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Report Reference #

E349607-A3-CB-1

IEC IECEE

Test Report issued under the responsibility of:



TEST REPORT IEC 60601-1 Medical Electrical Equipment Part 1:General requirements for safety				
Report Reference No	E349607-A3-CB-1			
Date of issue	2011-11-29			
Total number of pages:	23			
CB Testing Laboratory	UL International Germany GmbH			
Address:	Admiral-Rosendahl-Strasse 23, 63263 Neu-Isenburg (Zeppelinheim), Germany			
Applicant's name	TDK-LAMBDA UK LTD			
KINGSLEY AVE Addressi ILFRACOMBE				
DEVON				
	EX34 8ES UNITED KINGDOM			
Test specification:				
Standard:	IEC 60601-1:1988 + A1:1991 + A2:1995			
Test procedure:	CB Scheme			
Non-standard test method: N/A				
Test Report Form No.	IEC60601_1c/97-04			
Test Report Form originator:	UL LLC			
Master TRF	dated 97-04			
Convight @ 2008 IEC System for Conformity Testing and Cartification of Electrical Equipment				

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Test item description	Switch mode Power Supplies
Trade Mark:	TDK-Lambda
Manufacturer:	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Model/Type reference:	Series: Alpha 800, Alpha 800W. Models: CA800 (followed by various letters and numbers as defined in the model differences) Series: Alpha 1000, Alpha 1000W. Models: CA1000 (followed by various letters and numbers as defined in the model differences), CA1250 12C_MF_PP 12F_PP 12F_PP 12F_PP, CA1250 12C_MF 12FF 12FF 12FF
Ratings:	94.5 Vac to 240 Vac, (85-264Vac max. tolerance), 16A, 47-63 Hz Class I

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Testin	g procedure and testing location:		
[]	CB Testing Laboratory		
	Testing location / address::		
[]	Associated CB Test Laboratory		
	Testing location / address::		
	Tested by (name + signature) :		
	Approved by (name + signature):		
[]	Testing Procedure: TMP/CTF Stage	•	
	Tested by (name + signature) :		
	Approved by (+ signature):		
	Testing location / address::		
[]	Testing Procedure: WMT/CTF Stage 2		
	Tested by (name + signature) :		
	Witnessed by (+ signature):		
	Approved by (+ signature)		
	Testing location / address:		
[X]	Testing Procedure: SMT/CTF Stage 3 or 4	9	
	Tested by (name + signature) :	N. S. Marsh, S. Hirstwood	the first basterned
	Approved by (+ signature): :	K. P. Tizzard	A. P. W. S.
	Supervised by (+ signature):	Jakub Sobolewski	Jala & Sobole she
	Testing location / address::	TDK-Lambda, Kingsley Avenu United Kingdom.	e, Ilfracombe, EX34 8ES,
[]	Testing Procedure: RMT		
	Tested by (name + signature) :		
	Approved by (+ signature)		
	Supervised by (+ signature):		
	Testing location / address::		

List of Attachments

National Differences (3 pages)

Enclosures (137 pages)

Summary Of Testing

Unless otherwise indicated, all tests were conducted at TDK-Lambda, Kingsley Avenue, Ilfracombe, EX34 8ES, United Kingdom..

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Tests performed (name of test and test clause) Testing location / Comments

Temperature (42)

Abnormal Operation and Fault Conditions (52)

Summary of Compliance with National Differences:

Countries outside the CB Scheme membership may also accept this report.

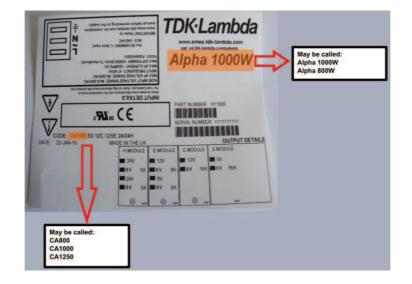
List of countries addressed: AT, AU, BE, BR, CA, CH, CZ, DE, DK, FI, FR, GB, GR, HU, IL, IN, IT, JP, KR, NL, NO, PL, RU, SE, SI, SK, UA, US

The product fulfills the requirements of: 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) EN 60601-1: 1990 + A1:1993 + A2:1995

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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.



