






Test Report issued under the responsibility of:



<b>TEST REPORT</b> <b>IEC 60601-1</b> <b>Part 1: General requirements for basic safety and essential performance</b>	
<b>Report Number</b> .....	<b>E349607-D9-CB-1</b>
<b>Date of issue</b> .....	<b>2015-04-30</b>
<b>Total number of pages</b> .....	<b>119</b>
<b>Name of Testing Laboratory preparing the Report</b> .....	UL International Demko A/S Borupvang 5A, 2750 Ballerup, Denmark
<b>Applicant's name</b> .....	TDK-LAMBDA UK LTD
<b>Address</b> .....	KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
<b>Test specification:</b>	
<b>Standard</b> .....	IEC 60601-1:2005 (Third Edition) + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1 (2012 reprint)
<b>Test procedure</b> .....	CB Scheme
<b>Non-standard test method</b> .....	N/A
<b>Test Report Form No</b> .....	IEC60601_1J_PS
<b>Test Report Form(s) Originator</b> .....	UL(US)
<b>Master TRF</b> .....	2014-09
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<b>This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.</b>	
<b>General disclaimer:</b>	
The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing CB Testing Laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	

<b>Test item description</b> .....:	Medical Switch Mode Power Supply	
<b>Trade Mark</b> .....:	<b>TDK·Lambda</b>	
<b>Manufacturer</b> .....	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM	
<b>Model/Type reference</b> .....:	EFE400M or EFE-400M series (see Model Differences for details of models and nomenclature)	
<b>Ratings</b> .....:	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)	
<b>Testing procedure and testing location:</b>		
<input type="checkbox"/> <b>CB Testing Laboratory:</b>	UL International Demko A/S	
<b>Testing location/ address</b> .....	Borupvang 5A, 2750 Ballerup, Denmark	
<input type="checkbox"/> <b>Associated CB Testing Laboratory:</b>		
<b>Testing location/ address</b> .....		
<b>Tested by (name + signature)</b> .....		
<b>Approved by (name + signature)</b> .....		
<b>Testing procedure: TMP/CTF Stage 1:</b>		
<input type="checkbox"/> <b>Testing procedure: TMP/CTF Stage 1:</b>		
<b>Testing location/ address</b> .....		
<b>Tested by (name + signature)</b> .....		
<b>Approved by (name + signature)</b> .....		
<b>Testing procedure: WMT/CTF Stage 2:</b>		
<input type="checkbox"/> <b>Testing procedure: WMT/CTF Stage 2:</b>		
<b>Testing location/ address</b> .....		
<b>Tested by (name + signature)</b> .....		
<b>Witnessed by (name + signature)</b> .....		
<b>Approved by (name + signature)</b> .....		

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

**List of Attachments (including a total number of pages in each attachment):**

Enclosures (99)

**Summary of testing****Tests performed (name of test and test clause):**

Humidity Preconditioning Treatment (5.7)  
 Voltage or Charge Limitation (8.4.3)  
 Working Voltage Measurement (8.5.4)  
 Dielectric Voltage Withstand (8.8.3)  
 Leakage Current Test (8.7)  
 Temperature Test (11)  
 Abnormal Operation and Single Fault Conditions (13)

**Testing location:**


TDK-Lambda UK Ltd, Kingsley  
 Avenue, Ilfracombe, Devon,  
 EX348ES, United Kingdom

**Summary of compliance with National Differences**

List of countries addressed: AT, CA, GB, KR, SE, US

The product fulfils the requirements of IEC60601-1:2005 + A1:2013, ANSI/AAMI ES60601-1:2005/C1:2009 and A2 2010, Canada - Differences to IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + A1 (2011)


Copy of marking plate



INPUT: IEC/EN/UL/CSA 60950-1, 100-240Vac nom. 6.1A  
 rms max, 45-440Hz, For IEC/EN/UL/CSA 60601-1 rating  
 limited to 100-240Vac nom, 6.1A rms max, 45-63Hz

Made in the UK  
 07-Jan-11

**TDK-Lambda *EFE-400M***  
[www.emea.tdk-lambda.com](http://www.emea.tdk-lambda.com)  
 Product Code : U6Y008Q  
 Serial Number : 8110050109  
 Description : EFE400M-24-5-ECMDL-YT

  
 8110050109

ENGINEERING SAMPLE

OUTPUT     24V_16.7A STANDBY    5V_2A	Refer to <a href="http://www.emea.tdk-lambda.com">www.emea.tdk-lambda.com</a> for installation manual.  For Test Certificate: Refer to <a href="http://testcert.emea.tdk-lambda.com">http://testcert.emea.tdk-lambda.com</a>
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<b>GENERAL INFORMATION</b>			
<b>Test item particulars (see also Clause 6):</b>			
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		
<b>Testing</b>			
Date of receipt of test item(s) .....	2014-11-21		
Dates tests performed .....	2014-12-01 to 2015-01-15		
<b>Possible test case verdicts:</b>			
- test case does not apply to the test object .....	N/A		
- test object does meet the requirement.....	Pass (P)		
- test object was not evaluated for the requirement .....	N/E (collateral standards only)		
- test object does not meet the requirement.....	Fail (F)		
<b>Abbreviations used in the report:</b>			
- normal condition .....	N.C.	- single fault condition.....	S.F.C.
- means of Operator protection .....	MOOP	- means of Patient protection ...	MOPP
<b>General remarks:</b>			
<p>"(See Attachment #)" refers to additional information appended to the report.            "(See appended table)" refers to a table appended to the report.            The tests results presented in this report relate only to the object tested.            This report shall not be reproduced except in full without the written approval of the testing laboratory.            List of test equipment must be kept on file and available for review.            Additional test data and/or information provided in the attachments to this report.</p> <p><b>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</b></p> <p>This Test Report Form is intended for the investigation of power supplies in accordance with IEC 60601-1:2005, 3<sup>rd</sup> edition + AM1. The Risk Management was excluded from the investigation; this shall be clearly identified in this report and on the accompanying CB Test Certificate.</p> <p>Additional test data and/or information may be provided in the attachments to this report.</p>			

