



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-A2-CB-1
Date of issue : 2011-12-01
Total number of pages : 22

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
Address : ILFRACOMBE
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

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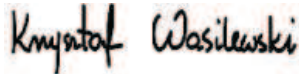
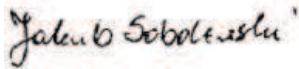
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General disclaimer

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 | 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 400, Alpha 400W, CA400, MA400, Alpha-400, Alpha-400W; models: CA400, CA-400, MA400, MA-400 |
| Ratings | Nominal Input Voltage Range: 100-240Vac, 7A max, 47-63 Hz. Output: See Model Differences |

| | |
|---|---|
| Testing procedure and testing location: | |
| <input checked="" type="checkbox"/> CB Testing Laboratory | |
| Testing location / address..... : | UL International Germany GmbH Admiral-Rosendahl-Strasse 23, 63263 Neu-Isenburg (Zeppelinheim), Germany |
| <input type="checkbox"/> Associated CB Test Laboratory | |
| Testing location / address..... : | |
| Tested by (name + signature) | Krzysztof Wasilewski  |
| Approved by (name + signature).... : | Jakub Sobolewski  |
| <input type="checkbox"/> Testing Procedure: TMP/CTF Stage 1 | |
| Tested by (name + signature) | _____ |
| Approved by (+ signature) | _____ |
| Testing location / address..... : | |
| <input type="checkbox"/> Testing Procedure: WMT/CTF Stage 2 | |
| Tested by (name + signature) | _____ |
| Witnessed by (+ signature)..... : | _____ |
| Approved by (+ signature) | _____ |
| Testing location / address..... : | |
| <input type="checkbox"/> Testing Procedure: SMT/CTF Stage 3 or 4 | |
| Tested by (name + signature) | _____ |
| Approved by (+ signature) | _____ |
| Supervised by (+ signature) | _____ |
| Testing location / address..... : | |
| <input type="checkbox"/> Testing Procedure: RMT | |
| Tested by (name + signature) | _____ |
| Approved by (+ signature) | _____ |
| Supervised by (+ signature) | _____ |
| Testing location / address..... : | |

| |
|---|
| List of Attachments |
| National Differences (5 pages) |
| Enclosures (127 pages) |
| Summary of Testing: |
| No tests were conducted |
| Summary of Compliance with National Differences: |

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Amendment 1 2015-05-27

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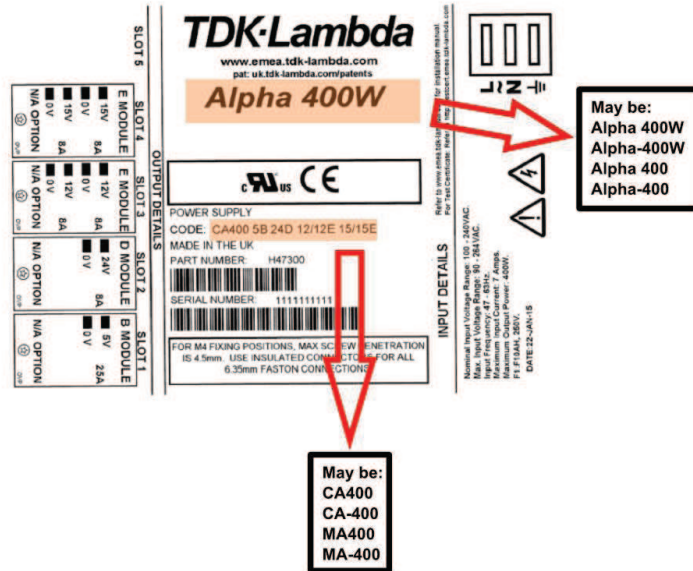
Countries outside the CB Scheme membership may also accept this report.

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: CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)

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.



| | |
|--|---|
| 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 |
| - operational insulation | OP - basic insulation |
| - basic insulation between parts of opposite polarity: | BOP - supplementary insulation |
| - double insulation | DI - reinforced insulation |
| Testing: | |
| Date(s) of receipt of test item | N/A |
| Date(s) of Performance of tests | N/A |
| General remarks: | |
| List of test equipment must be kept on file and be available for review. | |
| "(see Enclosure #)" refers to additional information appended to the report. | |
| "(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 IEC60061-1: | |
| | Yes |
| 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 GUANGZHOU GUANGDONG CHINA |

GENERAL PRODUCT INFORMATION:

Report Summary

The original report was modified on 2015-05-27 to include the following changes/additions:

The report was updated in order to:

- add series Alpha 400W, Alpha-400, Alpha-400W, models: MA-400, CA-400,
- add to report scope following national differences: AT, BE, BR, CZ, FR, GR, HU, JP, NL, PL, RU, SI, SK, UA,
- remove TRIO ENGINEERING CO LTD and TDK-LAMBDA GERMANY GMBH factories,
- add PANYUTRIO MICROTRONIC CO LTD factory,
- add following components to list of critical components: Connectors, Current sense transformer T202, Sleeving over fan wiring (sleeving only required in region of heatsink) and T101 triple insulated wiring, Alternate fan (LSF option only), Optional Coating,
- remove following components to list of critical components: Coating, for use on all parts of PSU,
- modify parameters of components on the list of critical components,

No testing was considered necessary to introduce above mentioned changes.

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, MFPF, _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.

MFPF = 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 | Forces paralleled modules to share load current. Additionally it also provides the module good signal |
| _PP, PJ | Provides either of the following functions: a) Reduces module current limit and caters for paralleled modules with bus bar 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 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.

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

Technical Considerations

- 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

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 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. --