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Test item particulars :			
Classification of installation and use		for building-in	
Supply connection		for building-in	
Accessories and detachable parts included in the evaluation		None	
Options included	:	None	
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 does not meet the requirement	:	F(Fail)	
Abbreviations used in the report:			
- normal condition:	N.C.	- single fault condition:	S.F.C.
- operational insulation	OP	- basic insulation:	BI
 basic insulation between parts of opposite polarity: 	BOP	- supplementary insulation:	SI
- double insulation:	DI	- reinforced insulation:	RI
Testing:			
Date(s) of receipt of test item	:	2015-02-04 to 2015-02-17	
Date(s) of Performance of tests	:	2015-02-18 to 2015-02-19	
General remarks:			
List of test equipment must be kept on file and be	availa	able for review.	
"(see Enclosure #)" refers to additional information	n appe	ended to the report.	

Report Reference #

"(see E "(see appended table)" refers to a table appended to the report.

Throughout this report a 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 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

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 MICROTRONIC CO. LTD
	SHIJI INDUSTRIAL ESTATE
	DONGYONG
	NANSHA
	NANSHA
	GUANGZHOU GUANGDONG CHINA

Yes

GENERAL PRODUCT INFORMATION:

Report Summary

The original report was modified on 2015-05-27 to include the following changes/additions: Test report was updated in order to: -add new version of CA1000 power supply with fan Papst 612NGME or 612NME (lower airflow than fans fitted to standard Alpha 800/1000 PSUs), - update of models description. -add PANYU TRIO MICROTRONIC CO LTD factory -remove TRIO ENGINEERING CO LTD factory -change CBTL to UL International Germany GmbH Only limited testing was considered necessery.

Product Description

The subject units are switch mode power supply sub-assemblies incorporating semiconductor components. They are provided with isolating transformers and associated circuitry mounted on printed wiring boards, in addition to input connectors for connection to mating connectors or wiring within the end use equipment.

Model Differences

The Model Alpha 800 and Alpha 1000 Series Power Supplies are nearly electrically and mechanically identical. The difference between the two series relates to the fact that the Alpha 800 Series has a 800 W maximum output and the Alpha 1000 Series has a 1000 W maximum output. CA1250 models are special custom units which are identical to CA1000 except that they have a restricted input voltage range and 1250W output power.

Units may be marked with a Product Code: J1x or H1x for Alpha 1000 and J8 or H8 for Alpha 800, where x may be any number of characters.

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

RATINGS & LIMITATIONS:

Max power & per converter Max. Ampere Turns per conver Max. Ampere Turns (total) Max number of secondary windings per converter Max ambient Maximum operating altitude	erter 12 20 10 50	0		
Input voltage range/ frequency 90-99.9Vac, 47-63Hz 100-264Vac, 47-63Hz 85-264Vac, 47-63Hz 120-360Vdc 85-90Vac, 47-63Hz	Max input Current 16A 16A 16A 11A 16A	Max. ambient 45°C 50°C 50°C 45°C 50°C	Operating mode Continuous Continuous Continuous Intermittent	Max. output power 1000W 1000W 800W 800W 1000W

TRF No.: IEC60601_1C

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Amendme			0 01 23			·	2343007-73-00-1
Ampere T	urns is s	cycle is 30 sec. max a um of (Amperes x Nu verters in the psu: on	mber of Se	condary T	urns) for all outputs.		to 800W output.
and/or out stated.	tput conn	apply for all PSU mo ector housings are fil tion is fitted input vol	ted. Rating	gs apply to	Alpha 800 and 1000	ranges u	
The Alpha	a 800 or (CA800 or Alpha 1000	or CA1000) Series sh	all be followed by: L	L, RL, or ⁻	TL.
Where:							
RL = Red	uced Lea	e Input filter (Compon kage Input filter (Con input filter (Compone	nponents C	101, C106	, C107, C108 = 1nF	max.)	
followed b	by up to s	even of any of the fol	lowing:				
		A, AL, BB, B, CC, C, SS, S, TT, T, UU, U, V			FF, F, GG, G, JJ, J, I	KK, K, LL	, L, MM, M, NN,
or B/S opt	tionally fo	llowed by:					
_MF, _X, _D, _MG		E, MFE, MFU, MFV (or _MFV, M	IFPF, MFT	, _PA, _IN, _PP, _RF	P, RPA, R	PB, RPC, RPD,
@/@ (/ ca	an be rep	placed with a _)follow	/ed by: E, E	EB, EQ, EL	, EH, H, P or PL:		
where:							
@ and @/@= applicable voltage range and the following one or two letters are the module typeMF, MFE= Mains fail option (may also be called X).MFU= Mains fail option with uncommitted output connections.MFV= Mains fail option with VME busMFPF= Mains fail, module parallel, PSU/fan inhibit and 5V, 50mA auxiliary outputMFT= Mains fail, PSU/fan inhibit and 12V, 150mA auxiliary outputMFL, _XL= Mains fail latchB/S= Blanking slot which occupies one 23mm slot.							
	Only up to seven 23 mm slots may be filled up per unit, noting that all modules occupy one 23 mm slot except for AA, A, F, FF, G, J, K, R, S or T modules which occupy two 23 mm slots.						
Valid voltage ranges for @ and @/@ for each module are as follows:							
Module A AA AL BB B	Voltage (V) @4.5 - 6 @4.5 - 7 @4.75 - @4.5 - 7 @4.5 - 6	5.3	Current (A) 60 60 60 25 25	Width (mm) 46 46 46 23 23	Occupied Slots 2 2 2 1 1	Turns 1 1 1 1 1	Ampere Turns 60 60 60 25 25

