


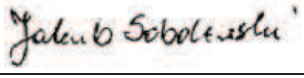


TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1:General requirements for safety

Report Reference No	E349607-A30-CB-1
Date of issue	
Total number of pages	87
CB Testing Laboratory	UL International Demko A/S
Address	Borupvang 5A, 2750 Ballerup, Denmark
Applicant's name	TDK-LAMBDA UK LTD
Address	KINGSLEY AVE ILFRACOMBE DEVON 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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Test item description	Switch mode power supply
Trade Mark	TDK-LAMBDA
	
Manufacturer	TDK-LAMBDA UK LTD KINGSLEY AVE 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)

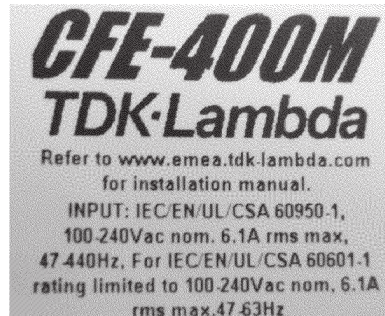
Testing procedure and testing location:		
<input type="checkbox"/>	CB Testing Laboratory	
	Testing location / address..... :	
<input type="checkbox"/>	Associated CB Test Laboratory	
	Testing location / address..... :	
	Tested by (name + signature)	_____
	Approved by (name + signature).... :	_____
<input 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 checked="" type="checkbox"/>	Testing Procedure: SMT/CTF Stage 3 or 4	
	Tested by (name + signature)	T. Burgess S. Hirstwood 
	Approved by (+ signature)..... :	K.P. Tizzard 
	Supervised by (+ signature)	Jakub Sobolewski 
	Testing location / address..... :	TDK-LAMBDA UK LTD, KINGSLEY AVE, ILFRACOMBE, DEVON, EX34 8ES, UNITED KINGDOM
<input type="checkbox"/>	Testing Procedure: RMT	
	Tested by (name + signature)	_____
	Approved by (+ signature)..... :	_____
	Supervised by (+ signature)	_____
	Testing location / address..... :	_____

List of Attachments
National Differences (4 pages)
Enclosures (90 pages)
Summary Of Testing
Unless otherwise indicated, all tests were conducted at TDK-LAMBDA UK LTD, KINGSLEY AVE, ILFRACOMBE, DEVON, EX34 8ES, UNITED KINGDOM.

Tests performed (name of test and test clause)	Testing location / Comments
Dielectric Voltage Withstand (20.4) Temperature (42) Humidity Preconditioning Treatment (44.5) Abnormal Operation and Fault Conditions (52) Transformer Overload and Short-Circuit (57.9.1)	
Summary of Compliance with National Differences: 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: EN 60601-1: 1990 + A1:1993 + A2:1995 UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA) 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 into host equipment
Supply connection	host equipment consideration
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	2014-07-14 to 2014-11-28
Date(s) of Performance of tests	2014-07-28 to 2014-12-01
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 2015-04-20 to include the following changes/additions:

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 in PSU intended for permanently installed end equipment only.
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)
9. CBTL change from UL International (UK) Limited to UL International Demko A/S.
10. Change of applicant address from "KINGSLEY AVE, ILFRACOMBE, EX34 8ES UNITED KINGDOM" to "KINGSLEY AVE, ILFRACOMBE, DEVON, EX34 8ES UNITED KINGDOM"
11. Japanese national differences were added to the report.
12. Added logo for TDK-Lambda

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

Product Description

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

Model Differences

CFE400M or CFE-400M model as described below:

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

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 <300µA Leakage, R <150µA Leakage, T <75µA Leakage

Input Parameters

Standard	60601-1
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	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:

- * Can be adjusted at the factory only.
- Maximum continuous power output 400W.
- † Peak power of 450W for 10 seconds maximum, maximum rms power of 400W.
- See Cooling for customer air below for forced air and convection cooled models.
- †† Fan output follows channel 1 output up to 14.4V max.
- Fan models: Channel 1 maximum output voltage is 13.2V for 12V model and 26.4 for 24V unit.
- 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	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:

- * Can be adjusted at the factory only.
- Maximum continuous power output 250W.
- † Peak power of 450W for 10 seconds maximum, maximum rms power of 250W.
- See Cooling for customer air below for convection cooled models.
- †† Fan output follows channel 1 output up to 14.4V max.
- 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	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:

- * Can be adjusted at the factory only.
- Maximum continuous power output 300W.
- † Peak power of 450W for 10 seconds maximum, maximum rms power of 300W.
- See Cooling for customer air below for convection cooled models.
- †† Fan output follows channel 1 output up to 14.4V max.
- Channel 1 output de-rated 5W/°C from 40°C - 50°C.

Standard model at 40°C maximum ambient convection cooled:

Output Channel	Vout Nom.	Adjustment Range	Maximum Output	Maximum
Power		(V)	Current (A)	(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:

- Maximum continuous power output 300W.
- † 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.
- 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 equipment.

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 - 3000m	-200m - 5000m
Pressure	70kPa - 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

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 stabilized.

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
ASY4-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.

Technical Considerations

- The product was investigated to the following additional standards: EN 60601-1: 1990 + A1:1993 + A2:1995, UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA), 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 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

Engineering Conditions of Acceptability

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 SELV: All --
- 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 OBJ2 insulation system with the indicated rating greater than Class A (105°C): Transformer TX1, TX3 and TX5 - See table 56.1 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 - secondary output circuits: Double/Reinforced --
- Insulation (Separation) between primary - earth: Basic --
- Insulation (Separation) between secondary circuits - earth: Basic (at mains) --
- Connecting output in series is not allowed without further evaluation in end product. --
- Leakage current measurements with non-frequency weighted measuring device according to Japanese national differences clause 19.4e 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 --