

Issue Date: 2012-03-20
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Report Reference #

E349607-A23-UL

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:	NVM-175 or NVM175 (see Model Differences for details of models and nomenclature)
Rating:	100-240Vac nom, 3A rms max, 45-63Hz. (See Model Differences for details of ratings).
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.

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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 NVM-175 Series are switched mode power supplies for building into host equipment. Both supply lines are fused (except -FL option). Appropriate cooling conditions must be fulfilled by the end-use product.

Model Differences

NVM175 or NVM-175 models as described below:

Units may be marked with a Product Code: X5x or NVM1x where x may be any number of characters.

Unit Configuration Code (Description): may be prefixed by NS # followed by / or - (where # may be any number of characters indicating non- safety related model differences).

Unit Configuration Code:
NVMxy-abcdefghijklm

Where:

- x = 1 for 175 or 1D (1D for Double insulated or Class II unit)
- y = Blank for Y2 capacitors from output to earth (except 1D models)
- P for Y1 capacitors from output to earth (except 1D models)
- a = Number of Outputs: 1.
- b = Channel 1 Output Voltage where: T is for 12V, F is for 15V and G is for 24V.
- c = O (for omit).
- d = O (for omit).
- e = O (for omit).
- f = Standby supply:
 - Blank for no standby and no remote on/off (enable) or '-' followed by
 - S for 12V version with power good, logic level high enables main output.
 - S1 for 12V version with power good, logic level low enables main output.
 - S2 for 12V version with Channel 1 good, logic level high enables main output.
 - S3 for 12V version with Channel 1 good, logic level low enables main output.
 - S4 for 12V 0.8A version with power good, logic level low enables main output.
 - S5 for 5V 0.5A version with power good, logic level low enables main output.
 - S6 for 5V 0.5A version with power good, logic level high enables main output.
 - 0 for no standby and no remote on/off (enable).
- g = U for U chassis, C for U chassis with cover, K for custom chassis with cover and IEC inlet or blank for Open Frame.
- h = Blank is the standard upright output connector, R is for the right angle output connector, S is for the screw terminal.
- i = Blank for standard leakage, L for low leakage, Zx is for custom leakage which is less than standard leakage and x is a number between 1 and 9 for different custom leakage current options.
- jkl = Blank for standard output setting or '-' followed by three numbers from 0 to 9 which denotes various output voltages and currents within the specified range of channel 1 output for a particular unit.
- m = Blank for dual fuse input or -FL for single fuse input in the Live line

Output Parameters

There are three NVM1 standard models with various options, and 3 non-standard models with output parameters shown in the tables below:

Voltage	Vout	Adjustment	Output	Maximum
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Output Channel	Designation	Nom.	Range (V)	Current (A)	Power (W)
Channel 1	T	12	12 - 15.5	15	180
	F	15	12 - 15.5	15	180
	G	24	24 - 28.5	7.5	180
Standby output	S	12	Fixed	0.2	2.4
	S1	12	Fixed	0.2	2.4
	S2	12	Fixed	0.2	2.4
	S3	12	Fixed	0.2	2.4
	S4	12	12 - 13	0.8	10.4
	S5	5	Fixed	0.5	2.5
	S6	5	Fixed	0.5	2.5

Variations and limitations of use:

NVM175 PSUs can output 180W from channel 1 plus 10.4W maximum from the standby output. Component temperatures must be monitored in the end use application as described in the "COOLING FOR UNIT" section. All ratings apply for ambient temperatures up to 50°C. From 50 to 70°C the total output power and current ratings are both derated at 2.5% per deg C.

Non-Standard Model:

Non- Standard model: X50001# (# can be any letter), (modified NVM1-1T000-S1-K-R-L)

Output Channel	Designation	Voltage	Vout	Adjustment	Output	Maximum
		Nom.		Range (V)	Current (A)	Power(W)
Channel 1	T	12		12 - 15.5	15	180
Standby output	S1	12		Fixed	0.2	2.4

Additional Variations and limitations of use for Non- Standard model X50001#:

Ratings apply for ambient temperatures up to 60°C. From 60 to 65°C the total output power and current ratings are both derated at 2.5% per deg C. Component temperatures must be monitored in the end use application as described in the "COOLING FOR UNIT" section.

X50005# - (# can be any letter), (modified NVM1-1T model) with 5V 0.5A standby option.

X50007# - NVM1D - 1G-f-g-h-j

may be any letter where this indicates any of the options described in the nomenclature table above for f, g, h and j and where g will always be blank (open frame). D indicates that the product is double insulated (no earth connections). This product has 18-way output connector. Maximum storage temperature 65°C.

For ambient temperature requirements see Conditions of Acceptability and user manual (Enclosure 6-01).