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C, CC	@5 -	16	16	23	1	2	32	
CL	@4.6	6 - 5.6	16	23	1	2	32	
CM	@5 -		16	23	1	2	32	
CH	@11.	.4 - 13.5	16	23	1	2	32	
D, DD	@18		9	23	1	4	36	
E	@/@	5 - 16 / 5 - 16	8/8	23	1	2/2	16/16	
EL		7 / 11 - 13	8/8	23	1	2/2	16/16	
EH	@11	- 13 / 11 - 13	8/8	23	1	2/2	16/16	
EB	@/@	4.5 - 5.5 / 4.5 - 5.5	9/9	23	1	1/1	9/9	
EQ	@/@	4.5 - 5.5 / 2.7 - 3.9	9/9	23	1	1/1	9/9	
F	@9 -	16	33	46	2	2	66	
FF	@9 -	16	34.5	46	2	2	69	
G, GG	@17.	.5 - 29	25	46	2	4	100	
Н	@/@	18 - 32 / 18 - 32	5/5	23	1	4/4	20/20	
J, JJ	@30	- 48	10	46	2	8	80	
K, KK	@18	- 31	15	35	2	4	60	
L, LL	@1.8	3 - 3.2	25	23	1	1	25	
M, MM	@5 -	16	8	23	1	2	16	
N, NN	@18	- 32	5	23	1	4	20	
Р		18 - 29 / 5 - 16	5/8	23	1	4/2	20/16	
PL	@22	- 26 / 5 - 7	5/8	23	1	4/2	20/16	
Q, QQ	@2.	7 - 3.9	25	23	1	1	25	
R, RR	@2.	7 - 3.9	60	46	2	1	60	
S, SS	@1 -	5.7	85	46	2	1	75	
T, TT	@1.8	3 - 3.2	60	46	2	1	60	
U, UU	@10	- 21	16	23	1	3	48	
W, WW	@4.5	5 - 5.5	15	23	1	1	15	
Z, ZZ	@4.5	5 - 5.7	25	23	1	1	25	
1								

A, AA and AL modules can be used up to 37A in slots 6 and 7 and used up to 60A in all other slots. B and BB modules can be used up to 15A in slot 7 and used up to 25A in all other slots.

(a) C CC, CL, CM & CH modules can be used up to 16A for outputs up to 12V. For 15-16V outputs C

modules can be used at up to 12A. Maximum module output current derates linearly between 12V and 15V. (b) C, CC, CL, CM & CH modules can be used up to 10A in slot 7 and up to 16A in all other slots, subject to the limitations of (a).

D & DD modules can be used at up to 9A at up to 24V in all slots. At greater than 24V D & DD modules can be used at up 8A in all slots.

E, EL & EH modules can be used up to 5A in slot 7 and up to 8A in all other slots.

EQ and EB modules can be used up to 5.6A in slot 7 and up to 9A in all other slots.

F modules can be used up to 20A in slots 6 and 7 and up to 33A in all other slots.

FF modules can be used up to 34.5A in all slots.

G & GG modules can be used up to 15A in slots 6 and 7 and up to 25A in all other slots.

H modules can be used up to 3Å in slot 7 and up to 5Å in all other slots. For 29.01 - 32V output current is limited to 1Å max for all slots.

J & JJ modules can be used up to 6A in slots 6 and 7 (for 30-48V). For all other slots the max. permitted current is limited to 8A at 48V and 10A at 41V. For intermediate voltages interpolation is used to determine the max. permitted current. For outputs in the range

36-41V max. current is 10A.

K & KK modules can be used up to 10A in slot 6/7 and up to 15A in all other slots.

L & LL modules can be used up to 15A in slot 7 and used up to 25A in all other slots.

M & MM modules can be used up to 5A in slot 7 and up to 8A in all other slots.

(a) N & NN modules can be used up to 5A for outputs up to 29V. For 29-32V output current is limited to 1A max.

