



Test Report issued under the responsibility of:



IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

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CB Testing Laboratory: UL International Polska Sp. z o.o.

Address: UL International Polska Sp. z o.o. Aleja Krakowska 81 05-090
Sekocin Nowy Warszawy POLAND

Applicant's name: TDK-LAMBDA UK LTD

Address: KINGSLEY AVE
ILFRACOMBE, DEVON EX34 8ES UNITED KINGDOM

Test specification:

Standard: IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007
+ A1:2012
(or IEC 60601-1: 2012 reprint)

Test procedure: CB Scheme

Non-standard test method.....: N/A

Test Report Form No.....: IEC60601_1K

Test Report Form Originator: UL(US)

Master TRF: 2015-11

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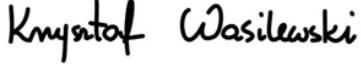

This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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 CB testing laboratory. 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:	TDK Lambda	
Manufacturer:	Same as Applicant	
Model/Type reference:	NV350, NV-350, NF350, NV350FEP, NF3, and NV3 Series (See model differences)	
Ratings:	100-240Vac nominal (85-264V max. tolerance), 47-63Hz, 5.5A (See model differences)	
Testing procedure and testing location:		
<input checked="" type="checkbox"/> CB Testing Laboratory:		
Testing location/ address:	UL International Polska Sp. z o.o. UL International Polska Sp. z o.o. Aleja Krakowska 81 05-090 Sekocin Nowy Warszawy POLAND	
<input type="checkbox"/> Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name, function, signature):	Hubert Koszewski (Project Handler)	
Approved by (name, function, signature):	Krzysztof Wasilewski (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):		
Testing procedure: CTF Stage 3:		
Testing procedure: CTF Stage 4:		
Testing location/ address:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON	

	EX34 8ES UNITED KINGDOM	
Tested by (name, function, signature):	Nick S. Marsh, Steve Hirstwood, Testers	
Witnessed by (name, function, signature):		
Approved by (name, function, signature):	Krzysztof Wasilewski (Reviewer)	
Supervised by (name, function, signature):	Hubert Koszewski (Project Handler)	

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 D of this report if testing was performed as part of this evaluation.

Summary of compliance with National Differences

List of countries addressed: Austria, Korea, Republic of, USA, Canada, United Kingdom, Sweden

[X] The product fulfils the requirements of IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012

(or IEC 60601-1: 2012 reprint).

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.

GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of Installation and Use:	For building-in
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location):	To provide DC power for electronic circuits within medical equipment.
Mode of Operation:	Continuous
Supply Connection:	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)
Accessories and detachable parts included:	None
Other Options Include:	None
Testing	
Date of receipt of test item(s)	2014-05-19 to 2014-10-07
Dates tests performed	2014-05-20 to 2014-10-07
Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement.....	Pass (P)
- test object was not evaluated for the requirement	N/E
- test object does not meet the requirement.....	Fail (F)
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
General remarks:	
<p>Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "J" of TRF for IEC for 60601-1 3rd edition with Amendment 1.</p> <p>"(See Attachment #)" refers to additional information appended to the report.</p> <p>"(See appended table)" refers to a table appended to the report.</p> <p>The tests results presented in this report relate only to the object tested.</p> <p>This report shall not be reproduced except in full without the written approval of the testing laboratory.</p> <p>List of test equipment must be kept on file and available for review.</p> <p>Additional test data and/or information provided in the attachments to this report.</p>	
Throughout this report a point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1:2012	
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

GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.
 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

Series NV3 is identical to the NV350 and NV-350.

Series NV350FEP and NF3 are identical to the NF350.

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

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

Unit Configuration Code:

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

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

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

followed by: S, J or I, where:

Option Letter	Input Option
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S Screw input terminals
 I IEC input
 J IEC dual fused input

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

Option Letter	Global Option
EN#V	AC good, global module good, PSU enable, 5-5.5V, 2A standby output
EN12V	AC good, global module good, PSU enable, 12V, 1A standby output
EN13.5V	AC good, global module good, PSU enable, 13.5V, 1A standby output
IN#V	AC good, global module good, PSU inhibit, 5-5.5V, 2A standby output
IN12V	AC good, global module good, PSU inhibit, 12V, 1A standby output
IN13.5V	AC good, global module good, PSU inhibit, 13.5V, 1A standby output
ES#V	AC good, PSU enable, 5-5.5V, 2A standby output
ES12V	AC good, PSU enable, 12V, 1A standby output
ES13.5V	AC good, PSU enable, 13.5V, 1A standby output
IS#V	AC good, PSU inhibit, 5-5.5V, 2A standby output
IS12V	AC good, PSU inhibit, 12V, 1A standby output
IS13.5V	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.

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 (A)	Output Voltage	Occupied Slots		Maximum Average Current According to Slot Position			
		Slot 1	Slot 2	Slot 3	Slot 4	Slot 5	Slot 6
B	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.

†††† - 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,	180 - 264	664W continuous	65	2.5% per °C

	standard fan (fixed speed & temp. controlled)		(740W peak if 600W average #)		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).

