



Test Report issued under the responsibility of:



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

Report Number..... : E349607-D8  
 Date of issue ..... : 2015-05-27  
 Total number of pages ..... 152

Name of Testing Laboratory preparing the Report ..... : **UL International Germany GmbH**  
**Admiral-Rosendahl-Strasse 9**  
**63263 Neu-Isenburg (Zeppelinheim), Germany**

Applicant's name ..... : **TDK-Lambda UK Ltd**  
 Address ..... : **Kingsley Avenue, Ilfracombe, Devon, EX34 8ES,**  
**UNITED KINGDOM**

**Test specification:**

Standard ..... : IEC 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1 (2012 reprint)  
 Test procedure..... : CB Scheme  
 Non-standard test method ..... : N/A

Test Report Form No..... : IEC60601\_1J\_PS  
 Test Report Form(s) Originator.... : UL(US)  
 Master TRF ..... : 2014-09

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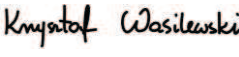

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

**This report is not valid as a CB Test Report unless signed by an approved 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.

<b>Test item description .....</b>	Switch Mode Power Supply	
<b>Trade Mark .....</b>	<b><i>TDK-Lambda</i></b>	
<b>Manufacturer .....</b>	TDK-Lambda UK Ltd Kingsley Avenue Ilfracombe Devon EX34 8ES, United Kingdom	
<b>Model/Type reference.....</b>	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	
<b>Ratings.....</b>	94.5 Vac to 240 Vac, (85-264Vac max. tolerance), 16A, 47-63 Hz, Class I	
<b>Testing procedure and testing location:</b>		
<input type="checkbox"/>	<b>CB Testing Laboratory:</b>	
<b>Testing location/ address .....</b>		
<input type="checkbox"/>	<b>Associated CB Testing Laboratory:</b>	
<b>Testing location/ address .....</b>		
<b>Tested by (name + signature).....</b>		
<b>Approved by (name + signature) .....</b>		
<input type="checkbox"/>	<b>Testing procedure: TMP/CTF Stage 1:</b>	
<b>Testing location/ address .....</b>		
<b>Tested by (name + signature).....</b>		
<b>Approved by (name + signature) .....</b>		
<input type="checkbox"/>	<b>Testing procedure: WMT/CTF Stage 2:</b>	
<b>Testing location/ address .....</b>		
<b>Tested by (name + signature).....</b>		
<b>Witnessed by (name + signature) .....</b>		
<b>Approved by (name + signature) .....</b>		

<input checked="" type="checkbox"/>	<b>Testing procedure: SMT/CTF Stage 3 or 4:</b>	
<b>Testing location/ address .....</b>		TDK-Lambda UK Ltd, Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United Kingdom
<b>Tested by (name + signature).....</b>		N. S. Marsh, S. Hirstwood 
<b>Witnessed by (name + signature) .....</b>		K.P. Tizzard 
<b>Approved by (name + signature) .....</b>		Krzysztof Wasilewski 
<b>Supervised by (name + signature).....</b>		Jakub Sobolewski 

<b>List of Attachments (including a total number of pages in each attachment):</b>	
<b>National Differences (7 pages)</b>	
<b>Enclosures (21 items)</b>	
<b>Summary of testing</b>	
<p>Unless otherwise indicated, all tests were conducted at TDK-Lambda Ltd., Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United kingdom.</p> <p>Report was issued based on E349607-A18-CB-1 (issued: 2012-05-09, amended: 2012-07-18 and 2012-12-07) test report, test certificate no. DK-26096-UL. Only limited testing was considered necessary to meet the requirements of IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 based on standard similarity.</p> <p>Following changes were introduced in comparison to E349607-A18-CB-1 (issued: 2012-05-09, amended: 2012-07-18 and 2012-12-07) test report:</p> <ul style="list-style-type: none"> <li>-addition of new version of CA1000 power supply with fan Papst 612NGME or 612NME (lower airflow than fans fitted to standard Alpha 800/1000 PSUs),</li> <li>-addition of PANYU TRIO MICROTRONIC CO LTD factory</li> <li>-removing TRIO ENGINEERING CO LTD factory</li> <li>-change of CBTL to UL International Germany GmbH</li> </ul>	
<b>Tests performed (name of test and test clause)</b>	<b>Testing location / Comments</b>
Temperature Test (11)	
Abnormal Operation and Single Fault Conditions (13)	