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(b) N & NN modules can be used up to 3A in slot 7 and up to 5A in all other slots.

P and PL modules can be used up to 5A in the 18-29V channel in slots 1 to 6 and up to 3A in slot 7.

P and PL modules can be used up to 8A in the 5-16V channel in slots 1 to 6 and up to 5A in slot 7.

Q & QQ modules can be used up to 25A in any slot.

R & RR modules can be used up to 60A in any slot.

S & SS modules can be used up to 75A in slots 1/2, 76A in slots 2/3; 51A in slots 6/7 and up to 85A in all other slots. When the psu is operated in a horizontal orientation (with the ratings label uppermost) the S & SS modules may be used up to 85A in slots 2/3.

T & TT modules can be used up to 37A in slot 6 and 7 and used up to 60A in all other slots.

U & UU modules can be used up to 16A in all slots.

W & WW modules can be used up to 15A in all slots.

Z & ZZ modules can be used up to 15A in slot 7 and used up to 25A in all other slots.

Secondary Options:

Option Description

MG Provides a module good signal with indicates output voltage is within limits.

PA Forces paralleled modules to share load current. Additionally it also provides the module good signal.

PΡ Provides either of the following functions:

a) Reduces module current limit and caters for paralleled modules with busbar linking. For use with modules providing a max output of up to 16V only; or

b) Identical to _PA except that the module is paralleled at the output of the module with busbar linking.

Provides an external signal which may be used to inhibit the output of the module. IN

Provides a delay in the turn on time of a module output. Additionally allows an external signal ΕN voltage to enable a module output (output off when no signal applied).

RP Provides remote programming of the module output voltage.

RPA

Provides voltage programming of the module output voltage only.

RPB Provides voltage programming of the module output voltage and has an output VA limiting circuit. RPC Provides an output VA limiting circuit

- RPD Provides voltage programming of the module output voltage and has an output VA limiting circuit.
- D Delay option. Provides a delay in the turn on time of the output.

Note:

The RPA option can only be used on modules with output voltages rated up to 32V.

The RP, RPB, RPC and RPD options can only be used on modules with output voltages rated up to 16V. Not for use with a module voltage range of 18-29V or twin output modules.

Custom Models:

Model: CA1000LSF 5.25B 12.7C 16/16E 24G 18D 18D (NS-FOSS-002) Input: 90 - 264Vac. 47-63Hz Max. Output(s): 6V, 3A; 13.7V, 9A; 16V, 0.5A; 16V, 0.5A; 25V, 25A; 19V, 2.5A; 19V, 2.5A (877.3W) Max. Ambient: 40°C Orientation: Vertical with airflow upwards Cooling: Papst 612 fans. Forward direction airflow. CA1000RA B/S MF 5S PP 5B PP 12F (NS-AMD-001) Input voltage range: 198 - 264Vac.

Outputs: S Module: 5.5V max., 80A max. B Module: 5.5V max., 25A max. F Module: 12.5V max., 33A max.

Page 11 of 23 Report Reference # Amendment 2 2015-05-27 All orientations are permitted. CA1000 B/S MF 24G PP 24D PP 15/15E 5M IN Input voltage range: 90 - 264Vac. Outputs: G Module: 24V max., 20A max. D Module: 24V max., 8A max. E Module: 15/15V max., 8/6A max. N Module: 5V max., 8A max. Permitted orientation: Vertical with the fans lowest. Fans: Papst 612NGM (lower airflow than fans fitted to standard Alpha 800/1000 PSUs). CA1000 LSF B/S_MF 24G 15/15E 5M_IN (NS-TEG-010) Input voltage range: 85 - 264Vac. Outputs: G Module: 24V max., 20A max. E Module: 15/15V max., 4/4A max. M Module: 5V max., 8A max. Permitted orientation: Horizontal Fans: Papst 612NML or 612NGML (lower airflow than fans fitted to standard Alpha 800/1000 PSUs). CA1000 LSF B/S_MF 24G 15/15E 5M_IN 36J (NS-TEG-011) Input voltage range: 85 - 264Vac. Outputs: G Module: 24V max., 18A max. E Module: 15/15V max., 3/3A max. M Module: 5V max., 8A max. J Module: 36V max., 5.5A max. Permitted orientation: Horizontal Fans: Papst 612NML or 612NGML (lower airflow than fans fitted to standard Alpha 800/1000 PSUs). CA1250 12C MF PP 12F PP 12F PP 12F PP (NS-AMD-002) Input voltage range: 207 - 264Vac. Outputs: C Module: 13V max., 16A max. F Module: 13V max., 30A max. F Module: 13V max., 30A max. F Module: 13V max., 30A max. Permitted orientation: All except vertical with airflow downwards. CA1250 12C MF 12FF 12FF 12FF (NS-AMD-005) Input voltage range: 207 - 264Vac. Outputs: C Module: 13V max., 16A max. F Module: 13V max., 30A max. F Module: 13V max., 30A max. F Module: 13V max., 30A max. Permitted orientation: Horizontal only. CA1000 LSFLL 22K IN 12C-IN 48J-IN 24N IN 24N IN (J10077A) Input voltage range: 90 - 264Vac. Outputs: K Module: 22V max., 15A max. C Module: 12V max., 10A max. J Module: 48V max., 5A max. N Module: 24V max., 5A max. N Module: 24V max., 5A max. Permitted orientation: Horizontal only. Max. Ambient: 40°C

