Underwriters Laboratories (UL LLC)
Safety Certification Body (CB) Report

Model:	NV700x or NV-700x Series followed by abcd May be prefixed by SP followed by / or – (SP represents a sales code) (may be prefixed by NS – # / or – where # may be any characters indicating non-safety related model differences. Units may be additionally marked with a product code: K7x or NV7x where x may be up to any six letters and/or numbers 0 to 9. x = H or blank for hold up option a = S, C or U for airflow option b = S or I for input option c = S,M,L,R or T for leakage option d = optionally followed by EN#V, EN*V, IN#V, IN*V, ES#V, ES*V, IS#V, IS*V where # represents standby output voltage of 5-5.5V and # represents standby output voltage of 12-13.5V followed by up to 4 modules
Device Description:	Switch Mode Power Supply
Applicant:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE, DEVON EX34 8ES UNITED KINGDOM
Manufacturer:	Same as Applicant
Manufacturing Facility(ies):	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE, DEVON EX34 8ES UNITED KINGDOM PANYU TRIO MICROTRONICS CO LTD SHIJI INDUSTRIAL ESTATE DONGYONG, NANSHA, GUANGZHOU, GUANGDONG 511453 CHINA TDK-Lambda (China) Electronics Co Ltd No.95, Zhujiang Rd, Xinwu District Wuxi Jiangsu, 214028 PR China
Report No.:	E349607-D1042-1/A0/C0-CB
Report (Re)Issue Date:	2025-02-17
Base Standard(s):	IEC 60601-1:2005, AMD1:2012, AMD2:2020
Additional Standards:	EN 60601-1:2006 /A2:2021; ANSI/AAMI ES60601-1: 2005/A2: 2021; CAN/CSA C22.2 No. 60601-1:14 AMD2: 2022
Report Types:	This report consists of the following report types: - CB Report & Certificate

This report covers the Safety evaluation of the referenced model(s) according to the standard(s) specified above.

The **CB Certificate** is provided as a separate enclosure to this report and not provided in the body of this report.

Table of Contents

Report Modifications Summary

The following changes were made to this report. If none listed in the below table, this report is the originally issued report.

The following scheme is used throughout this report to reflect the **Report No.**:

(File No.) – (Report Ref. No.) – (x) / A(y) / C(z) – YYY, where:
(x) = Report (Re)Issue No.
(y) = Amendment No.
(z) = Correction No.
YYY = Report Type (UL/CB/IEC)

*NOTE: The **CB Certificate** may not be updated for report corrections that don't affect the CB Certificate contents; therefore if this report includes a correction number (z), it may not be reflected in the CB Certificate.*

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2025-02-17	This Test Report is a reissue of CB Test Report E349607-D1041-CB dated 2024-12-10 with CB Test Certificate DK-160971-UL dated 2024-12-11 , with the following changes: 1. Upgrade standard to IEC/UL/CSA 60601-1 Edition 3.2 2. Correct Typo in Insulation Table from MOOP to MOPP for below locations - Location B 'DA module TX1 pins to earth' - Location B 'Bridge Heatsink to Earth pad' - Location B 'C14 track To Earth pad' - Location E 'C, CM modules TX2 primary leadouts to secondary winding via core' - Location F 'CM module across capacitor C6 (negative output to earth with positive output earthed' 3. Add Japan National Deviation in report Enclosure. 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 and no tests were considered necessary	Steve Chiu

Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1: General requirements for basic safety and essential performance

Report Number. .....:	E349607-D1042-1/A0/C0-CB
Date of issue .....:	2025-02-17
Total number of pages.....:	208
Name of Testing Laboratory preparing the Report.....:	UL International Demko A/S Borupvang 5A, 2750 Ballerup, Denmark
Applicant's name.....:	TDK-LAMBDA UK LTD
Address .....:	KINGSLEY AVE ILFRACOMBE, DEVON EX34 8ES UNITED KINGDOM
Test specification:	
Standard.....:	IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012, IEC 60601-1:2005/AMD2:2020
Test procedure .....:	CB Scheme
Non-standard test method……..:	N/A
TRF template used. .....:	IECEE OD-2020-F1:2020, Ed.1.3
Test Report Form No.....:	IEC60601_1U
Test Report Form(s) Originator ....:	UL(US)
Master TRF.....:	2023-08-24

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

This report is not valid as a CB Test Report unless signed by an approved IECEE Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.
This report shall not be reproduced, except in full, without the written approval of the Issuing NCB. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.