**Summary of compliance with National Differences**

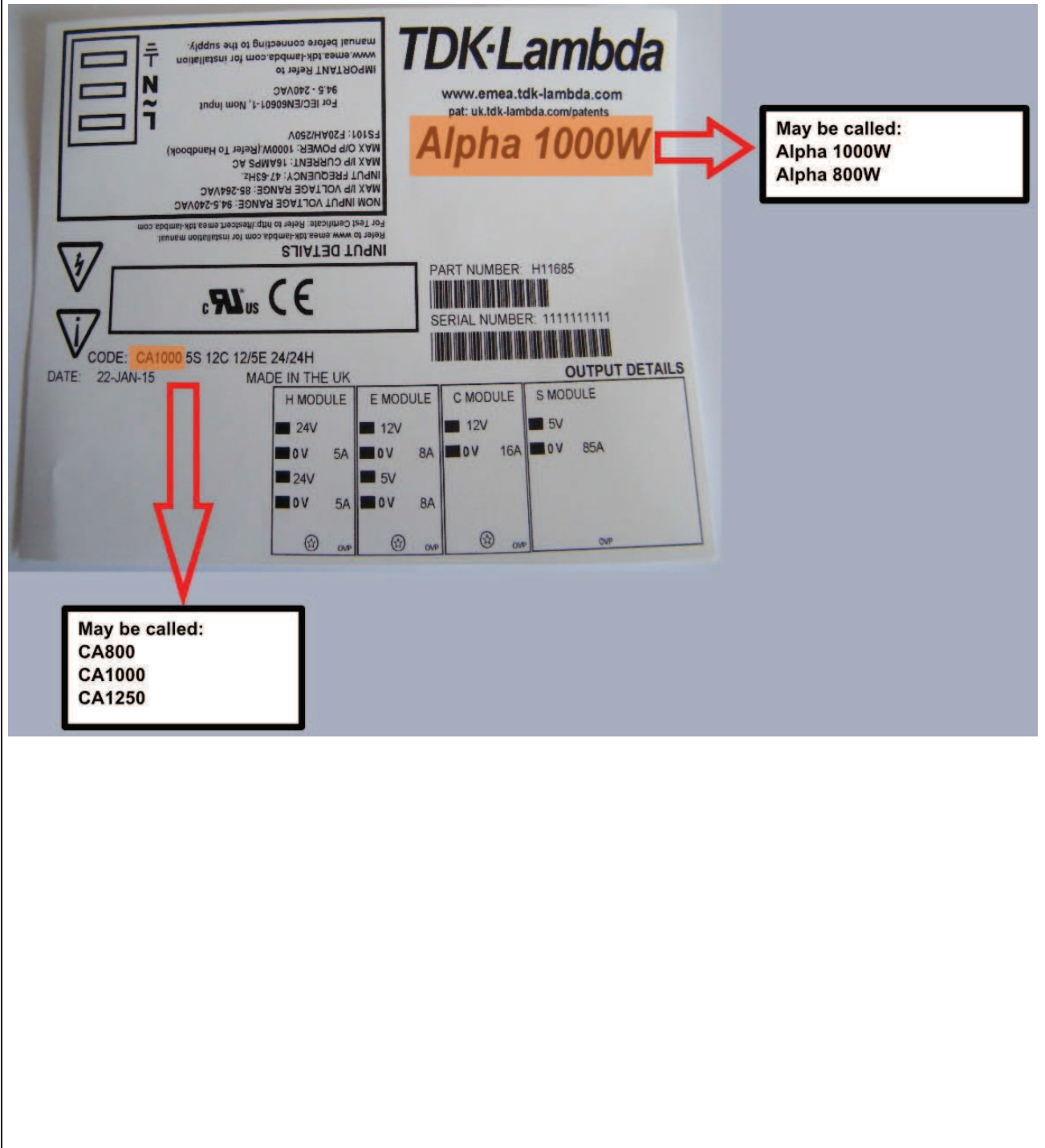
List of countries addressed: AU, KO, US, CAN, UK, SW

The product fulfils the requirements of

- EN 60601-1:2006/A1:2013 (IEC60601-1, Edition 3.1),
- ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012 Medical Electrical Equipment - Part 1 (IEC 60601-1:2005, Mod),
- CAN/CSA-C22.2 NO. 60601-1:14 - Medical electrical equipment - Part 1 (Adopted IEC 60601-1:2005, third edition, 2005-12, incl. Am1:2012, with Canadian deviations), Third Edition

