



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-D7-CB-2

Date of issue: 2015-06-01

Total number of pages.....: 316

Name of Testing Laboratory preparing the Report.....: **UL International Germany GmbH**
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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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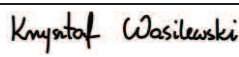
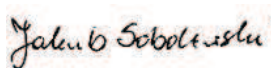
This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

General disclaimer:

The test results presented in this report relate only to the object tested.

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Test item description	Switch Mode Power Supply	
Trade Mark	TDK-Lambda	
Manufacturer	TDK-Lambda UK Ltd Kingsley Avenue 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, 47-63Hz Output: See Model Differences (see model differences for details of model ratings)	
Testing procedure and testing location:		
<input type="checkbox"/>	CB Testing Laboratory:	
Testing location/ address		
<input type="checkbox"/>	Associated CB Testing Laboratory:	
Testing location/ address		
Tested by (name + signature)		
Approved by (name + signature)		
<input type="checkbox"/>	Testing procedure: TMP/CTF Stage 1:	
Testing location/ address		
Tested by (name + signature)		
Approved by (name + signature)		
<input type="checkbox"/>	Testing procedure: WMT/CTF Stage 2:	
Testing location/ address		
Tested by (name + signature)		
Witnessed by (name + signature)		
Approved by (name + signature)		

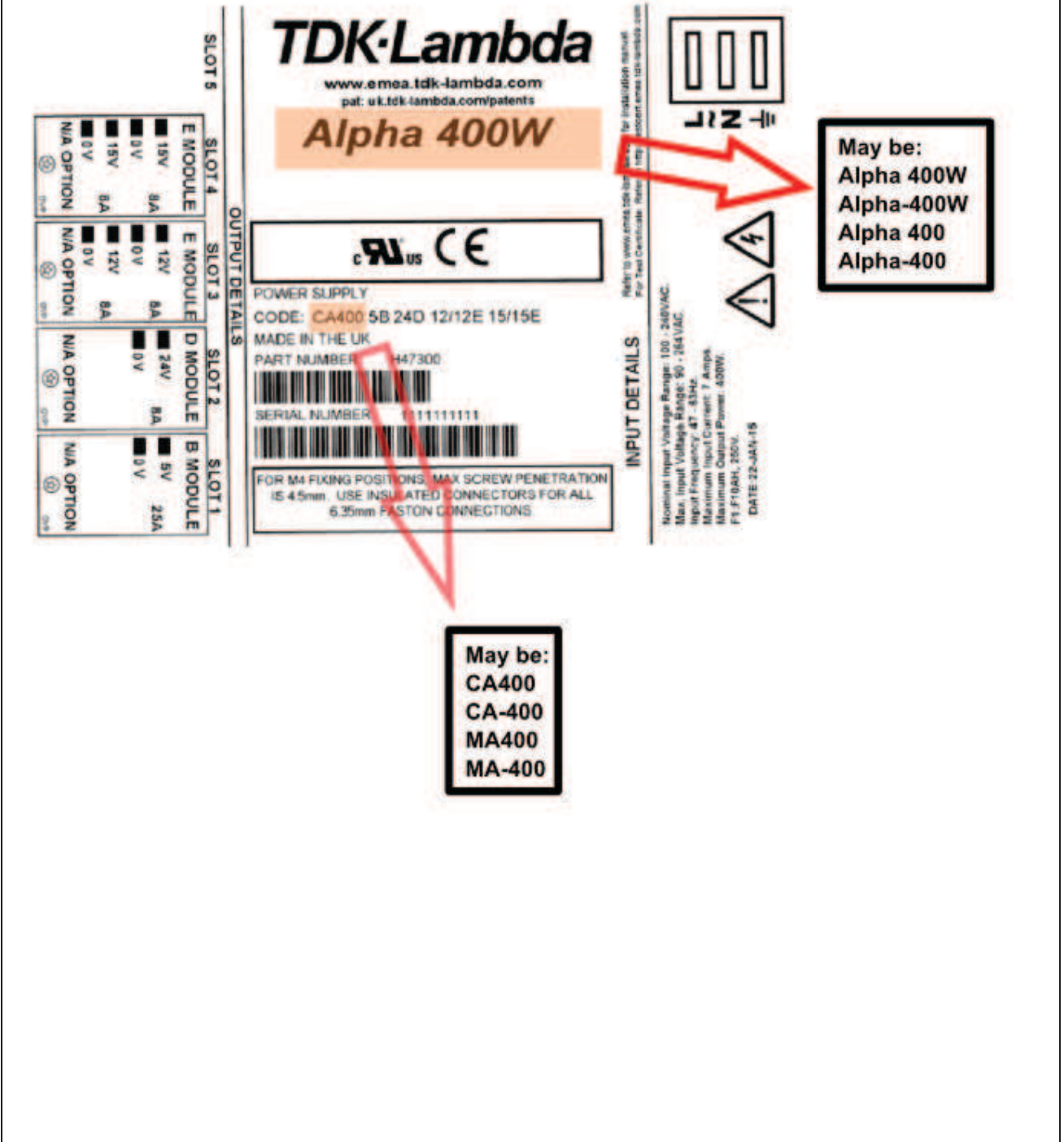
<input checked="" type="checkbox"/>	Testing procedure: SMT/CTF Stage 3 or 4:	
Testing location/ address		TDK-Lambda UK Ltd, Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United Kingdom
Tested by (name + signature).....		T. Burgess  S. Hirstwood 
Witnessed by (name + signature)		K.P. Tizzard 
Approved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

