

## UL TEST REPORT AND PROCEDURE

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|------------------------------------|---|
| <b>Standard:</b>                   | UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety)<br>CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1: General Requirements for Safety) |
| <b>Certification Type:</b>         | Component Recognition   |
| <b>CCN:</b>                        | QQHM2, QQHM8 (Power Supplies, Medical and Dental)   |
| <b>Product:</b>                    | Switch mode Power Supplies  |
| <b>Model:</b>                      | Series: Alpha 400, Alpha 400W, CA400, MA400, Alpha-400, Alpha-400W; models: CA400, CA-400, MA400, MA-400  |
| <b>Rating:</b>                     | Nominal Input Voltage Range: 100-240Vac, 7A max, 47-63 Hz.<br>Output: See Model Differences   |
| <b>Applicant Name and Address:</b> | TDK-LAMBDA UK LTD<br>KINGSLEY AVE<br>ILFRACOMBE<br>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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Prepared by: Krzysztof Wasilewski

Reviewed by: Jakub Sobolewski

**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 Alpha 400, CA 400 and MA 400 Series Power Supplies are electrically and mechanically identical. The system build is further specified by additional suffixes, described as follows:  
may be followed by A, LL, RL, ML, TL or no letter; where

A=Class A input filter  
LL=Low Leakage Input Filter  
RL=Reduced Leakage Input filter  
TL= Tiny Leakage Input filter  
ML = Medium Leakage input filter  
No letter = Class B input filter

may be followed by LSF, QF or RA; where

LSF=Low Speed Fan  
QF=Quiet Fan  
RA=Reverse Air Fan

followed by up to five 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: \_X, \_MF, MFE, MFU, MFV or \_MFV, MFPP, \_PA, \_IN, \_PP, MJ, RJ, PJ, IJ, \_RP, RPA, RPB, RPC, RPD, \_MG or \_D

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

where @ and @/@ or @\_@ = 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 or \_MFV = Mains fail option with VME bus

\_PA, \_PP, \_IN, \_RP = Secondary module options

B/S = blanking slot which occupies one 23 mm slot.

MFPP = Mains fail, module parallel, PSU/fan inhibit and 5V, 50mA auxiliary output

MJ = Mains fail option

Only up to five 23 mm slots may be filled up per unit, noting that all modules occupy one 23 mm slot except for AA, A, F, G, J, K, R, S and T modules which occupy two 23 mm slots. All primary MF options can only be fitted in slot 1.

Valid voltage ranges for @ and @/@ or @\_@ for each module are as follows:

| Module | Voltage Range   |
|--------|-----------------|
| A      | @ = 4.5 - 6V    |
| AA     | @ = 4.5 - 7V    |
| AL     | @ = 4.75 - 5.3V |
| BB     | @ = 4.5 - 7V    |
| B      | @ = 4.5 - 6V    |
| C, CC  | @ = 5 - 16V     |

|       |                                      |
|-------|--------------------------------------|
| CL    | @ = 4.6 - 5.6V                       |
| CM    | @ = 5 - 7V                           |
| CH    | @ = 11.4 - 13.5V                     |
| D, DD | @ = 18 - 29V                         |
| E     | @/@ or @_@ = 5 - 16V / 5 - 16V       |
| EL    | @/@ or @_@ = 5 - 7V / 11 - 13V       |
| EH    | @/@ or @_@ = 11 - 13V / 11 - 13V     |
| EB    | @/@ or @_@ = 4.5 - 5.5V / 4.5 - 5.5V |
| EQ    | @/@ or @_@ = 4.5 - 5.5V / 2.7 - 3.9V |
| F     | @ = 9 - 16V                          |
| G, GG | @ = 17.5 - 29V                       |
| H     | @/@ or @_@ = 18 - 32V / 18 - 32V     |
| J, JJ | @ = 30 - 48V                         |
| K, KK | @ = 18 - 31V                         |
| L, LL | @ = 1.8 - 3.2V                       |
| M, MM | @ = 5 - 16V                          |
| N, NN | @ = 18 - 32V                         |
| P     | @/@ or @_@ = 18 - 29V / 5 - 16V      |
| PL    | @/@ or @_@ = 22 - 26V / 5 - 7V       |
| Q, QQ | @ = 2.7 - 3.9V                       |
| R, RR | @ = 2.7 - 3.9V                       |
| S, SS | @ = 1 - 5.7V                         |
| T, TT | @ 1.8V - 3.2V                        |
| U, UU | @ 10 - 21V                           |
| W, WW | @ 4.5 - 5.5V                         |
| Z, ZZ | @ 4.5 - 5.7V                         |