Test item description.....:	Switch Mode Power Supply
Trade Mark(s) .....:	TDK Lambda
Manufacturer .....:	Same as Applicant
Model/Type reference.....:	NV700x or NV-700x Series followed by abcd May be prefixed by SP followed by / or – (SP represents a sales code) (may be prefixed by NS – # / or – where # may be any characters indicating non-safety related model differences. Units may be additionally marked with a product code: K7x or NV7x where x may be up to any six letters and/or numbers 0 to 9. x = H or blank for hold up option a = S, C or U for airflow option b = S or I for input option c = S,M,L,R or T for leakage option d = optionally followed by EN#V, EN*V, IN#V, IN*V, ES#V, ES*V, IS#V, IS*V where # represents standby output voltage of 5-5.5V and # represents standby output voltage of 12-13.5V followed by up to 4 modules
Ratings.....:	100-240Vac nominal (90-264V max. tolerance), 47-63Hz, 11A rms Max (see Model Differences for details of model ratings) Risk Management process not evaluated

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):			
[X]	**CB Testing Laboratory:**		
Testing location/ address ..... :		UL International Demko A/S Borupvang 5A, 2750 Ballerup, Denmark	
Tested by (name, function, signature) ..... :		Steve Chiu (Project Handler)	
Approved by (name, function, signature) .. :		Grzegorz Kowalski, Reviewer	
[ ]	**Testing procedure: CTF Stage 1:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			

Approved by (name, function, signature) .. :		
[ ] **Testing procedure: CTF Stage 2:**		
Testing location/ address ..... :		
Tested by (name, function, signature) ..... :		
Witnessed by (name, function, signature) . :		
Approved by (name, function, signature) .. :		
[X] **Testing procedure: CTF Stage 3:**		
[ ] **Testing procedure: CTF Stage 4:**		
Testing location/ address ..... :	CTF3: TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM	
Tested by (name, function, signature) ..... :	Mark Gisbey, Tester	See GPI for details
Witnessed by (name, function, signature) . :	Maggie Chiu, Handler	See GPI for details
Approved by (name, function, signature) .. :	Grzegorz Kowalski, Reviewer	See GPI for details
Supervised by (name, function, signature) :	Steve Chiu, Project Handler	See GPI for details

List of Attachments (including a total number of pages in each attachment):

Refer to Appendix A of this report. All attachments are included within this report.

Summary of testing:

Tests performed (name of test and test clause):	**Testing location:**
Refer to the Test List in Appendix B of this report if testing was performed as part of this evaluation.	*Refer to the Test List in Appendix B of this report if testing was performed as part of this evaluation.*

Summary of compliance with National Differences (List of countries addressed):

List of countries addressed: United States of America, Canada, Japan
[X] The product fulfils the requirements of AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14. National standard JIS T 0601-1:2023

Statement concerning the uncertainty of the measurement systems used for the tests
(may be required by the product standard or client)

[ ] **Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:**
Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

[X] **Statement not required by the standard used for type testing**
(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

Test item particulars ..... :	
Classification of Installation and Use:	For building-in
Supply Connection:	For building-in
Device type (component/sub-assembly/ equipment/ system):	Component Power Supply
Intended use (Including type of patient, application location):	To provide DC power for electronic circuits within medical equipment.
Mode of Operation:	Continuous
Accessories and detachable parts included:	N/A
Other Options Include:	N/A
Supply Connection	For building-in
Possible test case verdicts:	
- test case does not apply to the test object .....:	N/A
- test object does meet the requirement .....:	P (Pass)
- test object was not evaluated for the requirement..... :	N/E (collateral standards only)
- test object does not meet the requirement .....:	F (Fail)
Abbreviations used in the report:	
- normal condition.....: N.C.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection ....: MOPP
Testing.....:	
Date of receipt of test item .....:	2014-05-21 to 2014-10-01, 2024-04-02 to 2024-07-29
Date(s) of performance of tests .....:	2014-06-09 to 2014-10-02, 2024-04-09 to 2024-07-31

General remarks:

"(See Enclosure #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided ..... :	Yes

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies)..... :	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE, DEVON EX34 8ES UNITED KINGDOM PANYU TRIO MICROTRONICS CO LTD SHIJI INDUSTRIAL ESTATE DONGYONG, NANSHA, GUANGZHOU, GUANGDONG 511453 CHINA

TDK-Lambda (China) Electronics Co Ltd
No.95, Zhujiang Rd, Xinwu District
Wuxi
Jiangsu, 214028
PR China

General product information and other remarks:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out in previous evaluation. See report modifications for details.

