

UL TEST REPORT AND PROCEDURE

Standard:	UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment, Part 1: General Requirements for Safety) CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment - Part 1: General Requirements for Safety)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Complementary CCN:	QQGQ2, QQGQ8 (Power Supplies for Information Technology Equipment Including Electrical Business Equipment)
Product:	Switch mode power supply
Model:	EFE400M or EFE-400M series (see Model Differences for details of models and nomenclature)
Rating:	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)
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.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Ermanno Rebecchi

Reviewed by: Dennis Butcher

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

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.

Technical Considerations

- 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
- 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

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:

- 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.

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.

Additional Standards

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)