

Underwriters Laboratories (UL LLC) Safety Report



Model: NV350 or NV3 or NV-350, followed by abcde

(may be prefixed by NS - # / or - where # may be up to any four letters and may be followed by - \$; where \$ maybe any number between 000 to 999, indicating non-safety related model differences. Units may be additionally marked with a product code: K3x or Q3x where x may be any number of characters).

(Where:-
a = Airflow option (which can be S, R, Q, P, V, C, T, U, K or L),
b = Input option (which can be S or I),
c = Leakage option (which can be S, M, L, R or T) optionally followed by
d = Global option (which can be EN#V, EN12V, EN13.5V, IN#V, IN12V, IN13.5V, ES#V, ES12V, ES13.5V, IS#V, IS12V or IS13.5V) # represents the standby output voltage and is in the range 5 to 5.5V.
e = modules)

K300yy#
(where yy can be 45x, 52x, which x is for revision changes not affecting safety. Where # can be any letter denoting non-safety related changes, e.g. extra labels on the unit and x is for revision changes not affecting safety.)

See report Model Differences for details.

Device Description: Medical 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,
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Report No.: E349607-D1038-1/A0/C0-ULCB

Report (Re)Issue Date: 2024-09-12

Base Standard(s): 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, AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, IEC60601-1:2005+A1:2012+A2:2020

Additional Standards: JIS T 0601-1:2023

Report Types: This report consists of the following report types:

- [Yes] US Certification (UL Recognition)
- [Yes] CAN Certification (cUL Recognition)
- [Yes] CB Report & Certificate
- [No] IEC/EN Informative Report

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.

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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
2024-09-12	<p>This report is based on the original report with amendments CBTR Ref. No.E349607-D1004-1/A2/C0, CBTC Ref. No.DK-70954-M2-UL, issued on 2024-07-26. It was modified to include the following:</p> <ol style="list-style-type: none"> 1. Standards upgraded to 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, IEC 60601-1:2005, AMD1:2012, AMD2:2020 2. TRF updated due to the standard upgrade. 3. Test Tables updated due to the standard upgrade. 4. Japan national differences TRF added in the Enclosure section. 5. Updated instruction manual with minor changes. <p>No testing was conducted under this report. All required tests were carried out under the original investigation. The test sample received dates and the test dates are from the original report. Per the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, it has been determined that the product continues to comply with the standard.</p>	Maggie Chiu



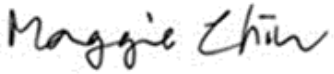
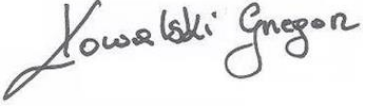
Test Report issued under the responsibility of:



IEC 60601-1	
Medical electrical equipment	
Part 1: General requirements for basic safety and essential performance	
Report Number	E349607-D1038-1/A0/C0-ULCB
Date of issue	2024-09-12
Total number of pages	234
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
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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:	Medical Switch Mode Power Supply
Trade Mark(s)	TDK Lambda
Manufacturer	Same as Applicant
Model/Type reference:	NV350 or NV3 or NV-350, followed by abcde (may be prefixed by NS - # / or - where # may be up to any four letters and may be followed by - \$; where \$ maybe any number between 000 to 999, indicating non-safety related model differences. Units may be additionally marked with a product code: K3x or Q3x where x may be any number of characters). (Where:- a = Airflow option (which can be S, R, Q, P, V, C, T, U, K or L), b = Input option (which can be S or I), c = Leakage option (which can be S, M, L, R or T) optionally followed by d = Global option (which can be EN#V, EN12V, EN13.5V, IN#V, IN12V, IN13.5V, ES#V, ES12V, ES13.5V, IS#V, IS12V or IS13.5V) # represents the standby output voltage and is in the range 5 to 5.5V. e = modules) K300yy# (where yy can be 45x, 52x, which x is for revision changes not affecting safety. Where # can be any letter denoting non-safety related changes, e.g. extra labels on the unit and x is for revision changes not affecting safety.) See report Model Differences for details.
Ratings:	100-240Vac nominal (85-264V max. tolerance), 47-63Hz, 5.5A (See model differences)

Responsible Testing Laboratory (as applicable), testing procedure and testing location(s):

<input checked="" type="checkbox"/>	CB Testing Laboratory:	
	Testing location/ address	UL International Demko A/S Borupvang 5A, 2750 Ballerup, Denmark
	Tested by (name, function, signature)	Maggie Chiu (Project Handler) 
	Approved by (name, function, signature) ..	Grzegorz Kowalski, Reviewer 
<input type="checkbox"/>	Testing procedure: CTF Stage 1:	
	Testing location/ address	
	Tested by (name, function, signature)	
	Approved by (name, function, signature) ..	