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

Product Description

The NV700 products are switched mode power supplies for building into host equipment. They are not intended to be accessible to an operator. However, if any surface of the product is accessible further tests may be necessary in the end application. Risk Management has not been applied to these products.
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

NV700 models as described below:
Unit Configuration (Description:) Code may be prefixed by NS # followed by / or - (where # may be any characters indicating non- safety related model differences)
May be prefixed by SP followed by / or – (SP represents a sales code)
.
Unit Configuration (Description :) Code:

NV-700x or NV7x (these models are identical) followed by abcd

Where x = H for high hold up or blank for standard hold up

a) followed by: S, C or U

where S = Forward airflow, standard fan C = Customer air, fan not fitted
U = Customer air, fan not fitted, cover not fitted

b) followed by: S or I

where S = Screw input terminals I = IEC input
c) followed by: S, M, L, R, or T where S = Standard Leakage (Filter)
M = Medium Leakage
L = Low Leakage
R = Reduced Leakage T = 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.

d) optionally followed by: EN#V, EN*V, IN#V, IN*V, ES#V, ES*V, IS#V, IS*V.

where EN#V = AC good, global module good, PSU enable, 5-5.5V, 2A standby output EN*V = AC good, global module good, PSU enable, 12-13.5V, 1A standby output IN#V = AC good, global module good, PSU inhibit, 5-5.5V, 2A standby output IN*V = AC good, global module good, PSU inhibit, 12-13.5V, 1A standby output ES#V = AC good, PSU enable, 5-5.5V, 2A standby output
ES*V = AC good, PSU enable, 12-13.5V, 1A standby output IS#V = AC good, PSU inhibit, 5-5.5V, 2A

standby output IS*V = AC good, PSU inhibit, 12-13.5V, 1A standby output

where # represents the standby output voltage and is in the range 5 to 5.5V where * represents the standby output voltage and is in the range 12-13.5V

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.
Modules:
Up to 4 of the following modules types may be fitted:
@B
or @C
or @CM
or @BH

where @ is the output voltage of the module and is within the range given in the single output module table.
or @/#DB 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 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 or B_S
where B/S or 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.
@/#BDB 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: NV-700 RSS IN5V 12BH 12BH

Maximum outputs: 12.5V, 20A; 12.5V, 20A (total power 500W max.)
Maximum ambient: 65°C with 2.5%/°C derating of total power and module current above 50°C
Orientations: Horizontal with chassis lowest, on either side or vertical with the airflow upwards.
Comments: PSU has reverse air.
Model: NV-700 CSS ES5V 12C (NV722DCC and NV7Y019T)
Maximum output: 12V, 37.5A (peak power rating as given in electrical and thermal ratings section on following page)
Maximum ambient: 65°C with 2.5%/°C derating of total power and module current above 50°C
Orientations: Horizontal with chassis lowest, on either side or vertical with the airflow upwards.
Maximum operating altitude: 5000m
Output Interface Assembly:
One of the following output interface assemblies may optionally be fitted:
Wxxx
where xxx is a number between 001 and 999. These assemblies attach to the module output(s) and contain circuitry providing one or more of the following: current sharing, reduced current limit, fusing, sequencing, diode or-ing, module good, filtering, connectors or terminal blocks for outputs or signalling purposes, indicator lamps or LEDs.

Documentation to be made available to the customer detailing ratings of all assembly outputs.
ELECTRICAL AND THERMAL RATINGS
Nominal Input Voltage 100 - 240 Vac
Input Voltage Range 90 - 264 Vac #
Input Frequency Range 47 - 63 Hz
Maximum Input Current 11 A rms
Subject to limitations, see table below.

Code	Cooling Option	Input Voltage) Range (Vac)	Total output power (W)	Maximum ambient (°C) Derating †
S	Forward airflow standard fan	90 - 99.9	700W continuous (850W peak if 700W average #)	65 2.5% per °C above 45°C
S	Forward airflow standard fan	100 - 149.9	700W continuous (850W peak if 700W average #)	65 2.5% per °C above 50°C
S	Forward airflow standard fan	150 - 264	1150W continuous (1450W peak if 1150W average #)	65 2.5% per °C above 45°C
C, U‡	Customer air fan not fitted	Refer to Customer Air Cooling section for details		

‡ 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.
† The total output power, module output currents and Global Option output currents are derated by the given value.
# 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.
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.
Permitted orientations: Horizontal with chassis lowest, on either side or vertical with the airflow upwards.
Single Output Modules:

Module	Nominal Voltage (V)	Voltage Range (V) #	Max. Current
B	3.3	3.135 - 3.6	40A
	5	4.75 - 5.5	4.75 - 5.0V: 40A 5.0 - 5.5V: Linearly derate from 40 to 36A
	8	7 – 9	7 - 8V: 22.5A 8 - 9V: Linearly derate from 22.5 to 20A
	12	12 - 15.5	12 - 12.5V: 19.5A 12.5 - 15.5V: Linearly derate from 19.5 to 15A
	24	24 - 28	24V: 10A 24 - 28V: Linearly derate from 10 to 8A
BH	12	12 - 15.5	12 - 12.5V: 20A 12.5 - 15.5V: Linearly derate from 20 to 15.5A
	24	24 – 28	24V: 10A 24 - 28V: Linearly derate from 10 to 8.5A

C & CM † above 12V	12	12 - 13.2	12V: 37.5A. Derated to 450W
above 16V	16	15 - 17.6	15 - 16V: 28.12A. Derated to 450W
above 24V	24	24 - 26.4	24V: 18.75A. Derated to 450W
above 27V	30	27 - 32	27V: 16.67A. Derated to 450W

† C & CM modules may output up to 600W for up to 10 seconds providing that the average power from the module does not exceed 450W.
Dual Output Modules:
Dual Output Modules, Output 1

Module	Nominal Voltage (V)	Voltage Range (V) #	Max. Current
DA	12	12.25	3A
DB	3.3	3.135 - 3.6	25A
	5	4.75 - 5.5	25A
	6 ‡	5.5 - 6.5	25A
	12	12 - 15.5	12 - 12.5V: 13A 12.5 - 15.5V: Linearly derate from 13 to 10A
	24	24 - 28	24 - 25V: 7A 25 - 28V: Linearly derate from 7 to 6A

Dual Output Modules, Output 2

Module	Nominal Voltage (V)	Voltage Range (V) #	Max. Current(A)	Max. Power(W)
DA	12	(-)11.6 - (-)11.9	1	11.9
DB	5	3.3 - 6	10	60
	12	7 - 15.5	5	60
	24	24 - 32	2	50

Voltage measured at the module power terminals. This voltage must not be exceeded when remote sense
is used.
‡ DB modules with 6V nominal channel 1 derated as follows:
Ch.1 : 5.5 - 6V Ch.1 + Ch.2 : 195W total.
Ch.1 : 6.01 - 6.5V Ch.1 + Ch.2 : 170W total.
The DB module may be used with output 1 up to 24V at 8.3A and output 2 up to 16V at 3.13A provided the ambient temperature does not exceed 42°C.

SELV and Outputs Connected In Series:
All individual outputs are SELV. Outputs connected in series are non-SELV if the total output voltage + 30% of the highest of those outputs exceeds 60Vdc (the 30% addition allows for a single fault in any one individual channel).
If the total voltage of outputs connected in series exceeds the 60Vdc SELV limit then all outputs must be considered non-SELV.
The total voltage of outputs connected in series must not exceed 160V.
Non-SELV outputs are hazardous and must be guarded or a deflector fitted during installation to avoid a service engineer making inadvertent contact with the output terminals, or dropping a tool onto them.
All outputs have operational spacings to earth, and due consideration must be given to this in the end product design.

Additional Information

Customer Air Cooling:
The following method must be used for determining the safe operation of PSUs when C or U options (Customer Air) are fitted, i.e. fan not fitted to PSU. The minimum permitted airflow for customer air cooling is 0.5m/s.
For PSUs and assemblies cooled by customer supplied airflow the components listed in the following table must not exceed the temperatures given. Additionally ratings specified for units with an internal fan shall still be complied with, e.g. mains input voltage range, maximum output power, module voltage / current ratings and maximum ambient temperature. To determine the component temperatures the heating tests shall be conducted in accordance with the requirements of IEC60601-1. Consideration should also be given to the requirements of other safety standards.
Test requirements include: PSU/assembly to be fitted in its end-use equipment and operated under the most adverse conditions permitted in the end-use equipment Instruction manual/specification and which will result in the highest temperatures in the PSU/assembly. To determine the most adverse conditions consideration shall be given to the end use equipment maximum operating ambient, the PSU/assembly loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers, etc.
Temperatures shall 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 shall be run until all temperatures have stabilised.

Circuit Ref.	Description	Max Temperature (°C)
L2, L3	Filter/PFC assy: Choke winding	155
C1, C3, C4	Filter/PFC assy: X capacitors	100
L1	Filter/PFC assy: Boost choke winding	130
C12, C13	Filter/PFC assy: Electrolytic capacitor	105
T1	Filter/PFC assy: Flyback transformer winding	130
RL1	Filter/PFC assy: Relay	100
TX1, TX2	Modules: Power transformer windings	130
L1, XL1	B, BH & DB module chokes	125
L1 C & CM	module chokes	140
T2	Global Options: Transformer winding	130
Various	All other choke & transformer windings	110
Various	All <=10mm diameter electrolytic capacitors	105
Various	All 12.5mm diameter electrolytic capacitors	105

The schematics are kept in file at the CBTL and can be provided by the manufacturer upon request by NCB's/CBTL's.

