

UL TEST REPORT AND PROCEDURE

Standard:	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
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Switch Mode Power Supply
Model:	Series: Alpha 400, Alpha 400W, CA400, MA400, Alpha-400, Alpha-400W; models: CA400, CA-400, MA400, MA-400
Rating:	Nominal Input Voltage Range: 100 - 240 Vac, 7A max, 47-63 Hz. Output: See Model Differences
Applicant Name and Address:	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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Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

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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

Products are component AC/DC Switch Mode Power Supplies intended to be used as part of Medical Electrical 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 and TL, or no letter; where

A = Class A input filter

TL = Tiny Leakage Input Filter

RL = Reduced Leakage Input filter

LL = Low Leakage Input filter

ML = Medium Leakage 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 Flow Fan is fitted

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, _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.

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.
- The product is Classified only to the following hazards: Casualty, Fire, Shock.
- Manufacturer's Recommended Ambient: 0 - 50°C
- Classification of installation and use: Building-in.
- Risk Management was excluded from this investigation.

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:

- Component was not preconditioned in humidity chamber before the tests. Humidity test shall be performed in end product.
- The following Production-Line Tests are conducted for this product: Electric Strength, Earthing Continuity.
- The End-Product Electric Strength Test it to be based upon a max working voltage of: Primary-Secondary: Vrms=336, Vpk=864 and Primary to Earthed Cover: Vrms=295, Vpk=400.
- All outputs were individually referenced to earth to obtain max working voltage.
- The Power Supply terminals and/or connectors are: Not investigated for field wiring.
- The max investigated branch circuit rating is: 20A.
- These products have been assessed for Class I, Pollution Degree 2, Material Group IIIB, Overvoltage category II, Altitude up to 3000 metres, Max Ambient 50 degrees C (higher ambient permitted for specific custom models).
- Proper bonding to the End-Product main protective earthing termination is: Required.
- The following magnetic devices (e.g. transformers or inductors) are provided with an OBJ3 insulation system with the indicated rating greater than Class A (105 degC). See critical components table for details.
- The following End-Product enclosures are required: Fire, Mechanical and Electrical.
- 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. ,

- Consideration of spacings to the connections optional screw terminal input in the End-Product is required.
- Output circuits have not been evaluated for direct patient connection (Type B, BF, CF)
- This product must be installed in a restricted access location, accessible to authorised competent personnel only.
- Power Supply provides the following: 2 MOOPS isolation from Primary to Secondary; provides 1 MOOP isolation from Primary to Earth.
- Considerations to the applied parts requirement, to be conducted as end-product.
- 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 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
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation
- The PWB is rated: see table Critical Components
- The products were tested on a 20A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- Legibility of Marking to be considered / investigated in end use product. Durability test not conducted. ,
- 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
- Leakage current measurements with non-frequency weighted measuring device shall be performed during end product evaluation.
- 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
- Only L line is protected by a fuse. When power supply unit is used in not permanently connected installed equipment necessity of overcurrent protection in line N shall be considered.
- 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