<b>Manufacturer's Declaration per sub-clause 4.2.5 of IEC 60601-1:2012</b>	
<p><b>The application for obtaining a CB Test Certificate includes more than one factory location 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 .....</b> :</p> <p><b>When differences exist; they shall be identified in the General product information section.</b></p>	<p><input checked="" type="checkbox"/> <b>Yes</b></p> <p><input type="checkbox"/> <b>Not applicable</b></p>
<p><b>Name and address of factory (ies).....</b> :</p> <p>Factory ID: 478831-002)</p> <p>Factory ID: (477652-002)</p>	<p>TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM</p> <p>PANYU TRIO MICROTRONIC CO., LTD, SHIJI INDUSTRIAL ESTATE, DONGYONG, NANSHA , GUANGZHOU GUANGDONG CHINA</p>
<p><b>General product information:</b></p> <p>This report is a reissue of CBTR Ref. No. E349607-A17-CB-1 dated 2012-05-31 and E349607-A17-CB-1 amendment 1 dated 2012-11-15, CB Test Certificate Ref. No. DK-26432-A1-UL dated 2012-11-16, due to upgrade to IEC 60601-1 3rd Edition + Amd 1 with the following changes:</p> <ol style="list-style-type: none"> <li>1. Enclosures updated.</li> <li>2. Adding/removing alternates, making corrections and updating component Certificates in the Critical Components list.</li> <li>3. Adding alternate Y.S. Tech FD124020UB-H-NAH fan. (Thermal test)</li> <li>4. Assessed for Class II, EFE400MxD models with increased Y1 capacitor values to 4n7. (leakage test, limitation added to Condition of Acceptability, working voltage)</li> <li>5. Nomenclature change to allow a single input fuse in the live/+ line.</li> <li>6. Increased X capacitor C7 from 330n to 470n max, XR54 and XR55 discharge resistors reduced to 270kohm max. (discharge test)</li> <li>7. F2 fault test. (fault test for F2 non Safety critical component)</li> <li>8. Increased Y capacitors C21 and C22 from 3n3 to 4n7. (leakage test)</li> <li>9. Addition/deletion of multilayer PWBs to critical component list.</li> <li>10. Perforated Cover option added. (Creepage and Clearance assessment, Electric Strength)</li> <li>11. Assessed to MOPP input to Earth and output to Earth.</li> </ol> <p>Based on previously conducted testing and the review of product construction, only the following additional tests were considered necessary:</p> <ul style="list-style-type: none"> <li>- Clause 5.7 Humidity Conditioning</li> <li>- Clause 8.4.3 Voltage or charge limitation</li> <li>- Clause 8.5.4 Working voltage measurement</li> <li>- Clause 8.7 Leakage current test</li> <li>- Clause 8.8.3 Dielectric Voltage Withstand</li> <li>- Clause 11 Temperature</li> <li>- Clause 13 Abnormal operation and single fault conditions</li> </ul> <p>All other required tests were carried out under the original investigation.</p> <p><b>Model Differences:</b></p>	

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

#### Technical Considerations:

- 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.
- Multilayer PWB's accepted under CBTR Ref. No. E349607-A23 dated 2014-07-31 and letter report Enclosure 8-05 of this report.

**1. Scope of Power Supply evaluation defers the following clauses to be determined as part of the end product investigation:**

- Clause 7.5 (Safety Signs),
- Clause 7.9 (Accompanying Documents),
- Clause 9 (ME Hazard), except 9.1 and 9.3 are evaluated,
- Clause 10 (Radiation),
- Clause 14 (PEMS),
- Clause 16 (ME Systems)
- Risk Management was excluded from this investigation.

**2. Risk Controls/ Engineering Considerations for component power supply:**

**For use only in or with complete equipment where the acceptability of the combination is determined by the CB Testing Laboratory, when installed in an end-product, consideration must be given to the following:**

For Power Supplies with No RM: End product Risk Management Process to include consideration of requirements specific to the Power Supply.

**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: 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.

- For open frame models H4 is the PWB fixing point connecting to J1 protective earth.
- The equipment has been evaluated as a Class 1 unit (and Class II for EFE400MxD models), 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.
- Output circuits have not been evaluated for direct patient connection (Type B, BF or CF)
- The product was submitted and evaluated for use at the maximum ambient temperature (T<sub>ma</sub>) 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: 240Vrms, 340Vpeak
- Insulation separation between: Primary and Earth is one MOPP: 381Vrms, 672Vpeak
- Insulation separation between: Primary and secondary is 2 MOPP: 396Vrms, 922Vpeak
- Altitude of operation: 3000m
- The perforated cover when fitted to the EFE400MxD models (Class II) must be treated as a live part with 1 MOPP insulation to primary and 1 MOPP insulation to secondary.
- Clause 8.7 Leakage Currents and Patient Auxiliary Currents for EFE400MxD models requires assessment in the end equipment.