

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

Report Reference No : E349607-A10-CB-1
Date of issue :
Total number of pages : 45

CB Testing Laboratory : UL International Demko A/S
Address : Borupvang 5A, 2750 Ballerup, Denmark

Applicant's name : TDK-LAMBDA UK LTD
KINGSLEY AVE
Address : 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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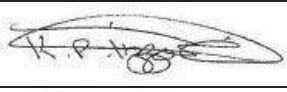
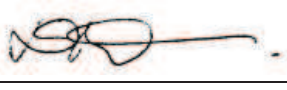
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Test item description	Switch mode power supply
Trade Mark	TDK-Lambda 
Manufacturer	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Model/Type reference	EFE400M or EFE-400M series (see Model Differences for details of models and nomenclature)
Ratings	94.5-240Vac nom, 45-63Hz, 6.1A rms max. or 100-240Vac nom, 45-63Hz, 6.1A rms max. (See Model Differences for details of ratings)

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	Testing location / address..... :
	Tested by (name + signature) :
	Approved by (+ signature) :
<input type="checkbox"/> Testing Procedure: WMT/CTF Stage 2	Testing location / address..... :
	Tested by (name + signature) :
	Witnessed by (+ signature)..... :
	Approved by (+ signature) :
<input checked="" type="checkbox"/> Testing Procedure: SMT/CTF Stage 3 or 4	Testing location / address..... :
Tested by (name + signature) :	S. Hirstwood
Approved by (+ signature) :	K. P. Tizzard
Supervised by (+ signature) :	Dennis Butcher
Tested by (name + signature) :	
Approved by (+ signature) :	
Supervised by (+ signature) :	
Tested by (name + signature) :	TDK-Lambda UK Ltd, Kingsley Avenue, Ilfracombe, Devon, EX348ES, United Kingdom
<input type="checkbox"/> Testing Procedure: RMT	Testing location / address..... :
	Tested by (name + signature) :
	Approved by (+ signature) :
	Supervised by (+ signature) :
	Testing location / address..... :

List of Attachments
National Differences (2 pages)
Enclosures (99 pages)
Summary Of Testing
Unless otherwise indicated, all tests were conducted at TDK-Lambda UK Ltd, Kingsley Avenue, Ilfracombe, Devon, EX348ES, United Kingdom.

Tests performed (name of test and test clause)	Testing location / Comments
Voltage Limitation - Part 1 (15B) Leakage Current (19) Dielectric Voltage Withstand (20.4) Temperature (42) Humidity Preconditioning Treatment (44.5) Abnormal Operation and Fault Conditions (52) Working Voltage Measurement (20.3)	
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 - Refer to Enclosure titled Marking Plate for copy.	

Test item particulars :	
Classification of installation and use	Connection to mains via host equipment
Supply connection	The EFE400M Series is a range of switched mode power supplies for building into host equipment
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	2010-10-02, 2010-05-22, 2012-12-10, 2104-11-20, 2014-11-21
Date(s) of Performance of tests	2014-12-01 to 2015-01-15
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 IEC60060-1:	
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
CHINA

GENERAL PRODUCT INFORMATION:

Report Summary

The original report was modified on 2015-06-03 to include the following changes/additions:

This report is an amendment to CBTR Ref. No. E349607-A10-CB-1 dated 2011-11-30 and E349607-A10-CB-1 amendment 1 dated 2012-05-31 and E349607-A10-CB-1 amendment 2 dated 2012-11-05, CB Test Certificate Ref. No. DK-5211-A2-UL dated 2012-11-05.

