# **UL TEST REPORT AND PROCEDURE**

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(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)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
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 under the indicated Test Procedure as being covered by UL's Follow-Up Service under the indicated Test Procedure.

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Prepared by: Wojciech Czerniak (Project Handler) Reviewed by: Dennis Butcher (Reviewer)

### 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 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.

#### 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:

#### Airflow Option Option Letter

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

followed by: S, J or I, where:

Option Letter	nput Option
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- Screw input terminals S
- IEC input L
- IEC dual fused input J

followed by: S, M, L, R, or T, where:

- Leakage Option Option Letter
- Standard Leakage (Class B Filter) S
- Medium Leakage Μ
- 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 AC good, global module good, PSU enable, 5-5.5V, 2A standby output EN#V AC good, global module good, PSU enable, 12V, 1A standby output EN12V EN13.5V AC good, global module good, PSU enable, 13.5V, 1A standby output AC good, global module good, PSU inhibit, 5-5.5V, 2A standby output IN#V AC good, global module good, PSU inhibit, 12V, 1A standby output IN12V IN13.5V AC good, global module good, PSU inhibit, 13.5V, 1A standby output AC good, PSU enable, 5-5.5V, 2A standby output ES#V AC good, PSU enable, 12V, 1A standby output ES12V ES13.5V AC good, PSU enable, 13.5V, 1A standby output AC good, PSU inhibit, 5-5.5V, 2A standby output IS#V AC good, PSU inhibit, 12V, 1A standby output IS12V IS13.5V AC 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
or	@BH
or	@C

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.

or @/#DA

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.

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Input Parameters

Nominal input voltage (V)	100 - 240
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 Ac	cording to	Slot Position (A)
		Slot 1	Slot 2	Slot 3	Slot 4	Slot 5	Slot 6	
В	3.14-3.6V 2	40	-	40	40	40	-	
	4.75-5.5V	40*	-	40*	40*	40*	-	
	7-9V	22.5**	-	22.5**	22.5**	22.5**	-	
	12-15.5V	16***	-	16***	16***	16***	-	
	24-28V	8****	-	8****	8****	8****	-	
BH	12-15.5V 2	20#	-	20#	20#	20#	-	
	24-28V	10##	-	10##	10##	10##	-	
C	12-13.2V 3	33.34†	-	33.34†	33.34†	-	-	
	15-16.5V	26.67†	-	26.67†	26.67†	-	-	
	24-26.4V	16.67†	-	16.67†	16.67†	-	-	
	27-32V	14.82††	-	14.82††	14.82††	-	-	
CM	24-26.4V 3	-	16.67†††	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	-	
	24-32V	2	-	2	2	2	-	

\* - 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.

2017-05-26 tttt - 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 + O/P 2 : Linearly derate from 195 to 170W total. O/P 1 : 6 - 6.5V Cooling option Q O/P 1 : 5.5 - 6V O/P 1 + O/P 2 : 180W total. O/P 1 + O/P 2 : Linearly derate from 180 to 140W total. O/P 1 : 6 - 6.5V O/P 1 : 5.5 - 6.5V O/P 1 + O/P 2 : 120W total. Cooling options P & R 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.  $\frac{1}{100}$  + Linearly derate from 13 to 10A over the voltage range 12.5 to 15.5 V.  $\frac{1}{2} = \frac{1}{2} + \frac{1}$ ‡ - Voltage measured at the module power terminals. This voltage at the power terminals must not be exceeded when remote sense is used. Cooling Options: Total PSU output power (W) Max. ambient Cooling Option Input Voltage Range (Vac) Code Derating † (°C) Forward airflow, standard fan (fixed speed & temp. controlled) 90 - 264 ‡ 350W Ś, V, Т continuous (400W peak if 350W average #) 2.5% per °C above 50°C 65 Forward airflow, standard fan (fixed speed & temp. controlled) 115 - 264 450W continuous (510W S, V 2.5% per °C above 50°C peak if 450W average #) 65 Forward airflow, standard fan (fixed speed & temp. controlled) 180 - 264 664W continuous (740W S. V. T 2.5% per °C above 50°C peak if 600W average #) 65 Reverse airflow, standard fan 90 - 264 ‡ 250 W continuous (no peak rating) 65 R 65 Forward airflow, quiet fan 90-264 ± 350 W continuous (no peak rating) Q 350 W continuous (no peak rating) Т Top fan for model K30052x only 90 - 264 ‡ 250 W continuous (no peak rating) 60 Ρ Reverse airflow, quiet fan 90 - 264 ‡ Refer to Customer Air Cooling section in for details. C, U Customer air, fan not fitted † 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)

