

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
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.

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Reviewed by: Jonathon Kerkhofs

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

EFE400M or EFE-400M series are switch mode power supplies for building into host equipment.

Model Differences

EFE400M or EFE-400M series 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 (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:

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

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, no fan, with 12V / 1A fan supply.

HC for Cover + chassis, no fan, with 12V / 1A fan supply.

EC for Cover + chassis, end fan (temp controlled).

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

NU for U chassis, no fan, no fan supply.

NC for Cover + chassis, 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 dual fused input.

f = L for low Leakage, R for reduced Leakage, T for tiny Leakage. (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)

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 indicating non safety-related model differences)
(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 : for building-in
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : To supply regulated power
- Mode of operation : Continuous
- Supply connection : For building into host equipment
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and

Essential Performance) (includes Deviations for United States), EN 60601-1:2006 + CORR:2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance), CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada)

- 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
- Risk Management has not been applied to these products.
- Options include a variable speed (temperature controlled) fan.

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:

- All results contained within this report with the exception of the Low voltage reliability test have been reproduced from the previous 60601-1 2nd edition report reference E349607-A10-CB-1.
- 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: 396 Vrms, 922 Vpk, Primary-Earthed Dead Metal: 381 Vrms, 672 Vpk, Secondary outputs - Earthed Dead Metal: 240Vrms, 340Vpk.
- The following secondary output circuits are SELV: All
- 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, fan output
- 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
- Proper bonding to the end-product main protective earthing termination is: Required
- An investigation of the protective bonding terminals has: Been conducted
- The following magnetic devices (e.g. transformers or inductor) are provided with a Class F (155°C) insulation system: Transformer TX1 and TX2 - 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 the indicated maximum temperature measurements during component-level testing: Models without a fan require component temperatures monitored as detailed in the Additional Information.
- Open frame models require PCB fixing points H1 to H4 and H7 connecting to protective earth.
- The equipment has been evaluated as a class 1 unit, but is not intended to be used to terminate the

end equipment to the incoming mains supply. Need for PE marking shall be determined in the end product investigation.

- No essential performance has been considered
- The risk management requirements of the standard were not addressed and must be considered in the end product investigation.
- The following tests shall be conducted in the end product: , Legibility of Markings (7.1.2), Durability of Marking Test (7.1.3)
- Output circuits have not been evaluated for direct patient connection (Type B, BF of CF)
- The product was submitted and evaluated for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification of: 70°C (output de-rated 2.5% per °C above 50°C).
- Insulation separation between: Secondary and Earth is one MOPP for EFE400MP models and one MOOP for all other models: 240Vrms, 340Vpeak
- Insulation separation between: Primary and Earth is one MOOP: 381Vrms, 672Vpeak
- Insulation separation between: Primary and secondary is 2 MOPP: 396Vrms, 922Vpeak
- Altitude of operation: 3000m

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 give 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):

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.

Project 12CA41747 Amendment 1:

The original Test Report Ref. No.: E349607-A17-CB-1-Original, dated 2012-05-31 was additionally modified on to include the following changes and/or additions, which were considered technical modifications:

1. Coatings in the CCL have been updated with UL approved coatings.
2. CCL list has been updated with new/changed/added certificates.
3. Unit has been assessed to MOPP's from MOOP's. (Dielectric test carried out)
4. The 48V L8 resonant choke has been assessed for use in the 24V model. (Thermal test carried out)
5. The description in models and ratings has been changed as follows: EFE400M or EFE-400M series (see Model Differences for details of models and nomenclature). However the description in detail like it was before can be found in model differences now.

After review of the construction, only the following additional tests were considered necessary:

- Clause 5.7 Humidity Conditioning
- Clause 8.8.3 Dielectric Voltage Withstand
- Clause 11 Temperature

All other required tests were carried out under the original investigation.

Additional Standards

The product fulfills the requirements of: EN 60601-1:2006 + CORR:2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada) ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States)

Markings and instructions

Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.

Refer to instruction manual/booklet	
Warning: dangerous voltage	
Special Instructions to UL Representative N/A	

Production-Line Testing Requirements			
Test Exemptions - The following models are exempt from the indicated test			
Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
Required	Required	Required	Exempt
Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:			
Component			
N/A			
Sample and Test Specifics for Follow-Up Tests at UL			
The following tests shall be conducted in accordance with the Generic Inspection Instructions			
Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
N/A			