List of Attachments (including a total number of pages in each attachment):	
National Differences (7 pages)	
Enclosures (30 items)	
Summary of testing	
Unless otherwise indicated, all tests were conducted at TDK-Lambda Ltd., Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United kingdom.	
Report was issued based on E349607-A29-CB-1 (issued: 2012-07-02) test report, test certificate no. DK-26881-UL. No 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.	
Following changes were introduced in comparison to E349607-A29-CB-1 (issued: 2012-07-02) test report:	
<ul style="list-style-type: none"> - addition of series Alpha 400W, Alpha-400, Alpha-400W, models: MA-400, CA-400, - addition to report scope following national differences: AT, CA, KR, SE, GB, US - removal of TRIO ENGINEERING CO LTD and TDK-LAMBDA GERMANY GMBH factories, - addition of PANYUTRIO MICROTRONIC CO LTD factory, - change of test report CBTL to UL International Germany GmbH, - addition of following components to list of critical components: Connectors, Current sense transformer T202 (component existed in previously evaluated construction, omitted by mistake), Sleeving over fan wiring (sleeving only required in region of heatsink) and T101 triple insulated wiring(accepted based on triple insulated wire license), Alternate fan (LSF option only), Optional Coating, - removal following components to list of critical components: Coating, for use on all parts of PSU, - modification of parameters of components on the list of critical components, 	
No testing was considered necessary to introduce above mentioned changes.	
Tests performed (name of test and test clause)	Testing location / Comments
Power Input Test (4.11)	Tests were performed for E349607-A29-CB-1 (issued: 2012-07-02) test report, test certificate no. DK-26881-UL prepared by UL International Demko A/S.

Low Voltage Reliability (8.4.2 and 8.11.1)	Tests were performed for E349607-A29-CB-1 (issued: 2012-07-02) test report, test certificate no. DK-26881-UL prepared by UL International Demko A/S.
Voltage or Charge Limitation (8.4.3)	Tests were performed for E349607-A29-CB-1 (issued: 2012-07-02) test report, test certificate no. DK-26881-UL prepared by UL International Demko A/S.
Earthing and Potential Equalization Test (8.6.4a)	Tests were performed for E349607-A29-CB-1 (issued: 2012-07-02) test report, test certificate no. DK-26881-UL prepared by UL International Demko A/S.
Leakage Current Test (8.7)	Tests were performed for E349607-A29-CB-1 (issued: 2012-07-02) test report, test certificate no. DK-26881-UL prepared by UL International Demko A/S.
Dielectric Voltage Withstand (8.8.3)	Tests were performed for E349607-A29-CB-1 (issued: 2012-07-02) test report, test certificate no. DK-26881-UL prepared by UL International Demko A/S.
Temperature Test (11)	Tests were performed for E349607-A29-CB-1 (issued: 2012-07-02) test report, test certificate no. DK-26881-UL prepared by UL International Demko A/S.
Abnormal Operation and Single Fault Conditions (13)	Tests were performed for E349607-A29-CB-1 (issued: 2012-07-02) test report, test certificate no. DK-26881-UL prepared by UL International Demko A/S.
Transformer Overload and Short-Circuit Tests (15.5.1)	Tests were performed for E349607-A29-CB-1 (issued: 2012-07-02) test report, test certificate no. DK-26881-UL prepared by UL International Demko A/S.
<p>Summary of compliance with National Differences</p> <p>List of countries addressed: AU, KO, US, CAN, UK, SW</p> <p>The product fulfils the requirements of</p> <ul style="list-style-type: none"> • 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.



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use	For building-in
Device type (component/sub-assembly/ equipment/ system):	Component Power Supply
Intended use (Including type of patient, application location) :	For building-in MD and to supply regulated power
Mode of operation	Continuous
Supply connection	For building-in
Accessories and detachable parts included	None
Other options include	None
Testing	
Date of receipt of test item(s)	2004-11-05, 2011-03-02, 2012-05-04, 2012-05-11
Dates tests performed	2004-11-05, 2012-05-04 to 2012-05-16
Possible test case verdicts:	
- 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)
Abbreviations used in the report:	
- normal condition	N.C.
- single fault condition.....	S.F.C.
- means of Operator protection	MOOP
- means of Patient protection	MOPP
General remarks:	
<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>Throughout this report a point is used as the decimal separator.</p> <p>This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3rd 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>	

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, _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: <ul style="list-style-type: none"> 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
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Vertical with no fan	$P = 14.7 + 3.67 \cdot V_{in}$
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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.

This report has been re-issued to change the test dates and sample received date.

The label sample represents all Models in the Series.

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 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 critical. The coatings are not used for any safety purpose.

No Risk Management evaluation has been carried out on this product, therefore Essential Performance has not been specified, as this depends on the End Equipment.

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.

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:

- 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: $V_{rms}=336$, $V_{pk}=864$ and Primary to Earthed Cover: $V_{rms}=295$, $V_{pk}=400$.
- 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 OBJY3 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