



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-D4-CB-1-ORIGINAL

Date of issue: 2015-04-21

Total number of pages..... 181

Name of Testing Laboratory
 preparing the Report.....: **UL International Germany GmbH**
Admiral-Rosendahl-Strasse 9
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

Copyright © 2014 IEC System of Conformity Assessment Schemes for Electrotechnical Equipment and Components (IECEE System). All rights reserved.

This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.

If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.






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.

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 Supply	
Trade Mark	TDK-Lambda	
Manufacturer	TDK-Lambda UK Ltd Kingsley Avenue Ilfracombe Devon EX34 8ES, United Kingdom	
Model/Type reference	CFE400M or CFE-400M series switch mode power supplies (see report Model Differences for details of nomenclature)	
Ratings	100-240Vac nom, 47-63Hz, 6.1A rms max (see report Model Differences for details)	
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 (27 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-A25-UL (issued: 2012-06-29, revised: 2014-01-14) test report. Only limited 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.	
Tests performed (name of test and test clause)	Testing location / Comments
Humidity Preconditioning Treatment (5.7)	
Dielectric Voltage Withstand (8.8.3)	
Temperature Test (11)	
Abnormal Operation and Single Fault Conditions (13)	
Summary of compliance with National Differences	
List of countries addressed: AT, KR, US, CA, GB, SE	
The product fulfils the requirements of	
<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 Switch Mode Power Supply
Intended use (Including type of patient, application location) :	To provide DC power for electronic circuit within medical equipment
Mode of operation	Continuous
Supply connection	Connection to mains via host equipment
Accessories and detachable parts included	None
Other options include	None
Testing	
Date of receipt of test item(s)	2014-07-14 to 2014-11-28
Dates tests performed	2014-07-28 to 2014-12-01
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.
- means of Operator protection	MOOP
- single fault condition.....	S.F.C.
- 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>	

Manufacturer's Declaration per sub-clause 4.2.5 of IEC 60060-1:2012

The application for obtaining a CB Test Certificate includes more than one factory location 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..... :

Yes

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies)..... :

Factory ID: (478831-002)

TDK-Lambda UK Limited
Kingsley Avenue,
Ilfracombe,
Devon,
EX34 8ES, UNITED KINGDOM

Factory ID: (477652-002)

Panyu Trio Microtronic Co. Ltd,
Shiji Industrial Estate,
Dongyong,
Nansha,
Guangzhou Guangdong CHINA

General product information:**Product Description:**

CFE400M or CFE-400M series switch mode power supplies
(See Model Differences for details of nomenclature)

Model Differences:

CFE400M or CFE-400M series as described below:

Units may be marked with a Product Code: U7x or Y7x where x may be any number of letters and/or numbers 0 to 9.

Unit Configuration (Description :) Code may be prefixed by NS # followed by / or - (where # may be any number of characters indicating non- safety related model differences).

Unit Configuration Code:

CFE400Mx-a-bc-defg-hi-j-k-lmn-o

Where:

x = Blank for Y2 capacitors from output to earth
P for Y1 capacitors from output to earth

a = Channel 1 output Voltage (see Ch1 in the table below, adjustment range column).

b = Standby voltage (see standby in the table below, adjustment range column).
N for no supply

c = N no for supply.
C for 0.1A.

H for 2A.

d = NN for no fan, no fan supply.

N1 for 12V nom / 0.25A fan supply. (V varies with Ch1 output voltage)

TF for chassis with fan fitted to cover.

e = U for chassis only.

C for chassis with perforated or top fan cover.

S for chassis with cover.

f = M for Molex KK type 41791 input connector or equivalent.

S for screw terminal input connector.

g = L for low Leakage,

R for reduced Leakage,

T for tiny Leakage*

h = Y for Oring FET included.

N for no Oring FET.

i = N for no inhibit or enable.

T for inhibit.