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followed by: S, R, or C, where:

2017-05-26 Page 8 of 32 Report Reference # E349607-A14-UL Issue Date: 2017-05-26 Forward airflow, standard fan S = 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 AC good, PSU enable, 12-13.5V, 1A standby output ES12V = AC good, PSU inhibit, 5-5.5V, 2A standby output IS5V = AC good, PSU inhibit, 12-13.5V, 1A standby output IS12V = 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 Max. Power (W) Nominal Voltage (V) Voltage Range (V) # Max. Current (A) 11.5 - 13.2 29.2 350\* 12 FE Module, Output 2 Nominal Voltage (V) Voltage Range (V) Max. Current (A) Max. Power (W) Fixed 12V2 24.2\* 12 \* - 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** COOLING OPTION TOTAL POWER

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R (REV	WARD ERSE	AIRFLOW) AIRFLOW) R AIR)	350W 350W 350W		
The abo he moo	ove rati dule cu	ngs apply for a rrent ratings are	mbient temperatures up both derated at 2.5% p	to 50°C. From 50 to 65°C the to er °C.	tal output power and
Global output p	Option power,	standby output but they are su	s (12V at 1A or 5V at 2A bject to the output currer	) should not be included when c ht deratings for operation above	alculating total PSU 50°C.
5V glob NV350		ons are derated	to 1.8A max. when the	psu is inhibited	
ELECT	RICAL	& THERMAL R	ATINGS:		
nput P	aramet	ers			
nrush	Current	t (A) <15			a la se alizza de la fila de la
Inrush For ing Cooling Output Max O Output	Param Voltag Voltag	ages between 8 ns Table. eters ower is 350W u e - 375V +/- 20	p to 50°C. Above 50°C, V	power is derated to 94% of the v derate by 2.5%/°C.	values given in the
nrush For ing Cooling Dutput Max O Dutput Fan Ou	Param Voltag Voltag utput P	ages between 8 ns Table. eters ower is 350W t e - 375V +/- 20 12V nom at 0.23	p to 50°C. Above 50°C, V		values given in the
nrush For ing Cooling Dutput Max O Dutput Fan Ou	Param Param utput P Voltag utput - ´ <b>ical Co</b>	ages between 8 ns Table. eters ower is 350W u e - 375V +/- 20 12V nom at 0.23 nsiderations	ip to 50°C. Above 50°C, V 5A max	derate by 2.5%/°C.	values given in the
nrush For ing Cooling Dutput Max O Dutput Fan Ou <b>Techn</b>	Param Param utput P Voltag utput - ^ <b>ical Co</b> Class	ages between 8 ns Table. eters ower is 350W u e - 375V +/- 20 12V nom at 0.22 onsiderations ification of insta	ip to 50°C. Above 50°C, V 5A max illation and use : For bui	derate by 2.5%/°C.	values given in the
nrush For ing Cooling Dutput Max O Dutput Fan Ou Fechn	Param Param utput P Voltag utput - ^ ical Co Class Devic	ages between 8 ns Table. eters ower is 350W t e - 375V +/- 20 12V nom at 0.22 misiderations ification of insta e type (compor	up to 50°C. Above 50°C, V 5A max Illation and use : For bui ient/sub-assembly/ equij	derate by 2.5%/°C. Iding-in oment/ system) : Component	
nrush For ing Cooling Dutput Max O Dutput Fan Ou <b>Techn</b>	Param Param utput P Voltag utput - ´ <b>ical Co</b> Class Devic Intend	ages between 8 ns Table. eters ower is 350W t e - 375V +/- 20 12V nom at 0.22 misiderations ification of insta e type (compor	ip to 50°C. Above 50°C, V 5A max Illation and use : For bui inent/sub-assembly/ equij	derate by 2.5%/°C.	
nrush For ing Cooling Dutput Max O Dutput Fan Ou Techn	Param utput P Voltag utput P Voltag utput - 2 ical Co Class Devic Intend circuit Mode	ages between 8 ns Table. eters ower is 350W u e - 375V +/- 20 12V nom at 0.23 ification of insta ification of insta to type (compor ded use (Includ ts within medica of operation : 0	up to 50°C. Above 50°C, V 5A max Illation and use : For bui nent/sub-assembly/ equip ing type of patient, applic al equipment. Continuous	derate by 2.5%/°C. Iding-in oment/ system) : Component cation location) : To provide DC	power for electronic