**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.



<b>GENERAL INFORMATION</b>	
<b>Test item particulars (see also Clause 6):</b>	
Classification of installation and use .....	Building in.
Device type (component/sub-assembly/ equipment/ system):	Component switch mode power supply
Intended use (Including type of patient, application location) :	To provide dc power for electronic circuits within medical equipment
Mode of operation .....	Continuous
Supply connection .....	To be determined in the end product
Accessories and detachable parts included .....	None
Other options include .....	None
<b>Testing</b>	
Date of receipt of test item(s) .....	2015-02-04 to 2015-02-17
Dates tests performed .....	2015-02-18 to 2015-02-19
<b>Possible test case verdicts:</b>	
- 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 (collateral standards only)
- test object does not meet the requirement.....	Fail (F)
<b>Abbreviations used in the report:</b>	
- normal condition .....	N.C.
- means of Operator protection .....	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection .....	MOPP
<b>General remarks:</b>	
<p>“(See Attachment #)” refers to additional information appended to the report.                      “(See appended table)” refers to a table appended to the report.                      The tests 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 testing laboratory.                      List of test equipment must be kept on file and available for review.                      Additional test data and/or information provided in the attachments to this report.</p> <p><b>Throughout this report a point is used as the decimal separator.</b></p> <p>This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3<sup>rd</sup> edition + AM1. The Risk Management was excluded from the investigation; this shall be clearly identified in this report and on the accompanying CB Test Certificate.</p> <p>Additional test data and/or information may be provided in the attachments to this report.</p>	

**Manufacturer’s Declaration per sub-clause 4.2.5 of IEC 60060-1:2012**

**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)..... :**

<b>Factory ID: (478831-002)</b>	<b>TDK-Lambda UK Limited Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, UNITED KINGDOM</b>
<b>Factory ID: (477652-002)</b>	<b>Panyu Trio Microtronic Co. Ltd, Shiji Industrial Estate, Dongyong, Nansha, Guangzhou Guangdong CHINA</b>

**General product information:**

**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	720W
Max. Ampere Turns per converter	120
Max. Ampere Turns (total)	200
Max number of secondary windings per converter	10
Max ambient	50°C
Maximum operating altitude	3000m

Input voltage range/	Max input	Max.	Operating	Max. output
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frequency	Current	ambient	mode	power
90-99.9Vac, 47-63Hz	16A	45°C	Continuous	1000W
100-264Vac, 47-63Hz	16A	50°C	Continuous	1000W
85-264Vac, 47-63Hz	16A	50°C	Continuous	800W
120-360Vdc	11A	45°C	Continuous	800W
85-90Vac, 47-63Hz	16A	50°C	Intermittent	1000W

Intermittent: Duty cycle is 30 sec. max at up to 1000W output followed by 60 sec. min. at up to 800W output. Ampere Turns is sum of (Amperes x Number of Secondary Turns) for all outputs. There are two converters in the psu: one for module slots 1-5 and the other for slots 3-7.

The above ratings apply for all PSU mounting orientations. The ratings also apply whether or not input and/or output connector housings are fitted. Ratings apply to Alpha 800 and 1000 ranges unless otherwise stated.

When an MFPF option is fitted input voltage range is limited to 180 - 264Vac only.

The Alpha 800 or CA800 or Alpha 1000 or CA1000 Series shall be followed by: LL, RL, or TL.

Where:

- LL = Low Leakage Input filter
- RL = Reduced Leakage Input filter
- TL = Tiny leakage input filter

followed by up to seven of any of the following:

@ followed by AA, A, AL, BB, B, CC, C, CL, CM, CH, DD, D, FF, F, GG, G, JJ, J, KK, K, LL, L, MM, M, NN, N, QQ, Q, RR, R, SS, S, TT, T, UU, U, WW, W, ZZ or Z.

or B/S optionally followed by:

\_MF, \_X, \_XL, MFL, MFE, MFU, MFV or \_MFV, MFPF, MFT, \_PA, \_IN, \_PP, \_RP, RPA, RPB, RPC, RPD, \_D, \_MG or \_CD

@/@ followed by: E, EB, EQ, EL, EH, H, P or PL:

where:

