, 1A standby output IN13.5V AC good, global module good, PSU inhibit, 13.5V, 1A standby output ES#V AC good, PSU enable, 5-5.5V, 2A standby output ES12V AC good, PSU enable, 12V, 1A standby output ES13.5V AC good, PSU enable, 13.5V, 1A standby output IS#V AC good, PSU inhibit, 5-5.5V, 2A standby output IS12V AC good, PSU inhibit, 12V, 1A standby output IS13.5VAC good, PSU inhibit, 13.5V, 1A standby output Where: # represents the standby output voltage and is in the range 5 to 5.5. The Global Options Inhibit and Enable functions permit the customer to turn off or on the main PSUs outputs and the fan. The standby supply is for use by the customer and provides an SELV output that continues to operate when all the main PSUs outputs have been turned off using the Inhibit or Enable functions. All the functions of the Global Option pass through a single 8 way PWB socket and are all rated SELV. NV350 Modules: Up to 3 of the following modules types may be fitted: @B @BH or @C or or @CM where @ is the output voltage of the module and is within the range given in the single output module table. or @/#DB where @ is the output voltage of channel 1 and # is the output voltage of channel 2 of the module. Voltages are within the range given in the DB module tables. @/#DA or where @ is the output voltage of channel 1 and # is the output voltage of channel 2 of the module. Voltages are within the range given in the DA module tables. Only 1 DA module may be fitted.

or B/S

where B/S indicates that a blanking plate is fitted in place of a module.

The following nomenclature may optionally be used for outputs connected in series: (Note that outputs may be connected in series even when this nomenclature is not used)

@BB or @ BHB or @BBH or @BHBH or @CC or @CCM

where @ is the total voltage of any two B, BH, C or CM modules connected in series.

or @/#BDB or @BHDB

where @ is the total series voltage of any B or BH module and DB module channel 1. # is the output voltage of the DB module channel 2. Voltages for # are within the range given in the DB module tables.

or @HDB

where @ is the total series voltage of any DB module channel 1 and channel 2.

For all outputs connected in series:

Permissible min. value for @ is given by summing the min. voltage ratings of the outputs connected in series. Permissible max. value for @ is given by summing the max. voltage ratings of the outputs connected in series.

Custom Models:

Model: NV350 SJS 24B 24/24DB 12/12DB (K30012) Maximum outputs: 24V, 8A; 24V, 7A; 24V, 2A; 12V, 13A; 12V, 5A (total power 350W max.) Maximum ambient: 50°C Orientations: Horizontal with chassis lowest, on either side or vertical with the airflow upwards. Comments: PSU is fitted with dual fused IEC inlet and double pole mains switch (option J).

Model: NV350 SJS 24B 24/24DB 24/12DB (K30036) Maximum outputs: 24V, 8A; 24V, 7A; 24V, 2A; 24V, 7A; 12V, 5A (total power 350W max.) Maximum ambient: 50°C Orientations: Horizontal with chassis lowest, on either side or vertical with the airflow upwards.

Comments: PSU is fitted with dual fused IEC inlet and double pole mains switch (option J). Model: NV350 LSS 24/24DB 15.5/5.5DB (K30045A)

Maximum outputs: 24V, 1A; 24V, 0.7A; 15.5V, 6.4A; 5.5V, 6.4A. (total power 175W max.) Maximum ambient: 50°C Orientations: Horizontal with chassis lowest, on either side. Comments: PSU has fan drive voltage fixed at 5.5V.

Model: NV350 LSS 24/24DB (K30045B) Maximum outputs: 24V, 7A; 24V, 0.7A. (total power 184.8W max.) Maximum ambient: 50°C Orientations: Horizontal with chassis lowest, on either side. Comments: PSU has fan drive voltage fixed at 5.5V.