Secondary Options:

| Option            | Description  |
|-------------------|--|
| _MG               | Provides a module good signal which indicates output voltage is within limits  |
| _PA, RJ<br>signal | Forces paralleled modules to share load current. Additionally it also provides the module good signal  |
| _PP, PJ           | Provides either of the following functions:<br>a) Reduces module current limit and caters for paralleled modules with bus bar linking. For use with<br>modules providing a max output of up to 16V only; or<br>b) Identical to _PA except that the module is paralleled at the output of the module with bus bar linking |
| _IN, IJ           | Provides an external signal which may be used to inhibit the output of the module  |
| _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                | Provides a delay to 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.

a) A, AA & AL modules can be used in slots 1-5 up to 60A/channel

b) BB & B modules can be used in slots 1-4 up to 25A/channel and in slot 5 up to 20A/channel

- c) C, CC, CL, CM & CH modules can be used in slots 1-5 up to 16A/channel if o/p is limited to 12V. At 15 to 16V C modules can be used up to 12A/channel. Module derates linearly between 12 and 15V
- d) D & DD modules can be used in slots 1-5 up to 8A/channel
- e) E, EL & EH modules can be used in slots 1-3 up to 8A/channel and in slots 4 and 5 up to 6A/channel
- f) EB modules can be used in slots 1-5 up to 9A/channel
- g) EQ modules can be used in slots 1-3 up to 9A/channel and in slots 4 and 5 up to 6.75A/channel
- h) F & FF modules can be used in slots 1-5 up to 33A/channel
- i) G & GG modules can be used in slots 1-5 up to 20A/channel
- j) H modules can be used in slots 1-3 up to 5A/channel and in slots 4 and 5 up to 4A/channel. For output voltages 30.01 to 32V maximum rated current is 1A
- k) J & JJ modules can be used in slots 1-5 at 30-41V at 10A max. For output of 48V at 8A max. For voltages between 41 and 48V the current is linearly interpolated
- l) K & KK modules can be used in slots 1-5 up to 15A
- m) M & MM modules can be used in slots 1-5 up to 8A/channel
- n) L & LL modules can be used in slots 1-4 up to 25A/channel and in slot 5 up to 20A per channel
- o) N & NN modules can be used in slots 1-5 up to 5A/channel for output voltages up to 29V. For output voltages 29.01 to 32V maximum rated current is 1A
- p) P & PL modules 18-29V outputs can be used in slots 1-3 up to 5A and in slots 4-5 at up to 4A. 5-16V outputs can be used in slots 1-3 up to 8A and in slots 3-4 at up to 6A
- q) Q & QQ modules can be used in slots 1-5 up to 25A/channel
- r) R & RR modules can be used in slots 1-5 up to 60A/channel
- s) S & SS modules can be used in slots 1/2 up to 75A, slots 2/3 up to 71A, slots 3/4 up to 69A & slots 4/5 up to 66A
- t) T & TT modules can be used in slots 1-5 up to 60A
- u) U & UU modules can be used in slots 1-3 up to 16A, slot 4 up to 15A and slot 5 up to 13A
- v) W & WW modules can be used in slots 1-5 up to 15A/channel
- w) Z & ZZ modules can be used in slots 1-4 up to 25A/channel and in slot 5 up to 20A per channel.