NV350 FEP or NF3 or NV-350FEP (these models are identical)

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

S = Forward airflow, standard fan
R = Reverse airflow, standard fan
C = Customer air, fan not fitted

followed by: S or I, where:

S = Screw input terminals
I = 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:

ES5V = AC good, PSU enable, 5-5.5V, 2A standby output
ES12V = AC good, PSU enable, 12-13.5V, 1A standby output
IS5V = AC good, PSU inhibit, 5-5.5V, 2A standby output
IS12V = AC good, PSU inhibit, 12-13.5V, 1A standby output

where # represents the standby output voltage.

The Global Options Inhibit and Enable functions permit the customer to turn off or on the main psu outputs and the fan. The standby supply is for use by the customer and provides an SELV output that continues to operate when all the main psu outputs have been turned off using the Inhibit or Enable functions. All the functions of the Global Option pass through a single 8 way PWB socket and are all rated SELV.

Followed by @FE

where @ is the output voltage of the module and is within the range given in the FE module table as follows:

NV350 FEP Module:

FE Module, Output 1

Nominal Voltage (V)	Voltage Range (V) #	Max. Current (A)	Max. Power (W)
12	11.5 - 13.2	29.2	350*

FE Module, Output 2

Nominal Voltage (V)	Voltage Range (V)	Max. Current (A)	Max. Power (W)
12	Fixed 12V	2	24.2*

* - Total Output Power must not exceed 350W.

Voltage measured at the module power terminals must not exceed the value shown in the table when remote sense is used. For 50°C max. ambient operation: 11.5 - 12.5V 350W total power. From 12.5 - 13.2V: Linearly derate total power from 350 to 306W. For 350W total output power (O/P 1 + O/P 2) : 11.5 - 12.5V: 50°C max. ambient. From 12.5 - 13.2V: Linearly derate max. ambient from 50 to 45°C

Cooling Options

COOLING OPTION	TOTAL POWER
S (FORWARD AIRFLOW)	350W
R (REVERSE AIRFLOW)	350W
C (CUSTOMER AIR)	350W

The above ratings apply for ambient temperatures up to 50°C. From 50 to 65°C the total output power and the module current ratings are both derated at 2.5% per °C.

Global Option standby outputs (12V at 1A or 5V at 2A) should not be included when calculating total PSU output power, but they are subject to the output current deratings for operation above 50°C.

5V global options are derated to 1.8A max. when the psu is inhibited

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 Parameters

Max Output Power is 350W up to 50°C. Above 50°C, derate by 2.5%/°C.

Output Voltage - 375V +/- 20V

Fan Output - 12V nom at 0.25A max

Additional Information

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

Project 4787707401 information:

This report is a reissue of CBTR ref No: E349607-A14-CB-2 dated 2015-01-13 including CB Test Certificate Ref. No. DK-42958-UL dated: 2015-01-13. Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard. No testing was deemed necessary.

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

- Standard updated to the latest edition.
- model NV-350 added
- Alternate Y1 capacitors (C5, C6, C7) added to the critical components list. Their licences added to the enclosures.
- CBTL changed to UL International Polska.

This report, to include IEC60601-1-1 amendment 1: 2013, is a re-issue of CBTR ref No: E349607-A14-CB-1, dated: 2012-02-01 including CB Test Certificate Ref. No. DK-5964-M1 dated: 2012-02-02. Based on the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard. Only the tests listed below was deemed necessary.

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

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

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

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

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

L option added to nomenclature for fixed speed fan (Non-standard only)

Alternative fuse testing (not mains input fuse)

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

Alternative/second source fan testing

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

Model: NV3 KISE5V 12/12DB 5B (X00004#) should have been : NV3 KISES5V 12/12DB 5B (X00004#)

Removed Avnet and Arrow from the manufacturers list.

Updated handbook

Addition/deletion of multilayer PWBs to critical component list

Correction/addition to the critical component list

Updated licenses

Updated drawings

Technical Considerations

- The product was investigated to the following standards:

Main Standard(s):

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CAN/CSA C22.2 No. 60601-1:14, IEC 60601-1 :2005 +A1 :2012

From Country Differences:

- Austria: EN 60601-1:2006/A1:2013
- Korea, Republic of: KS C IEC 60601-1
- USA: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
- United Kingdom: BS EN 60601:2006 A1
- Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

Additional Standards:

EN 60601-1: 2006 + CORR: 2010 + Amd 1, 2013 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance); CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)

- The following additional investigations were conducted:
- EN 60601-1: 2006 + CORR: 2010 + A1: 2013 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)
- CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada)
- ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)
- The 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:

- 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
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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 t to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1).

End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.

End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.

End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.

End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.

End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.

End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply

The PSU may output the given peak power for up to 10 seconds. When installed in an end product it shall ensure that the average power from the PSU does not exceed the stated value.

Repeat of leakage current testing and consideration of non-frequency weighted leakage test (Clause 8.7.3e) shall be considered in the end product application.

Report Modifications

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By
2018-02-07	This report is a reissue of CBTR ref No: E349607-A14-CB-2 dated 2015-01-13 including CB Test Certificate Ref. No. DK-42958-UL dated: 2015-01-13. Based on the previously	Hubert Koszewski

	<p>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. No testing was deemed necessary. The original report was modified to include the following changes/additions:</p> <ul style="list-style-type: none">- Standard updated to the latest edition.- model NV-350 added- Alternate Y1 capacitors (C5, C6, C7) added to the critical components list. Their licences added to the enclosures.- CBTL changed to UL International Polska.	