- @ and @/@ = applicable voltage range and the following one or two letters are the module type.
- \_MF, MFE = Mains fail option (may also be called X).
- MFU = Mains fail option with uncommitted output connections.
- MFV = Mains fail option with VME bus
- MFPF = Mains fail, module parallel, PSU/fan inhibit and 5V, 50mA auxiliary output
- MFT = Mains fail, PSU/fan inhibit and 12V, 150mA auxiliary output
- MFL, \_XL = Mains fail latch
- B/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	Voltage (V)	Current (A)	Width (mm)	Occupied Slots	Turns	Ampere Turns
A	@4.5 - 6	60	46	2	1	60
AA	@4.5 - 7	60	46	2	1	60
AL	@4.75 - 5.3	60	46	2	1	60
BB	@4.5 - 7	25	23	1	1	25



B	@4.5 - 6	25	23	1	1	25
C, CC	@5 - 16	16	23	1	2	32
CL	@4.6 - 5.6	16	23	1	2	32
CM	@5 - 7	16	23	1	2	32
CH	@11.4 - 13.5	16	23	1	2	32
D, DD	@18 - 29	9	23	1	4	36
E	@/@5 - 16 / 5 - 16	8/8	23	1	2/2	16/16
EL	@5 - 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
H	@/@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 - 3.2	25	23	1	1	25
M, MM	@5 - 16	8	23	1	2	16
N, NN	@18 - 32	5	23	1	4	20
P	@/@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 - 3.2	60	46	2	1	60
U, UU	@10 - 21	16	23	1	3	48
W, WW	@4.5 - 5.5	15	23	1	1	15
Z, ZZ	@4.5 - 5.7	25	23	1	1	25

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 to 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 3A in slot 7 and up to 5A in all other slots. For 29.01 - 32V output current is limited to 1A 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.

(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.
_PP	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.
_IN	Provides an external signal which may be used to inhibit the output of the module.
_EN	Provides a delay in the turn on time of a module output. Additionally allows an external signal 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.

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 LSF LL 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

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

**Additional Information**

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**Technical Considerations:**

- The product was investigated to the following additional standards:

EN 60601-1:2006/A1:2013 (IEC60601-1, Edition 3.1),

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012  
Medical Electrical Equipment - Part 1 (IEC 60601-1:2005, Mod),

CAN/CSA-C22.2 NO. 60601-1:14 - Medical electrical equipment - Part 1 (Adopted IEC 60601-

1:2005, third edition, 2005-12, incl. Am1:2012, with Canadian deviations), Third Edition

- The product was not investigated to the following standards or clauses:  
  
Electromagnetic Compatibility (IEC 60601-1-2),  
  
Clause 14, Programmable Electronic Systems,  
  
Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is: Ordinary
- The 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
- EMC compliance has not been verified nor has it been taken into consideration. An accredited EMC Test Report will be required in conjunction with the Certification of the end product.
- Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)
- Scope of Power Supply evaluation excludes the following: Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15 Battery related clauses: 7.3.3, 15.4.3 Hand Control related clauses: 8.10.4 Oxygen related clauses: 11.2.2 Fluids related clauses: 11.6.2 – 11.6.4 Sterilization clause: 11.6.7 Biocompatibility Clause: 11.7 (ISO 10993) Motor related clauses: 13.2.13.3, 13.4 Heating Elements related clause: 13.2 Flammable Anaesthetic Mixtures Protection: Annex G

#### **Risk Controls/ Engineering Considerations for component power supply:**

For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, 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.
- A fire, electrical and mechanical enclosure is required for this equipment.
- Additional fusing may be required in the end product to meet the requirement of Cl. 8.11.5, Mains fuses and Over Current Release. The product is only provided and tested with a single fuse.
- 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.

- The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application
- Power supply provides the following MOOP (means of operator protection): 2 MOOP based upon a working voltage 329 Vrms, 652 Vpk between Primary to Secondary, 1 MOOP based upon a working voltage 284 Vrms, 384Vpk between Primary and Earth
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests shall be considered as part of the end product evaluation.
- Proper bonding to the end-product main protective earthing termination is required.
- These products were considered to be a component part of a larger piece of Class 1 equipment. Full compliance with the standards will therefore depend on the installation in the final application.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tma) of 50°C
- Magnetic devices Flyback trx T4/T1 and T202, T302 employ a Class F (155°C) or higher insulation system
- The PWB is rated 130°C
- The products were tested on a 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary
- Leakage current measurements with non-frequency weighted measuring device shall be performed during end product evaluation.
  
- 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.
- 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 the movement of conductors as part of the power supply.
- 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.
- Temperature Test was conducted without Test Corner. 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