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Fans: Papst 612NGME or 612NME (lower airflow than fans fitted to standard Alpha 800/1000 PSUs).

Additional Information

The enclosed label sample represents all Models in the Series.

Technical Considerations

- The product was investigated to the following additional standards: 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) EN 60601-1: 1990 + A1:1993 + A2:1995 This product has been assessed for Class 1, Pollution Degree 2, Material Group IIIB, Overvoltage Category II, Altitude up to 3000 meters, maximum ambient 50 degrees C (higher ambient permitted for specific custom models).
- The product was not investigated to the following standards or clauses: Clause 52.1, Programmable Electronic Systems (IEC 601-1-4), Clause 48, Biocompatibility (ISO 10993-1), Clause 36, Electromagnetic Compatibility (IEC 601-1-2)
- The product is Classified only to the following hazards: Shock, Fire, Casualty
- The mode of operation is: Continuous
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen
 or with nitrous oxide: No
- The primary sub-assembly, including the primary windings of the main barrier transformer, is common to all products in this family. The secondary regulators are built into separate modules. --
- These products have been assessed for Class 1, Pollution Degree 2, Material Group IIIB, Overvoltage Category II, Altitude 3000 metres, maximum ambient 50 degrees C. --
- Testing Environment: An ambient temperature in the range 15 degrees C to 30 degrees C. A relative humidity in the range of 25 % to 75 %. And finally, an air pressure in the range of 86 kPa to 106 kPa.
- Testing was carried out on the basis of 7 slots being filled, each slot being one 23 mm module space wide. This is the maximum number of slots allowed under this approval, and provides the worst case situation. Heating tests were carried out with the maximum number of slots filled, but with numerous loading conditions to cover any condition of loading in any slot position. Also, the models tested under Clause 4.5 represent the least efficient, highest current module configurations. Abnormals were carried out on the expected worse case situation for that abnormal and on as many configurations as considered necessary to represent the entire range of products covered by this approval. For other tests, the conditions and configurations used were the expected worst case. --
- These products were considered to be a component part of Class 1 equipment. Full compliance with
 the standards will therefore depend on the installation in the final application. Some modules could
 present an energy hazard. Additionally, outputs can be connected in series thus producing nonSELV levels, or in parallel thus producing new energy hazards, and this must be taken into account
 in the end-use application. When non-seriesed outputs are earthed in the end use equipment they
 are SELV. If the outputs are not earthed, they must be considered hazardous, as a single fault in the
 secondary may make them exceed SELV limits between output and earth. If any output is non-SELV,
 then all outputs become non-SELV. --

Engineering Conditions of Acceptability

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

- These units are forced-air cooled. They require a minimum of 50 mm clearance in the vicinity of the ventilation holes. Whilst relatively orientation insensitive, operation of these units when mounted vertically with air flow in a downward direction is affected by convection acting against the cooling airflow, and results in slightly hotter temperatures than if operated in the horizontal position. As a consequence of this, heating tests were carried out in the vertical orientation with airflow downwards to give the worst case temperatures, unless otherwise stated. --
- In general, no tests have been conducted on polymeric materials used in the construction of these
 products. Information was provided by the Client with regards to the classification of the polymeric
 materials. Acceptance of these materials is based on these declarations. All critical polymeric
 materials are UL Recognized as indicated in the Critical Components Table and where appropriate,
 have been tested in the application to verify that they are used within their RTI's. --
- This equipment has only been evaluated for Basic Insulation from Primary to Secondary across the main transformer. --
- A fire, electrical and mechanical enclosure is required for this equipment. --
- Leakage current measurements with non-frequency weighted measuring device according to Japanese national differences clause 19.4e shall be performed during end product evaluation. --