Input Parameters

Parameter	60601-1
Nominal input voltage	100 - 240 Vac
Input voltage range	90 - 264Vac

Input frequency range 45 - 63Hz
Maximum input current 3A rms

Environmental Specifications:

Description	Operation	Storage & Transportation
Use	Indoor	-
Temperature	0°C - +70°C (See O/P tables for deratings)	-40°C - +85°C
Humidity	5 - 95% RH, non-condensing	5 - 95% RH, non-condensing
Altitude	-200m - 4000m	-200m - 5000m
Pressure	63kPa - 106kPa	54kPa - 106kPa
Orientation	The unit may be mounted on either side, vertical with input lowest and horizontal. (Customer Air versions can be mounted in any orientation).	
Material Group	IIIb	
Pollution Degree	2	
Overvoltage Category	II	
Class	I or II (depending on model)	
Weight	1 Kg max	
IP Rating	IPX0	

Technical Considerations

- Classification of installation and use : For building in.
- Device type (component/sub-assembly/ equipment/ system) : Component Switched Mode Power Supply
- Intended use (Including type of patient, application location) : To provide DC power for electronic circuits within medical equipment.
- Mode of operation : Continuous
- Supply connection : connection to the mains via host equipment
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: 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), 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), EN 60601-1: 2006.10.01 Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- 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 following accessories were investigated for use with the product:: None
- 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
- Tests previously conducted for a strictly similar construction for the same applicant, covered in CBTR

Ref. No.: E349607-A23-CB-1, E349607-A9-CB-1 including Correction 1 and Amendment-1, CB Test Certificates Ref. No. DK-25447-UL, DK-5244-A1-UL were considered representative of the tests required for this report.

- The product was submitted and tested for use at the maximum ambient temperature (T_{ma}) permitted by the manufacturer's specification of: 50°C (full load); 70°C (output power decreasing linearly by 2.5%/°C above 50°C), see products covered section Enclosure 6-01 for model difference
- An optional Appliance Coupler is used on some models. This has not been evaluated for Pluggable Type A in this product.

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:

- Insulation (Separation) between primary - secondary output circuits: 2MOPPs.
- Insulation (Separation) between primary - earth: 1MOOP
- Insulation (Separation) between secondary circuits - earth: 1MOPP (at mains), except NVM1D - which has no earth.
- Branch circuit protection required: 20A
- All outputs are considered non-hazardous and meet the requirements of clause 8.4.2
- NVM175 PSUs can output 180W from channel 1 plus 10.4W maximum from the standby output.
- Component temperatures must be monitored in the end use application as described in the COOLING FOR UNIT section of the handbook. 1 m/s blown air was used for temperature test.
- NVM175 ratings apply for ambient temperatures up to 50°C. From 50 to 70°C the total output power and current ratings are both derated at 2.5% per degree C
- X50001# ratings apply for ambient temperatures up to 60°C. From 60 to 65°C the total output power and current ratings are both derated at 2.5% per deg C.
- This power supply shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings and segregation requirements of the end use application.
- The need for Enclosure and Patient leakage current tests should be considered as part of the end product evaluation
- A suitable Electrical and Fire enclosure shall be provided by the end use product.
- The maximum working voltage of isolation transformers T1, T2 is 275V and T3 is 410V.
- Transformers providing insulation barrier T1, T2 and T3 are built in class F insulation system.
- NVM1D max storage temp is 65C

Additional Information

Cooling for units:

The following method must be used for determining the safe operation of PSUs.

The components listed in the following table must not exceed the temperatures given. To determine the component temperatures the heating tests must be conducted in accordance with the requirements of the standard in question. Consideration should also be given to the requirements of other safety standards. Test requirements include: PSU to be fitted in its end-use equipment and operated under the most adverse conditions permitted in the end-use equipment handbook/specification and which will result in the highest temperatures in the PSU. To determine the most adverse conditions consideration should be given to the end use equipment maximum operating ambient, the PSU loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers, etc. Temperatures should be monitored using type K

fine wire thermocouples (secured with cyanoacrylate adhesive or similar) placed on the hottest part of the component (out of any direct airflow) and the equipment should be run until all temperatures have stabilised.

Cooling for unit temperature table:

Circuit Ref.	Description	Max. Temperature (°C)
L3, L7	Common mode choke winding	115 (155)
C1, C4	X capacitors	100
C6	Capacitor	105
C12	Resonant capacitor	105
T3	Aux trx windings	130
L2	Boost choke winding	120 (155)
C7	Electrolytic capacitor	70 (105)
T1, T2	Transformer winding	130
L1	Primary choke (24V channel 1 only)	140
XU3, XU4, XU106	Opto-couplers on control board	100
U1, U2	Opto-couplers on base board	100
L5	Channel 1 output choke	125 (140)
L4	Standby output choke	85
J2	Input connector	105
J1	Output connector	105
Various	All other electrolytic capacitors	90 (105)

Higher temperature limits (in brackets) may be used but product life may be reduced.

Additional Standards

The product fulfills the requirements of: 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)