<input type="checkbox"/>	Testing procedure: CTF Stage 2:	
Testing location/ address :		
Tested by (name, function, signature) :		
Witnessed by (name, function, signature) .. :		
Approved by (name, function, signature) .. :		
<input checked="" type="checkbox"/>	Testing procedure: CTF Stage 3:	
<input type="checkbox"/>	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 original test report for signatures.
Witnessed by (name, function, signature) .. :		N/A See original test report for signatures.
Approved by (name, function, signature) .. :		Grzegorz Kowalski, Reviewer See original test report for signatures.
Supervised by (name, function, signature) :		Maggie Chiu, Project Handler See original test report for signatures.

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):**

Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.

Testing location:

Refer to the Test List in Appendix D 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, 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: Supply Connection: Device type (component/sub-assembly/ equipment/ system): Intended use (Including type of patient, application location): Mode of Operation: Accessories and detachable parts included: Other Options Include: Supply Connection	For building-in Units configured with an appliance inlet are suitable for connection to the mains supply via an appliance coupler; Units configured with a mains terminal block to be supplied by the host equipment (upon installation) Component To provide DC power for electronic circuits within medical equipment. Continuous None None Units configured with an appliance inlet are suitable for connection to the mains supply via an appliance coupler; Units configured with a mains terminal block to be supplied by the host equipment (upon installation)
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.
- means of Operator protection	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection	MOPP
Testing.....	
Date of receipt of test item	2014-05-19 to 2014-10-07, N/A (A1), 2019-09-04, 2024-04-02, 2024-05-23 (A2)
Date(s) of performance of tests	2014-05-20 to 2014-10-07, N/A (A1), 2024-04-08 to 2024-04-15 (A2)
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 <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60060-1:	
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 Sheng, 214028 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 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

Unit Configuration Code:

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

(may be prefixed by NS - # / or - where # may be up to any four letters and may be followed by - \$; where \$ maybe any number between 000 to 999, indicating non-safety related model differences)

Unit Configuration Code (Description :) may be prefixed by SP followed by / or – (SP represents a sales code). Units may be additionally marked with a product code: K3x or Q3x where x may be any number of characters).

Where a = S, R, Q, P, V, C, T, U, K or L 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
L	Fixed speed fan (see non-standards below)

Where b = S or I where:

Option Letter	Input Option
S	Screw input terminals
I	IEC input

Where c = S, M, L, R, or T, where:

Option Letter	Leakage Option
S	Standard Leakage (Class B 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.

Optionally followed by d = EN#V, EN12V, EN13.5V, IN#V, IN12V, IN13.5V, ES#V, ES12V, ES13.5V, IS#V, IS12V or IS13.5V. Where:

Description	Option Description
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 of 12-13.5V.

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 ES1 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 ES1.

Where e = NV350 or NV3 or NV-350 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 (/ can be replaced with a _)

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 (/ can be replaced with a _)

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 (/ can be replaced with a _)

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.

Note.

For all outputs connected in series:

Series modules are non-standard units.

Refer to the Instruction Manual for Energy Source Classification of series modules.

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.

Note: Series connection of one NV350 unit to another NV350 unit is not permitted.

Custom Models:

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.

Model: NV350 TSS 24B 15BH 5/15DB (K30052X, where X can be any character)

Maximum outputs: 350W max.

Comments: PSU has top fan fitted.