E for enable.

j = Omit for standard channel 1 output voltage with no droop.

Dx where D is for units with programmed negative load regulation,

x is the voltage of the regulation in 100mVolts and is within the Output Adjustment range

(example, D5 = 0.5V of negative load regulation).

k = Omit for no secondary comms.

lmn = Blank for standard output settings or three numbers from 0 to 9 which denotes various output voltage/current settings within the specified ranges of each output for a particular unit. (may define non-safety related parameters/feature, e.g. reduced primary current limit, reduced OVP)

o = Blank for dual fuse input or -FL for single fuse input in the live line. FL version shall be used in permanently installed end equipment only.

* L <300 μ A Leakage, R <150 μ A Leakage, T <75 μ A Leakage

Input Parameters

Standard	60950-1
Nominal input voltage	100 - 240 Vac
Input voltage range	85 - 264 Vac
Input frequency range	47 - 63 Hz
Maximum input current	6.1A rms (6.4A rms 450W peak)

All ratings apply for ambient temperatures up to 50°C. (see variations and limitations below)

Output Parameters

There are three CFE400M standard models with various options and output parameters shown in the tables below.

Standard models:

Standard models at 50°C maximum ambient in forced air and top fan models:

Output Channel	Vout Nom.	Adjustment Range (V)	Maximum Output Current (A)	Maximum Power (W)
Channel 1	12	9 - 14.4	33.33 (35.7†)	400 (450†)
	15	14.4 - 15.5	24.67	370
	24	18 - 28.8	16.67 (18.75†)	400 (450†)
	48	36 - 54	8.34 (9.38†)	400 (450†)
Fan output (optional)	12	9 - 12	0.25	3
Standby output (optional)	5	5 - 5.5*	2	11
Standby output (optional)	5	5	0.1	0.5

Variations and limitations of use for Standard models at 50°C maximum ambient in forced air and fan models:

1. * Can be adjusted at the factory only.
2. Maximum continuous power output 400W.
3. † Peak power of 450W for 10 seconds maximum, maximum rms power of 400W.
4. See Cooling for customer air below for forced air and convection cooled models.
5. Channel 1 output de-rated 10W/°C from 50°C - 70°C.

Standard model at 50°C maximum ambient convection cooled:

Output Channel	Vout Nom.	Adjustment Range (V)	Maximum Output Current (A)	Maximum Power (W)
Channel 1	12	9 - 14.4	20.83 (35.7†)	250 (450†)
	15	14.4 - 15.5	15.4	231
	24	18 - 28.8	10.41 (18.75†)	250 (450†)
	48	36 - 54	5.21 (9.38†)	250 (450†)
Fan output (optional)	12	9 - 12	0.25	3
Standby output (optional)	5	5 - 5.5*	2	11
Standby output (optional)	5	5	0.1	0.5

Variations and limitations of use for Standard models at 50°C maximum ambient convection cooled:

1. * Can be adjusted at the factory only.
2. Maximum continuous power output 250W.
3. † Peak power of 450W for 10 seconds maximum, maximum rms power of 250W.
4. See Cooling for customer air below for convection cooled models.
5. Channel 1 output de-rated 10W/°C from 50°C - 60°C.

Standard model at 40°C maximum ambient convection cooled:

Output Channel	Vout Nom.	Adjustment Range (V)	Maximum Output Current (A)	Maximum Power (W)
Channel 1	12	9 - 14.4	25 (35.7†)	300 (450†)
	15	14.4 - 15.5	18.46	277
	24	18 - 28.8	12.5 (18.75†)	300 (450†)
	48	36 - 54	6.25 (9.38†)	300 (450†)
Fan output (optional)	12	9 - 12	0.25	3
Standby output (optional)	5	5 - 5.5*	2	11
Standby output (optional)	5	5	0.1	0.5

Variations and limitations of use for Standard models at 40°C maximum ambient convection cooled:

1. * Can be adjusted at the factory only.
2. Maximum continuous power output 300W.
3. † Peak power of 450W for 10 seconds maximum, maximum rms power of 300W.
4. See Cooling for customer air below for convection cooled models.
5. Channel 1 output de-rated 5W/°C from 40°C - 50°C.