ELECTRICAL & THERMAL RATINGS:

Input Parameters

100 - 240 Nominal input voltage (V) Input voltage range (V) 85 - 264 Input frequency range (Hz) 47 - 63 Maximum input current (A) 5.5 Inrush Current (A) <15 For input voltages between 85 and 89.9V the output power is derated to 94% of the values given in the Cooling Options Table. Output modules: Module Output Voltage Occupied Slots Maximum Average Current According to Slot Position (A) Slot 5 Slot 1 Slot 2 Slot 3 Slot 4 Slot 6 В 40 3.14-3.6V 2 40 40 40 4.75-5.5V 40* 40* 40* 40* 22.5** 22.5** 22.5** 22.5** 7-9V 16*** 16*** 16*** 12-15.5V 16* 8**** 8**** 8**** 8**** 24-28V BH 2 20# 20# 12-15.5V 20# 20# 24-28V 10## 10## 10## 10## С 33.34† 33.34† 33.34† 12-13.2V З --26.67† 26.67† 15-16.5V 26.67† -24-26.4V $16.67 \pm$ 16.67 16.67 27-32V 14.82†† 14.82++ 14.82 СМ 24-26.4V 16.67††† 3 16.67††† 16.67+++ DA CH1 11.88-12.25V 1 3¥ DA CH2 -11.9 to -11.6V 1¥¥ _ DB CH1 3.14-3.6V 2 25 25 25 25 4.75-5.5V 25 25 25 25 -5.5-6.5V†††† 25 25 25 25 12-15.5V 13¥¥¥ _ 13¥¥¥ 13¥¥¥ 13¥¥¥ 24-28V 7¥¥¥¥ 7¥¥¥¥ 7¥¥¥¥ 7¥¥¥¥ --DB CH2 3.3-6V‡ 10 10 10 10 _ 7-15.5V 5 5 5 5 -_ 2 2 2 2 24-32V * - Linearly derate from 40 to 36A over the voltage range 5.2 to 5.5 V. ** - Linearly derate from 22.5 to 20A over the voltage range 8 to 9V. *** - Linearly derate from 16 to 13A over the voltage range 13.5 to 15.5 V. **** - Linearly derate from 8 to 7A over the voltage range 26 to 28 V. # - Linearly derate from 20 to 16.5A over the voltage range 13.2 to 15.5 V. ## - Linearly derate from 10 to 8.5A over the voltage range 25.7 to 28 V. + - C & CM modules may output up to 600W for up to 10 seconds providing that the converter ratings are not exceeded and the average power from the module does not exceed the following: 400W for 115 -264Vac input or 350W for 90Vac input (average power may be linearly interpolated between 90 and 115Vac input). ++ - Derate to 400W above 27V. C & CM modules may output up to 600W for up to 10 seconds providing that the converter ratings are not exceeded and the average power from the module does not exceed the following: 400W for 115 - 264Vac input or 350W for 90Vac input (average power may be linearly interpolated between 90 and 115Vac input). +++ - CM Module cannot be fitted to slot 1 due to medical spacing requirements. ++++ - See Table below DB modules with 6V nominal, Output Channel1 O/P 1 : 5.5 - 6V O/P 1 + O/P 2 : 195W total. Cooling options C, S, T & V O/P 1 : 6 - 6.5V O/P 1 + O/P 2 : Linearly derate from 195 to 170W total.

