

## UL TEST REPORT AND PROCEDURE

<b>Standard:</b>	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
<b>Certification Type:</b>	Component Recognition
<b>CCN:</b>	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
<b>Product:</b>	Switch mode power supply
<b>Model:</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>Rating:</b>	94.5 Vac to 240 Vac, (85-264Vac max. tolerance), 16A, 47-63 Hz, Class I
<b>Applicant Name and Address:</b>	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

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**Supporting Documentation**

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

- A. Authorization - The Authorization page may include additional Factory Identification Code markings.
- B. Generic Inspection Instructions -
  - i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.
  - ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.
  - iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

**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/ frequency	Max input Current	Max. ambient	Operating mode	Max. output 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 MFPP 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, MFPP, 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
MFPP	= 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).

### 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

#### **Engineering Conditions of Acceptability**

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