Based on previously conducted testing and the review of product construction, only limited testing of model EFE400M was considered necessary for the following revisions:

1. Enclosures updated.
2. Adding/removing alternates, making corrections and updating component Certificates in the Critical Components list: "Various" changed with "interchangeable."
3. Adding alternate Y.S. Tech FD124020UB-H-NAH fan. (Thermal test)
4. Assessed for Class II, EFE400MxD models with increased Y1 capacitor values to 4n7. (leakage test, limitation added to Condition of Acceptability, working voltage)
5. Nomenclature change to allow a single input fuse in the live/+ line
6. Increased X capacitor C7 from 330n to 470n max, XR54 and XR55 discharge resistors reduced to 270kohm max. (discharge test)
7. F2 fault test. (fault test for F2 non Safety critical component)
8. Increased Y capacitors C21 and C22 from 3n3 to 4n7. (leakage test)
9. Addition/deletion of multilayer PWBs to critical component list.
10. Perforated Cover option added. (Creepage and Clearance assessment)

Product Description

The EFE400M or EFE-400M Series are a range of switched mode power supplies for building into host equipment.

Model Differences

EFE400M or EFE-400M models as described below:

Units may be marked with a Product Code: U6x or Y6x where x may be any number of characters.

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

Unit Configuration Code:

EFE400Mxy-a-b-cdef-gh-i-j-klm

where:

x = Nothing or J for Japanese models (may have non-safety differences).

y = Blank for Y2 capacitors from output to earth
P for Y1 capacitors from output to earth
D for Class II (with Y1 capacitors)

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

b = Standby voltage: see standby voltage in table below.

c = BC for cover and U chassis without fan grill, with fan fitted (temperature controlled). (Y60001x model only)

HN for Open frame, no fan, with 12V / 1A fan supply.

HU for U chassis (not EFE400MxD models), no fan, with 12V / 1A fan supply.

HC for Cover + chassis (not EFE400MxD models), no fan, with 12V / 1A fan supply.

EC for Cover + chassis (not EFE400MxD models), end fan (temp controlled).

NN for Open frame, no fan, no fan supply.

NU for U chassis (not EFE400MxD models), no fan, no fan supply.

NC for Cover + chassis (not EFE400MxD models), no fan, no fan supply.

HP for perforated cover, no fan, with 12V / 1A fan supply.

NP for perforated cover, no fan, no fan supply.

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

S for Molex Sabre type 43160 input connector or equivalent.

e = D for AC input with dual fusing.

F for AC/DC input with dual fusing.

E for single fuse input in the Live line.

G for single fuse input in the + line

f = L for low Leakage.

R for reduced Leakage.

T for tiny Leakage.

Z for EFE400MxD models (Class II).

where L < 300uA leakage, R < 150uA leakage and T < 75uA leakage.

g = Y for Oring FET included.

N for no Oring FET.

h = T for inhibit.

E for enable.

i = V for vertical output connector or nothing for horizontal output connector.

j = Nothing for standard channel 1 output voltage, xD or xPD where D is for units with programmed negative load regulation, PD is for units with programmed positive load regulation, x is the voltage of the regulation in 100mVolts and is within the Output Adjustment range (example, 7D = 0.7V of negative load regulation, 18PD = 1.8V of positive load regulation).

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

Input Parameters

Standard	60601-1
Nominal input voltage	100 - 240 Vac
Input voltage range	90 - 264Vac*
Input frequency range	45 - 63Hz
Maximum input current	6.1A rms

* Input de-rated, see variations and limitations below.

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

Output Parameters

There are three EFE400M standard models and two non-standard models with various options and output parameters shown in the tables below.

Standard models:

Output Channel	Vout Nom.	Adjustment Range (V)	Output Current (A)	Maximum Power (W)
Channel 1	12	11.4 - 13.2*	33.33	400 (530**)
	24	22.8 - 26.4*	16.67	400 (530**)
	48	47 - 50*	8.33	400 (470**)
Fan output (optional)	12	12	1	12
Standby output	5	5	2	10
	12	12 - 12.2*	1	12.2

Variations and limitations of use for Standard models:

1. Output power de-rated 1% per volt from 100V to 90V input (channel 1 power 360W at 90V input).
2. Output power further de-rated 2% per volt from 90V to 85V input (channel 1 power 320W at 85V input).
3. Maximum ambient 70°C (de-rating output power 2.5% per °C above 50°C).
4. * Can be adjusted at the factory only.
5. Maximum continuous power output 400W (including fan output).
6. ** Peak power for 10 seconds maximum, maximum rms power of 400Wrms:

Non-Standard Models:

Non- Standard model: Y60001# (# can be any letter) (EFE400M-48-5-BCSDL-NT)

Output Channel	Vout Nom.	Adjustment Range (V)	Output Current (A)	Maximum Power (W)
Channel 1	48	47 to 50*	8.33	400
Standby output	5	fixed	2	10

Variations and limitations of use for Non- Standard model Y60001#:

1. Output power de-rated 1% per volt from 100V to 90V input. (e.g. channel 1 power 360W at 90V input)
2. Maximum ambient 50°C.
3. * Can be adjusted at the factory only.

Additional Information

Cooling for units with customer supplied air (all models except -BC and -EC)

The following method must be used for determining the safe operation of PSUs.

The components listed in the following table must not exceed the temperatures given. To determine the component temperatures the heating tests must be conducted in accordance with the requirements of the standard in question. Consideration should also be given to the requirements of other safety standards. Test requirements include: PSU 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. To determine the most adverse conditions consideration should be given to the end use equipment maximum operating ambient, the PSU loading and input voltage, ventilation, end use equipment orientation, the position of doors & covers, etc. Temperatures should 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 should be run until all temperatures have stabilised.

Cooling for unit temperature table (see layout drawings below in the handbook):

Circuit Ref.	Description	Max. Temperature (°C) †
J1	input connector	105 (75††)
C12, C8, C7	X cap	100
L1, L2	Common mode choke winding	130 (145)
L6	Series mode choke winding	130
TX1	Standby trx winding	130
U2, U3, U5, U6, U7	Opto-coupler	100
TX2	Primary, secondary windings and core	130
C5	Capacitor	85 (105)
C9	Boost capacitor	70 (105)
L3	Boost choke winding	130 (140)
L7	Channel 1 output choke	130
XQ225	Boost FET (ASY2 primary IMS)	125 (130)
Q2	Channel 1 output FET (ASY4 secondary IMS)	125 (130)
L8	Primary resonant choke (not 12V model)	130 (140)
J2	Output connector	105
XL701	1A fan output choke	110 (125)
C1, C11, C19, C20	Electrolytic capacitors	75 (105)

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

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 (IPX0)
- The mode of operation is: Continuous
- Multilayer PWB's accepted under CBTR Ref No. E349607-A23 dated 2014-07-31 and letter report in Enclosure 8-05 of this report. --

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

- Insulation (Separation) between primary - secondary output circuits: Double/Reinforced. --
- Insulation (Separation) between primary - earth: BASIC. , Insulation (Separation) between secondary circuits - earth: BASIC (at mains). , Branch circuit protection required: 20A. , All outputs are considered SELV. Testing has therefore been applied to ensure compliance with the limits specified in clause 2.4.3. , --
- A suitable mechanical, electrical and fire enclosure shall be provided in the end application. --
- Open frame models, H4 is connected to the input connector earth --
- Models without a fan require component temperatures monitored as detailed in the Additional Information --
- The product was submitted and tested for use at the maximum ambient temperature (T_{ma}) 50°C in normal conditions permitted by the manufacturer, (higher temperatures with de-ratings are described in Additional Information --
- Marking of the Protective earth terminal shall be provided by the end use equipment (clause 6.2.f) --
- Clause 19 Continuous Leakage Currents and Patient Auxiliary Currents for EFE400MxD models requires assessment in the end equipment. --
- The perforated cover when fitted to the EFE400MxD models (Class II) must be treated as a live part with Basic/Supplementary insulation to primary and Basic/Supplementary insulation to secondary. --