O/P 1 : 5.5 - 6V O/P 1 + O/P 2 : 180W total. Cooling option Q O/P 1 : 6 - 6.5V O/P 1 + O/P 2 : Linearly derate from 180 to 140W total. Cooling options P & R O/P 1 : 5.5 - 6.5V O/P 1 + O/P 2 : 120W total. DB modules with 6V nominal channel 1 are not allowed when channel 2 exceeds 5.5V. ¥ - 3A forward air. 2A reverse air. ¥¥ - 1A forward air, 0.6A reverse air. YYY < VV > - Linearly derate from 13 to 10A over the voltage range 12.5 to 15.5 V. ¥¥¥¥ <////> - Linearly derate from 7 to 6A over the voltage range 25 to 28 V. + - Voltage measured at the module power terminals. This voltage at the power terminals must not be exceeded when remote sense is used. Cooling Options: Code Cooling Option Input Voltage Range (Vac) Total PSU output power (W) Max. ambient (°C) Derating + S, V, T Forward airflow, standard fan (fixed speed & temp. controlled) 90 - 264 ‡ 350W continuous (400W peak if 350W average #) 65 2.5% per °C above 50°C Forward airflow, standard fan (fixed speed & temp. controlled) S. V 115 - 264 450W continuous 2.5% per °C above 50°C (510W peak if 450W average #) 65 S, V, T Forward airflow, standard fan (fixed speed & temp. controlled) 664W continuous 180 - 264 (740W peak if 600W average #)65 2.5% per °C above 50°C R Reverse airflow, standard fan 90 - 264 ‡ 250 W continuous (no peak rating) 65 2.5% per °C above 50°C Q Forward airflow, quiet fan 350 W continuous (no peak rating) 65 90 - 264 ‡ 2.5% per °C above 50°C Т Top fan for model K30052x only 90 - 264 ‡ 65 350 W continuous (no peak rating) 2.5% per °C above 50°C Р Reverse airflow, quiet fan 90 - 264 ‡ 250 W continuous (no peak rating) 60 3.8% per °C above 50°C C, U Customer air, fan not fitted Refer to Customer Air Cooling section in for details. † Both the total output power and the module output currents are derated by the given value. ‡ For input voltages between 85 and 89.9V the output power is derated to 94% of the values given for 90V input. # The PSU may output the given peak power for up to 10 seconds providing that the average power from the PSU does not exceed the stated value. Continuous, peak and average power ratings may be linearly interpolated for input voltages between 90 and 180V. Global Option standby outputs (12-13.5V at 1A or 5-5.5V at 2A) should not be included when calculating total PSU output power, but they are subject to the current deratings for operation above 50°C. Global Options with output voltages between 5.01 and 5.5V have their max. output current linearly derated from 2A at 50°C ambient to 1.4A at 65°C ambient. For reverse airflow cooling all B, BH and DB modules are limited to a maximum output power of 150W (total for both channels on dual output modules). NV350 FEP or NF3 or NV-350FEP (these models are identical) followed by: S, R, or C, where: S Forward airflow, standard fan _ Reverse airflow, standard fan R = С Customer air, fan not fitted _ followed by: S or I, where: S=Screw input terminals IEC input =

followed by: S, where: S Standard Leakage (Class B Filter) Unit configuration may be given using the above code and/or by the option description. The input terminal type (screw or IEC) may alternatively be determined by examination of the unit. Optionally followed by: ES#V or IS#V, where: AC good, PSU enable, 5-5.5V, 2A standby output ES5V = ES12V =AC good, PSU enable, 12-13.5V, 1A standby output IS5V AC good, PSU inhibit, 5-5.5V, 2A standby output = IS12V = AC good, PSU inhibit, 12-13.5V, 1A standby output where # represents the standby output voltage. The Global Options Inhibit and Enable functions permit the customer to turn off or on the main psu outputs and the fan. The standby supply is for use by the customer and provides an SELV output that continues to operate when all the main psu outputs have been turned off using the Inhibit or Enable functions. All the functions of the Global Option pass through a single 8 way PWB socket and are all rated SELV. Followed by @FE where @ is the output voltage of the module and is within the range given in the FE module table as follows: NV350 FEP Module: FE Module, Output 1 Nominal Voltage (V) Voltage Range (V) # Max. Current (A) Max. Power (W) 12 11.5 - 13.2 29.2 350* FE Module, Output 2 Nominal Voltage (V) Voltage Range (V) Max. Current (A) Max. Power (W) Fixed 12V 24.2* 12 2 * - Total Output Power must not exceed 350W. # Voltage measured at the module power terminals must not exceed the value shown in the table when remote sense is used. For 50°C max. ambient operation: 11.5 - 12.5V 350W total power. From 12.5 - 13.2V: Linearly derate total power from 350 to 306W. For 350W total output power (O/P 1 + O/P 2) : 11.5 - 12.5V: 50°C max. ambient. From 12.5 - 13.2V: Linearly derate max. ambient from 50 to 45°C **Cooling Options** TOTAL POWER COOLING OPTION S (FORWARD AIRFLOW) 350W R (REVERSE AIRFLOW) 350W C (CUSTOMER AIR) 350W The above 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 °C. Global Option standby outputs (12V at 1A or 5V at 2A) should not be included when calculating total PSU output power, but they are subject to the output current deratings for operation above 50°C. 5V global options are derated to 1.8A max. when the psu is inhibited NV350 PFC **ELECTRICAL & THERMAL RATINGS:**