Variations and limitations of use for Standard models at 40°C maximum ambient convection cooled:

Output Channel	Vout Nom.	Adjustment Range (V)	Current (A)	Maximum Output (W)	Maximum Power (W)
Channel 1	40	38 - 42	6.25 (15†)	300 (630†)	
Standby output (optional)	5		5	0.1	0.5

Variations and limitations of use for Standard models at 40°C maximum ambient convection cooled:

1. Maximum continuous power output 300W.
2. † Peak power of 630W with Ch1: 10ms sawtooth current waveform of 42V at 15A to 5A for 10s followed by 42V at 1A for 30s minimum. Standby at 5V, 0.1A continuous.
3. See Cooling for customer air below for convection cooled models.

Output Limitations

All outputs are SELV.

Seriesing of outputs is not allowed without further evaluation in end use product.

All outputs have basic spacings to earth rated for mains - 250Vac, and due consideration must be given to this in the end product design.

Environmental parameters

Description	Operation	Storage
Use	Indoor	-
Temperature	0°C - +70°C *	-40°C - +70°C
Humidity	5 - 95% RH, non-condensing	5 - 95% RH, non-condensing
Altitude	-200m - 5000m	-200m - 5000m
Pressure	54kPa - 106kPa	54kPa - 106kPa
Orientation	Sides, vertical with input lowest, horizontal (customer air versions: all)	All
Material Group	IIIb	
Pollution Degree	2	
Overvoltage Category	II	
Class	I	

* See variations and limitations of use for each model above.

Additional Information

This report was issued based on CBTR. Ref. No. E349607-A25-CB-1 dated 2014-01-14 including amendments and corrections with CB Test Certificate Ref. No. DK-26845-A2-UL dated 2014-01-14. Only limited testing was considered necessary based on standard similarity.

Following changes were introduced in comparison to CBTR. Ref. No. E349607-A25-CB-1 dated 2014-01-14 including amendments and corrections with CB Test Certificate Ref. No. DK-26845-A2-UL dated 2014-01-14:

The original report was modified to include the following changes/additions:

1. Addition/deletion of multilayer PWBs to critical component list
2. Alternative transformer (TX1, TDK P/N 230071) and IC (Infineon ICE 3BR2565 L) added
3. Alternative F2 fuse to include 2A Daito DCP-20
4. Enclosures updated to include revised handbook, drawings, photograph and licenses.
5. Cemented joint test updated
6. New 15V range added
7. Added option to fit single fuse on the live line. No additional testing required as both fuses fail in abnormal conditions
8. In the list of critical components updated standard numbers for: PWB, F1 fuse, capacitors, optocouplers (U1, U2, U4, U5, U6, U7), transformers (TX1, TX3)

All applicable tests according to the referenced standards have been carried out.

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 investigation:

- Clause 7.5 (Safety Signs),
- Clause 7.9 (Accompanying Documents),
- Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- Clause 10 (Radiation),
- Clause 14 (PEMS),
- Clause 16 (ME Systems)
- 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:

- The following Production-Line tests are conducted for this product: Electric Strength, Earthing Continuity.
- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-SELV: 384 Vrms, 614 Vpk, Primary-Earthed Dead Metal: 340 Vrms, 614 Vpk.
- The following secondary output circuits are at hazardous energy levels: Channel 1.
- The following secondary output circuits are at non-hazardous energy levels: Standby supply and fan supply.
- The following output terminals were referenced to earth during performance testing: All outputs and their return lines individually referenced to earth to obtain maximum working voltage.
- The power supply terminals and/or connectors are: Not investigated for field wiring.
- The maximum investigated branch circuit rating is: 20 A.
- The investigated Pollution Degree is: 2.
- Proper bonding to the end-product main protective earthing termination is: Required.
- The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY3 insulation system with the indicated rating greater than Class A (105°C): Transformer TX1, TX3 and TX5 - See table 8.10 for details of insulation systems used.
- The following end-product enclosures are required: Fire, Mechanical, Electrical.
- The following components require special consideration during end-product thermal (heating) tests due to their indicated maximum temperature measurements during component-level testing: All non-fan models require component temperatures monitored as detailed in the Additional Information section of this report.
- Consideration of spacings to the connections of the optional screw terminal input in the end equipment is required
- Insulation separation between: Primary and Secondary is two MOPPs: 384Vrms, 614Vpeak
- Insulation separation between: Primary and Earth is one MOPP: 340Vrms, 614Vpeak
- Insulation separation between: Secondary and Earth is one MOPP: 240Vrms, 340Vpeak
- The following secondary output circuits meet the limits of 8.4.2.: Standby outputs and Fan output.
- The clearance and creepage distances have been assessed for suitability up to 5000m elevation.
- Connecting output in series is not allowed without further evaluation in end product.
- Leakage current measurements with non-frequency weighted measuring device shall be performed during end product evaluation.
- Leakage current measurements shall be repeated during end product evaluation.
- -FL option shall be used in permanently installed end equipment only
- 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
- Customer Air Cooling:

The following method must be used for determining the safe operation of PSUs when NN, U or S options (Customer Air) are fitted, i.e. fan not fitted to PSU. The minimum permitted airflow for customer air cooling is 0.5m/s.

For PSUs and assemblies cooled by customer supplied airflow the components listed in the following table must not exceed the temperatures given. Additionally ratings specified for units with an internal fan shall still be complied with, eg. mains input voltage range, maximum output power, module voltage / current ratings and maximum ambient temperature. To determine the component temperatures the heating tests shall be conducted in accordance with the requirements of IEC60950-1. Consideration should also be given to the requirements of other safety standards.

Test requirements include: PSU/assembly to be fitted in its end-use equipment and operated under the most adverse conditions permitted in the end-use equipment handbook/specification and which will result in the highest temperatures in the PSU/assembly. To determine the most adverse conditions consideration shall be given to the end use equipment maximum operating ambient, the PSU/assembly loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers, etc. Temperatures shall be monitored using type K fine wire thermocouples (secured with cyanoacrylate adhesive, or similar) placed on the hottest part of the component (out of any direct airflow) and the equipment shall be run until all temperatures have stabilised.

Circuit Ref.	Description	Max. Temperature (°C) †
J1	Input connector	105
C7, C8	X capacitor	100
L1, L2	Common mode choke winding	110
L9	Series mode choke winding	120 (130)
TX1††, TX3	Standby trx winding	110 (130)
U2, U7	Opto-coupler	100
ASY4-B	PFC FET	120
ASY4-C	Boost diode	120
L3, L5	Boost choke winding	110 (140)
C9	Boost capacitor	83 (105)
ASY5	Bridge	125 (130)
RLY1	Relay	100
L6 winding	Primary resonant choke winding	125 (145)
TX5-A	Primary wdg	110 (130)
TX5-B	Ch1 wdg	110 (130)
TX5-C	Sec aux wdg	110 (130)
XQ18	HS Ch1 synchronous rectifier	120 (130)
XL1	Channel 1 output choke	110 (130)
ASY7-C (††)	Stby switch	120

ASF4-F (††)	Oring FET	120
C1, C3, C5, C16, C17, C21 (††)	Electrolytic capacitors	82.5 (105)
C6, C18 (††)	Electrolytic capacitors	91 (105)

† The higher temperatures limits in brackets may be used but product life may be reduced.

†† When fitted.

Note the attached marking label is representative of all models in the series.