

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)
Product:	Switch mode power supply
Model:	EFE300M Series (see model differences for details of models and nomenclature)
Rating:	100-240Vac nom, 45-63Hz, 4.9A rms max. (see model differences for details of models and ratings)
Applicant Name and Address:	TDK-LAMBDA UK LIMITED, KINGSLEY AVENUE, 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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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 EFE300M Series are switched mode power supplies for building into host equipment.

Model Differences

Nominal Input Voltage Range	100 - 240V AC
Maximum Input Voltage Range	90** - 264V AC
Input Frequency	45-63Hz
Maximum Input Current	4.9A rms

** Channel 1 output is linearly derated from 90Vac to 85Vac, 4W per volt to 280W.

All ratings apply for ambient temperatures up to 50°C. From 50 to 70°C the output power is derated at 2.5% per deg C.

EFE300M or EFE-300M models as described below:

(may be prefixed by NS - # / where # may be any number of characters indicating non safety related model differences)

Products may additionally be marked with U5x or Y5x where x can be any number of characters indicating non-safety related model differences.

Unit Configuration Code: EFE300Mxy-a-b-cdef-ghijk
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 outputs table below, adjustment range column.
- b= Standby voltage: see standby voltage table below or 0 for omitted
- c= 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. CN for Open frame, no fan, with 12V / 0.25A fan supply. CU for U chassis, no fan, with 12V / 0.25A fan supply. CC for Cover + chassis, no fan, with 12V / 0.25A fan supply.
- d= M for molex input connector or equivalent, J for JST connector or equivalent.
- e= D for dual fused input.
- f= S for standard Leakage, L for low Leakage, R for reduced Leakage, T for tiny Leakage. *
- g= Y for Oring FET included or N for nothing.
- h= E for enable, T for inhibit, N for no inhibit, no enable.
- i= Nothing for horizontal output connector, -V for vertical output connector, -S for screw terminal
- 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, 24PD = 2.4V of positive load regulation).
- k= Nothing or -x where x is 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)

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

Output parameters:

O/P Channel	Vout nom (V).	Range (V)	Max O/P (A)	Max O/P (W)
CH1	12	11.4 - 13.2*	25	300 (400**)

	24	22.8 - 26.4*	12.5	300 (400**)
	28	27 - 32*	10.72	300 (400**)
	40	36 - 42*	7.5	300 (350***)
	48	47 - 50*	6.25	300 (350***)
	50	50.1 - 54*	6.0	300 (350***)
Standby	5	Fixed	2	10
	12	Fixed	1	12
	13.5	Fixed	1	13.5
Fan output	12	Fixed	0.25	3
	12	Fixed	1	12

* Can be adjusted from nominal at the factory only.

** Peak power of 400W for 10 seconds maximum, maximum rms power of 300W:

*** Peak power of 350W for 10 seconds maximum, in any 1 minute cycle, maximum rms power of 300W:

where T1 = peakpower time on
and T2 = reduced power time on

Maximum continuous power output 300W (excluding fan output)

Output Limitations

All standard outputs are SELV up to and including 48V nominal. Voltages above 48V nominal are non SELV and must not be accessible to an end operator..

All outputs have basic spacings to earth, and due consideration must be given to this in the end product design, except for Y50029# which has functional spacings to earth.

Non Standard models.

Model: Y5J008# (where # can be any letter) or EFE300MJ-12.1-5-008 or EFE300MJ-12.1-5-008-SGP

Maximum outputs: 12.1V, 21.49A, plus 5V, 2A standby.

Maximum ambient: As standard model.

Orientations: As standard model.

Comments: Fan speed is controlled at 6600rpm up to and between 45 to 50 degrees C ambient after which the fan resumes its normal nominal voltage rating. Can be fitted with or without fan guard.

Model: Y5J006# (where # can be any letter) or EFE300MJ-12-5-006.

Maximum outputs: 11.4V to 13.2V*, 25A, (300W max) plus 5V, 2A standby.

Maximum ambient: As standard model.

Orientations: As standard model.

Comments: Longer version than standard model to accommodate additional reservoir capacitor for a greater hold up time.

Model Y50029# (where # can be any letter), EFE300M-13-5-HNMDL-NT-S/NS-TLA

Maximum outputs: As standard model

Maximum ambient: As standard model.

Orientations: As standard model.

Technical Considerations

- 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 circuits 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
- The product was investigated to the following additional standards:: 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)
- 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 following accessories were investigated for use with the product:: None
- 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
- The power supply is Class I
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product was submitted and tested for use at the maximum ambient temperature (T_{ma}) permitted by the manufacturer's specification of: 50°C (full load); 70°C (output power decreasing linearly by 2.5%/°C above 50°C).
- The product was assessed for operation at an altitude of 3000m
- Classification of installation and use: Building-in
- The Printed Wiring Board Trace was evaluated for protective earthing/bonding.
- All outputs were evaluated for less than 60Vdc, 42.4Vpk. The applicant has declared the outputs as SELV for voltages up to and including 48V nominal for standard models. Testing has therefore been conducted to ensure compliance with the limits specified in clause 8.4.2(c).
- Risk Management has not been applied to these products.

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 and Secondary is two MOPP's: 408Vrms, 880Vpeak , Insulation separation between: Primary and Earth is one MOOP: 392Vrms, 668Vpeak , Insulation separation between: Secondary and Earth is one MOPP for EFE300MP models and one MOOP for all other models: 240Vrms, 340Vpeak ,
- Branch circuit protection required: 16A (20A For North America and Canada)

- The following outputs are considered SELV: All standard model outputs up to and including 48V nominal. Voltages , above 48V nominal are non-SELV and therefore all outputs become non SELV and must not be , accessible to an operator. ,
- Some PWB mounted components are rated at the minimum coating rating of 125°C
- Consideration should be given to repeating the Earth Leakage Tests in the end use equipment.