The following limitations also apply:

- (a) For power supplies having one or more A, AA, AL, R, RR, T and/or TT modules and mounted vertically with the airflow downwards, the output is limited to 350W.
- (b) For power supplies having one or more F or FF modules, the output is limited to 375W, only when operated in a vertical position with the fan on top of the power supply
- (c) For power supplies fitted with an LSF option fan, the output is limited to 300W and 60AT. Operation in a vertical orientation with the fan at the top is not permitted
- (d) For power supplies fitted with the fan reversed (RA option), the output is limited to 300W and 60AT. Operation in a vertical orientation is not permitted
- (e) For power supplies having input or output connector housings fitted the total output is limited as follows:

|                        |                                |
|------------------------|--------------------------------|
| PSU Orientation        | Total Power Output             |
| Vertical with no fan   | $P = 14.7 + 3.67 \cdot V_{in}$ |
| All other orientations | $P = 80 + 3.2 \cdot V_{in}$    |

subject to a maximum total power output of 400W and a minimum mains input voltage of 90Vac. Where P = maximum total output power and  $V_{in}$  = mains input voltage

An example of product would be: CA400 @B @B @C @/@E or @\_@E, @M where @ and @/@ or @\_@ would be written on the product label as numbers representing the voltage of the module eg. 5B

Additional Module limitations:

When using remote sense, the max output voltage will be reduced by 0.5V for L, S, T, Q and R modules, and by 1.0V for C, D, F, G, J, M, K, N, U Modules.

Ampere turns for J module is calculated as  $AT = (\text{output current} + 15A) \times 4$

Adjusting output voltage beyond the stated range may cause overvoltage protection (OVP) to operate, whereby all outputs will turn off. To reset OVP, turn back output voltage adjustment and remove the mains

supply for 30 seconds.

#### Technical Considerations

- 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
- The product was investigated to the following additional standards:: CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)
- 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 following accessories were investigated for use with the product:: None
- 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:: NA
- The CB Test Certificate is effective for three (3) years from the Date of Issue noted on the Certificate (IECEE 02 Clause 6.3.4). The NCB may challenge the Certificate when it is more than three years old or when the standard according to which it was issued is no longer in force in the country of the NCB. To maintain the validity of the CB Test Certificate and Report after 3 years, a review and necessary re-testing will be required to ensure continued conformity with the most current edition of the standard.
- This product has been assessed for Class 1, Pollution Degree 2, Material Group IIIB, Over voltage Category II, Altitude up to 3000 meters, maximum ambient 50 degrees C (higher ambients permitted for specific custom models).

#### 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:

- The original testing was carried out on the basis of 5 slots being filled, each slot being one 23mm module space wide. This is the maximum number of module 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 represent the least efficient, highest current module configurations. Abnormals were carried out on the expected worst 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 the other tests, the conditions and configurations used were the expected worst case.
- These units are internal forced-air cooled. They require a minimum of 50mm clearance in the vicinity of the ventilation holes. Whilst relatively orientation insensitive, operation of the these units when mounted vertically with the air flow in a downward direction is affected by convection acting against the cooling airflow, and results in slightly hotter temperatures (2 to 5 degrees) 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. No additional air flow during tests was applied, only the internal fans were used.
- 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.

- 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.
- This product must be installed in a restricted access location, accessible to authorized competent personnel only.
- 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.
- This equipment has only been evaluated for Basic Insulation from Primary to Secondary across the main transformer.
- The following secondary output circuits are at hazardous energy levels: modules A, AA, AL, C, CC, CH, D, DD, F, FF, G, GG, J, JJ, K, KK, R, RR, S, SS, T, TT, U and UU
- The following secondary output circuits are at non-hazardous energy levels: modules B, BB, CL, CM, E, EB, EH, EL, EQ, H, L, LL, M, MM, N, NN, P, PL, Q, QQ, W, WW, Z and ZZ
- Leakage current measurements with non-frequency weighted measuring device according to , Japanese national differences clause 19.4e shall be performed during end product evaluation.
- 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. Some modules could present an energy hazard. Additionally, outputs can be connected in series thus producing non-SELV 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 the SELV limits between output and earth. If any output is non-SELV then all outputs become non-SELV.

**Additional Information**

The schematics are kept on file at the CBTL and can be provided by the manufacturer upon request by NCB's/CBTL's.

The label sample represents all Models in the Series.

These products use optional coatings which are normally applied with a brush and are used within the primary area of the power supply on limited surface therefore deemed as non-safety

**Additional Standards**

The product fulfills the requirements of: CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)