Input Parameters

Nominal input voltage (V)100 - 240Input voltage range (V)85 - 264Input frequency range (Hz)47 - 63Maximum input current (A)5.5Inrush Current (A)<15</td>For input voltages between 85 and 89.9V the output power is derated to 94% of the values given in the Cooling Options Table.

Output Parameters

Max Output Power is 350W up to 50°C. Above 50°C, derate by 2.5%/°C. Output Voltage - 375V +/- 20V Fan Output - 12V nom at 0.25A max

Additional Information

Marking label of NV-350 is representative for all models in this Test Report.

Project 4787707401 information:

This report is a reissue of CBTR ref No: E349607-A14-CB-2 dated 2015-01-13 including CB Test Certificate Ref. No. DK-42958-UL dated: 2015-01-13. 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. Only the tests listed below was deemed necessary.

The original report was modified to include the following changes/additions:

- Standard updated to the latest edition.

- model NV-350 added

- Alternate Y1 capacitors (C5, C6, C7) added to the critical components list. Their licences added to the enclosures.

- CBTL changed to UL International Polska.

This report, to include IEC60601-1-1 amendment 1: 2013, is a re-issue of CBTR ref No: E349607-A14-CB-1, dated: 2012-02-01 including CB Test Certificate Ref. No. DK-5964-M1 dated: 2012-02-02. 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. Only the tests listed below was deemed necessary.

The original report was modified to include the following changes/additions:

Range approval for a dual fused input connector (option J). This option has been used before as a nonstandard. Thermal comparison with worst case configuration to allow use across the range. Range approval for top fan (option T). This option has been used before as a non-standard. Thermal comparison with worst case configuration to allow use across the range.

NV3 FEP restored back to original value :11.5 - 15.5V

DB module, CH2 voltage range may be extended up to 6.0V (60W max) for some PSU configurations. Consultation with the factory is required. This is in line with the 61010-1 report No: E331788-A17-CB-1 L option added to nomenclature for fixed speed fan (Non-standard only)

Alternative fuse testing (not mains input fuse)

Alternative J1 connector to include Tianli B825 series (same ratings no testing required)

Alternative/second source fan testing

C and CM modules assessed for MOPPs, input to output at 4000 meters.

Model: NV3 KISE5V 12/12DB 5B (X00004#) should have been : NV3 KISES5V 12/12DB 5B (X00004#) Removed Avnet and Arrow from the manufacturers list.

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: EN 60601-1: 2006 + CORR: 2010 + Amd 1, 2013 (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 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)
- The additional following investigations were conducted: EN 60601-1: 2006 + CORR: 2010 + A1: 2013 (Medical electrical equipment Part 1: General performance) requirements safety essential for basic and 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 + C1:09 + A2:10) (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 following accessories were investigated for use with the product:
- protection The degree of against harmful ingress Ordinary of water is: The mode of operation Continuous is: The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen with nitrous oxide: No or The product is Recognized only to the following hazards: Shock Fire Product evaluated for an operating temperature of 50°C (full load); 65°C (See enclosure 7-01 for details of 5000m. The product was assessed for an operational altitude Multi-layer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report. 7-05 Enclosure

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:

Modules B, BH, DA, DB and Global Options (SIP/SOP module) have 2 MOOP between the mains input and DC outputs. The requirements of clause 8.5 shall be considered in the end use application. Refer to the Isolation Diagram and associated table for further guidance. The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application. 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 customer air cooled versions (with and without a cover) 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 2 MOPP between the mains input and DC outputs. The requirements of clause 8.5 shall be considered in the end use application. Refer to the Isolation Diagram and associated table for further guidance. Except for permanently installed equipment and IEC60320 dual fused inlet models, the overall equipment in which these products are installed must be fitted with double pole fusing.