nrush For ing Cooling Dutput Max O Dutput Fan Ou <b>Techn</b>	Param Param utput P Voltag utput - ´ <b>ical Co</b> Class Devic Intenc circuit Mode Suppl suppl	ages between 8 ns Table. eters ower is 350W u e - 375V +/- 20 12V nom at 0.23 ification of insta e type (compor ded use (Includ ts within medica of operation : ( by connection : )	up to 50°C. Above 50°C, V 5A max Illation and use : For bui inent/sub-assembly/ equipting type of patient, applic al equipment. Continuous Units configured with an ince coupler; Units config	derate by 2.5%/°C. Iding-in oment/ system) : Component	power for electronic
nrush For ing Cooling Output Fan Ou Techn	Param utput P Voltag utput - <b>ical Co</b> Class Devic Inteno circuit Mode Supp suppl host e	ages between 8 ns Table. eters ower is 350W u e - 375V +/- 20 12V nom at 0.22 insiderations ification of insta e type (compor ded use (Includ ts within medica of operation : 0 ly connection : 1 y via an appliar equipment (upo	up to 50°C. Above 50°C, V 5A max Illation and use : For bui inent/sub-assembly/ equipting type of patient, applic al equipment. Continuous Units configured with an ince coupler; Units config	derate by 2.5%/°C. Iding-in oment/ system) : Component cation location) : To provide DC appliance inlet are suitable for o ured with a mains terminal block	power for electronic
For ing Cooling Output Max O Output Fan Ou <b>Techn</b>	Param utput P Voltag utput P Voltag utput - ^ ical Co Class Devic Intenc circuit Mode Supp suppl host e Acces Other	ages between 8 ns Table. eters ower is 350W u e - 375V +/- 20 12V nom at 0.23 ification of insta e type (compor ded use (Includ ts within medica of operation : 0 ly connection : 1 y via an appliar equipment (upo ssories and det r options include	p to 50°C. Above 50°C, V 5A max Illation and use : For bui nent/sub-assembly/ equip ing type of patient, applie al equipment. Continuous Units configured with an nee coupler; Units config n installation) achable parts included : e : None	derate by 2.5%/°C. Iding-in oment/ system) : Component cation location) : To provide DC appliance inlet are suitable for o ured with a mains terminal block	power for electronic connection to the mains < to be supplied by the

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 product is Recognized only to the following hazards: Fire , Shock
- Product evaluated for an operating temperature of 50°C (full load); 65°C (See enclosure 7-01 for details).
- The product was assessed for an operational altitude of 5000m.
- Multi-layer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report, Enclosure 7-05

## 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.

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- 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.

#### Additional Information

Project 4787707401 information:

This is Amendment 1 to the CB Test Report E349607-A14-CB-2 dated 2015-01-13.

This Amendment is published due to changes provided in Report Summary.

No additional testing has been done

This amendment shall be read in conjunction with Original Test Report and Test Certificate.

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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