ELECTRICAL & THERMAL RATINGS:

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	Slots	Maximum Average Current According to Slot Position (A)				
			Slot 1	Slot 2	Slot 3	Slot 4	Slot 5
B	3.14-3.6V	2	40	-	40	40	40
	4.75-5.5V	2	40*	-	40*	40*	40*
	7-9V	2	2.5**	-	22.5**	22.5**	22.5**
	12-15.5V	2	16***	-	16***	16***	16***
	24-28V	2	8****	-	8****	8****	8****
BH	12-15.5V	2	20#	-	20#	20#	20#
	24-28V	2	10##	-	10##	10##	10##
C	12-13.2V	3	33.34†	-	33.34†	33.34†	-
	15-16.5V	3	26.67†	-	26.67†	26.67†	-
	24-26.4V	3	16.67†	-	16.67†	16.67†	-
	27-32V	3	14.82††	-	14.82††	14.82††	-
CM	12-13.2V	3	-	33.34†††	33.34†††	33.34†††	-
	15-16.5V	3	-	26.67†††	26.67†††	26.67†††	-
	24-26.4V	3	-	16.67†††	16.67†††	16.67†††	-
	27-32V	3	-	14.82†††	14.82†††	14.82†††	-
DA CH1	11.88-12.25V	1	-	-	-	-	3¥
	11.9 to -						
DA CH2	11.6V	1	-	-	-	-	1¥¥
DB	3.14-3.6V	2	25	-	25	25	25
CH1	4.75-5.5V	2	25	-	25	25	25
	5.5-6.5V††††	2	25	-	25	25	25
	12-15.5V	2	13¥¥¥	-	13¥¥¥	13¥¥¥	
13¥¥¥	24-28V	2	7¥¥¥¥	-	7¥¥¥¥	7¥¥¥¥	
7¥¥¥¥							
DB	3.3-6V‡	2	10	-	10	10	10
CH2	7-15.5V	2	5	-	5	5	5
	24-32V	2	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.

†††† - See Table below

DB modules with 6V nominal, Output Channel1

Cooling options C, S, T & V O/P 1 : 5.5 - 6V O/P 1 + O/P 2 : 195W total.

O/P 1 : 6 - 6.5V O/P 1 + O/P 2 : Linearly derate from 195 to 170W total.

Cooling option Q

O/P 1 : 5.5 - 6V O/P 1 + O/P 2 : 180W total.

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.

¥¥¥ <||||> - 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
S, V	Forward airflow, standard fan (fixed speed & temp. controlled)	115 - 264	450W continuous (510W peak if 450W average #)	65 2.5% per °C above 50°C
S, V, T	Forward airflow, standard fan (fixed speed & temp. controlled)	180 - 264	664W continuous (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	90 - 264 ‡	350 W continuous (no peak rating)	65 2.5% per °C above 50°C
T	Top fan for model K30052x only	90 - 264 ‡	350 W continuous (no peak rating)	65 2.5% per °C above 50°C
P	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).

Additional Information

The following tests were selected as representative of the test program applicable to model covered by this CBTR:

4.11 POWER INPUT 8.4.3 VOLTAGE OR CHARGE LIMITATION 8.7.4.6 TOUCH LEAKAGE CURRENT
8.8.3 DIELECTRIC VOLTAGE WITHSTAND 11 TEMPERATURE 13 ABNORMAL OPERATION TESTING
15.3.2 ENCLOSURE FORCE

These tests have been witnessed for models selected as representative of the standard covered by this report and the applicable test program.

Technical Considerations

- The product was investigated to the following standards:

Main Standard(s):

IEC60601-1:2005+A1:2012+A2:2020

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:

JIS T 0601-1:2023

- 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), Risk management Evaluation
- The following accessories were investigated for use with the product:
- 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 section.

Engineering Conditions of Acceptability

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 intermittent 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 re-considered.

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 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.

Patient Circuit Dielectric Voltage Withstand production line testing was not conducted. This should be considered as part of the end product evaluation.

Report Modifications

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By
2024-09-12	<p>This report is based on the original report with amendments CBTR Ref. No.E349607-D1004-1/A2/C0, CBTC Ref. No.DK-70954-M2-UL, issued on 2024-07-26. It was modified to include the following:</p> <ol style="list-style-type: none"> 1. Standards upgraded to 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, IEC 60601-1:2005, AMD1:2012, AMD2:2020 2. TRF updated due to the standard upgrade. 3. Test Tables updated due to the standard upgrade. 4. Japan national differences TRF added in the Enclosure section. 5. Updated instruction manual with minor changes. <p>No testing was conducted under this report. All required tests were carried out under the original investigation. The test sample received dates and the test dates are from the original report. Per the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, it has been determined that the product continues to comply with the standard.</p>	Maggie Chiu