Insulation between the secondary and earthed chassis is functional except for units utilising 'CM'

output modules only, which additionally have 1 MOPP at a working voltage of 32Vdc. See Table to Insulation Diagram for details. Screw terminals are suitable for factory wiring only. For models with IEC60320 inlet connectors the IEC inlet face of the enclosure has been evaluated as operator accessible . Electrical and fire enclosures are to be provided in the end-use application. The equipment shall be properly bonded to protective earth in the end-product application. This equipment has been evaluated for Continuous Power. If intended for use with intermittant power where the average power is higher than the maximum continuous output power evaluated within this report (350W total at input voltages between 90-100Vac, or 664W total at input voltages between 90-100Vac), the Power Input, Normal Temperature and Abnormal Operation tests shall be reconsidered. The end product should ensure that the requirements related to accompanying documents, clause 7.9, are met. End product Risk Management Process to include consideration of requirements specific to the Power Supply. End product Risk Management Process to consider the need for simultaneous fault condition testing. End product Risk Management Process to consider the need for different orientations of installation during testing. Components were secured to prevent movement, however end product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply. End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply Except for permanently installed equipment, the overall equipment in which these products are installed must be fitted with double pole fusing. The available voltage for the secondary outputs does not exceed 42.4 V peak or 60 V dc, under normal and single fault conditions. However, if outputs are connected in series and the total voltage of the outputs exceeds the 60Vdc SELV limit, then all outputs must be considered non-SELV. The maximum working voltages measured between Primary to Ground is 343Vrms, 622Vpk and Primary to Secondary is 363Vrms, 650Vpk. Dielectric Voltage Withstand conducted on an end product shall be based on these values. Inductors and Transformer (TX1) have an Insulation Class F (155). Considerations to the applied parts requirement, to be conducted as end-product. 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 end-use product shall ensure that the power supply is used within its ratings. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF). The input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product. Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation. The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary. End product Risk Management Process t to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1). End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength. End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply. End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply. End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply. End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply. End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply

The PSU may output the given peak power for up to 10 seconds. When installed in an end product it shall ensure that the average power from the PSU does not exceed the stated value. Repeat of leakage current testing and consideration of non-frequency weighted leakage test (Clause 8.7.3e) shall be considered in the end product application.

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	\langle	
Supply Frequency	Rated frequency range in hertz	
Power Input	Amps, VA, or Watts	

Special Instructions to UL Representative

Both full assemblies and sub-assemblies of the NV350 series as described below, are made at TDK-Lambda UK Ltd., Kingsley Avenue, Ilfracombe, Devon, EX34 8ES.

Sub-assemblies built at TDK-Lambda UK Ltd., Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, are to be constructed in accordance with this Follow-Up Service Procedure. Sub-assemblies sent to final assembly locations given below shall 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 inspected in TDK-Lambda UK Ltd., Kingsley Avenue, Ilfracombe, Devon, EX34 8ES. If variations are found, the code shall be

removed by the manufacturer.

Sub-assemblies built at other locations must have a UL Recognition mark for CCN ZPVI2.

The final NV350 power supplies built at TDK-Lambda UK Ltd., Kingsley Avenue, Ilfracombe, Devon, EX34 8ES; Lambda GMBH, Karl-Bold-Str 40, Achern 77855 Germany; Arrow Electronics Inc,1955 E Sky Harbor Cir N, Phoenix Arizona 85034, USA and Avnet Inc, 60 South McKemy Avenue, Chandler, Arizona 85226, USA will consist of assembling all components listed as 'sub-assemblies' into a complete unit.

Production-Line Testing Requirements <u>Test Exemptions</u> - The following models are exempt from the indicated test			
Grounding Continuity	The following models are exempt from the indicated test:	All: required	
Dielectric Voltage Withstand	The following models are exempt from the indicated test:	All: required	
Patient Circuit Dielectric Voltage Withstand	The following models are exempt from the indicated test:	All: exempt	
Solid-State Components	The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:		