These power supplies have been previously evaluated by UL to Edition 3 IEC 60601-1: 2005, EN60601-1:2006, ANSI/AAMI ES60601-1: 2005, CAN/CSA C22.2 No. 60601-1: 2008 based on the previous Edition 2 IEC 60601-1:1988 + A1:1991 + A2:1995, EN 60601-1: 1990 + A1:1993 + A2:1995, 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), report reference E349607-D1-CB-1 (CB Test Certificate Ref. No. DK-5230 dated 29-NOV-2011 was prepared by UL International Demko A/S).
CB Test certificates for components are included in Licenses Enclosure. In accordance with the current rules of CB Scheme, CB Test certificate is effective for 3 years. Recognizing NCB may challenge the CBTC when certificates are more than 3 years old.
When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

Technical Considerations

- The product was investigated to the following standards:

Main Standard(s):

IEC 60601-1:2005, AMD1:2012, AMD2:2020

From Country Differences:

- United States of America: AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021
- Canada: CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14

Additional Standards:

EN 60601-1:2006 /A2:2021; ANSI/AAMI ES60601-1: 2005/A2: 2021;
CAN/CSA C22.2 No. 60601-1:14 AMD2: 2022

- The following additional investigations were conducted: N/A
- 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: N/A
- Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:
  Clause 7.5 (Safety Signs),
  Clause 7.9 (Accompanying Documents),
  Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
  Clause 10 (Radiation),
  Clause 14 (PEMS),
  Clause 16 (ME Systems)
  Risk Management was excluded from this investigation
  - The degree of protection against harmful ingress of water is: Ordinary
  - The product is suitable for use in the presence of a flammable anaesthetics mixture with air or oxygen or with nitrous oxide: No
  - The product is classified only to the following hazards: shock, fire, casualty
  - Product evaluated for an operating temperature of 50°C (full load), to 65°C maximum
  - The product has been assessed for an altitude of 5000 m.
  - Multilayer PWBs 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

When installed in an end-product, consideration must be given to the following:

When installed in an end-product, consideration must be given to the following:

- For use only in or with complete equipment where the acceptability of the combination is determined by

Underwriters Laboratories Inc.
- 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)
- Considerations to the applied part requirement, to be conducted as part of the end-product evaluation.
- The input/output connectors are not acceptable for field connections; they are only intended for factory wiring inside the end-use product
- The component shall be installed in compliance with the enclosure, mounting, marking, spacing and separation requirements of the end use application. Temperature, leakage current, protective earthing, dielectric voltage withstand and interruption of power supply tests should be considered as part of the end product evaluation.
- Proper bonding to the end-product main protective earthing 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 model configuration and output details for models and conditions to which the extended ambient applies).
- The products were tested on a 16 A (20 A for North America and Canada) branch circuit.
- The end-product evaluation shall 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.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture and dielectric strength
- Insulation (separation) between primary - secondary output circuits: 2 MOOPs
- Insulation (separation) between primary to earth: 1 MOPP
- Insulation (separation) between secondary circuits and earth: 1 MOPP (at working voltage) for CM module and 1 MOOP for all other modules.
- Insulation (separation) between input and output for CM modules: 2 MOPPs at 4000 m only
- 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).
- Consideration should be given to repeating the earth leakage tests in the end use equipment.
- 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 Instruction manual
- It should be noted that the power supplies have been assessed as a component part of end equipment. It is the installer's responsibility to ensure that the final installation is in accordance with the NV700 Instruction manual and that it is in compliance with the 60601-1 standards.
- 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.
- These power supplies have been assessed as a component part of a host equipment.
- This product must be earthed (class I).

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2025-02-17	This Test Report is a reissue of CB Test Report E349607-D1041-CB dated 2024-12-10 with CB Test Certificate DK-160971-UL dated 2024-12-11 , with the following changes: 1. Upgrade standard to IEC/UL/CSA 60601-1 Edition 3.2 2. Correct Typo in Insulation Table from MOOP to MOPP for below locations	Steve Chiu

	- Location B 'DA module TX1 pins to earth' - Location B 'Bridge Heatsink to Earth pad' - Location B 'C14 track To Earth pad' - Location E 'C, CM modules TX2 primary leadouts to secondary winding via core' - Location F 'CM module across capacitor C6 (negative output to earth with positive output earthed' 3. Add Japan National Deviation in report Enclosure. 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 and no tests were considered necessary	