
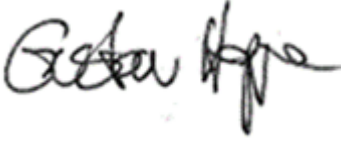





Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No.:	E349607-D1013-1/A2/C0-CB
Date of issue	2019-10-06; 2020-03-31 (A1); 2020-11-23 (A2)
Total number of pages:	246
CB Testing Laboratory:	UL International Demko A/S
Address	Borupvang 5A, DK-2750 Ballerup, Denmark
Applicant's name:	TDK-Lambda UK Limited
Address	Kingsley Avenue, Ilfracombe Devon, EX34 8ES United Kingdom
Test specification:	
Standard	IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)
Test procedure	CB Scheme
Non-standard test method:	N/A
Test Report Form No.:	IEC60601_1P
Test Report Form Originator	UL(US)
Master TRF	2019-10-11
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General disclaimer:	
<p>The test results presented in this report relate only to the object tested.</p> <p>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.</p>	

Test item description:	Switch mode power supply	
Trade Mark:	Trademark image(s):	
		
Original Product/Equipment Manufacturer	Same as Applicant	
Branding Manufacturer(s):		
Model/Type reference:	EFE300M Series (see model differences for details of models and nomenclature)	
Ratings:	100-240Vac nom, 45-63Hz, 4.9A rms max. (see model differences for details of models and ratings)	
Testing procedure and testing location:		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	
Testing location/ address	UL International Demko A/S Borupvang 5A, DK-2750 Ballerup, Denmark	
Tested by (name, function, signature)	Gustav Hoppe, Handler	
Approved by (name, function, signature) ..	Sven Friis, Reviewer	
<input type="checkbox"/>	Testing procedure: CTF Stage 1:	
Testing location/ address		
Tested by (name, function, signature)		
Approved by (name, function, signature) ..		
<input type="checkbox"/>	Testing procedure: CTF Stage 2:	
Testing location/ address		
Tested by (name, function, signature)		
Witnessed by (name, function, signature) ..		
Approved by (name, function, signature) ..		
<input checked="" type="checkbox"/>	Testing procedure: CTF Stage 3:	
<input type="checkbox"/>	Testing procedure: CTF Stage 4:	

Testing location/ address :	TDK-Lambda UK Limited Kingsley Avenue, Ilfracombe Devon, EX34 8ES United Kingdom	
Tested by (name, function, signature) :	M. Carter, Tester	See Original Test report for signatures.
Witnessed by (name, function, signature) . :	N/A	
Approved by (name, function, signature) .. :	Michael Jespersen, Approver	See Original Test report for signatures.
Supervised by (name, function, signature) :	Hedieh Naderi, Handler	See Original Test report for signatures.

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

Refer to Appendix A of this report. All attachments are included within this report.

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

Refer to the Test List in Appendix B of this report if testing was performed as part of this evaluation.

Summary of compliance with National Differences

List of countries addressed: Austria, Republic of Korea, USA, Canada, United Kingdom, Sweden, Japan, Israel

[X] The product fulfils the requirements of IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint).

Statement concerning the uncertainty of the measurement systems used for the tests

(may be required by the product standard or client)

Internal procedure used for type testing through which traceability of the measuring uncertainty has been established:

Procedure number, issue date and title:

Calculations leading to the reported values are on file with the NCB and testing laboratory that conducted the testing.

Statement not required by the standard used for type testing

(Note: When IEC or ISO standard requires a statement concerning the uncertainty of the measurement systems used for tests, this should be reported above. The informative text in parenthesis should be delete in both cases after selecting the applicable option)

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

GENERAL INFORMATION			
Test item particulars(see also Clause 6):			
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		
Testing			
Date of receipt of test item(s)	2019-05-23		
Dates tests performed	2019-06-11		
Possible test case verdicts:			
- 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)		
Abbreviations used in the report:			
- normal condition	N.C.	- single fault condition.....	S.F.C.
- means of Operator protection	MOOP	- means of Patient protection	MOPP

General remarks:

"(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.

Throughout this report a point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IEC60060-1:2012

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: Yes

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies)..... :

TDK-LAMBDA UK LTD
Kingsley Avenue, Ilfracombe
Devon, EX34 8ES United Kingdom

TRIO MICROTRONIC CO LTD
SHIJI INDUSTRIAL ESTATE, DONGYONG,
PANYU, GUANGZHOU
GUANGDONG China

TDK-LAMBDA CORPORATION
2701 TOGAWA SETTAYA, NAGOAKA-SHI
NIIGATA KEN, 940-1195 JAPAN

Trio-Tronics (Thailand) Ltd
7/295 Mu. 6 Map Yang Phon Sub-District Pluak
Daeng District Rayong Province Thailand

General product information:**Report Summary**

This report is a technical amendment of CBTR Ref. No.: E349607-D1013-1/A0/C0-CB , CB Test Certificate Ref. No. DK-88634-UL. Based on the previously conducted testing and a review of product technical documentation including photos, schematics, wiring diagrams and similar, it has been determined that the product continues to comply with the standard.

Within this project (4789388532) the EN standard has been added to the report. Austria, United Kingdom, Sweden and Korea have been added in the country differences section.

Refer to the Report Modifications for any modifications made to this 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.

Additional Information

This report was generated on the basis of report E349607-D6-CB-1 issued on 2015-05-12 by UL International Demko A/S certificate DK-45751-UL to assess AM1 of 60601-1 3rd Edition.

1. Modification of base PWBs to accommodate 2x additional discharge resistors with relevant testing to show continued compliance.
2. Updates to the CCL.
3. Updates to the enclosures.

Technical Considerations

- The product was investigated to the following standards:

Main Standard(s):

IEC 60601-1 Edition 3.1 (2012)

From Country Differences:

- Austria: EN 60601-1:2006/A1:2013

- Republic of Korea: KS C IEC 60601-1

- USA: ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and

A2:2010/(R)2012

- Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
- United Kingdom: BS EN 60601:2006 A1
- Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014
- Japan: National standard JIS T 0601-1:2017 (IEC 60601-1:2005 + A1:2012(MOD))
- Israel: SI 60601 Part 1 (2018-06)

Additional Standards:

EN 60601- 1:2006/A12:2014 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)

ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)

CSA CAN/CSA-C22.2 NO. 60601-1:14 for US and Canada national differences.

- The following additional investigations were conducted: IEC 60601-1 Edition 3.1 (2012) ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) and CSA CAN/CSA-C22.2 NO. 60601-1:14
- 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 following accessories were investigated for use with the product: None
- 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
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 manufacturers 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.

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.

Engineering Conditions of Acceptability

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

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: 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.

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.
- For Power Supplies with No RM: End product Risk Management Process to consider the acceptability of risk for the following components that were identified as High-Integrity Component: i.e. Fuse (F1).
- For Power Supplies with No RM: End product Risk Management Process to consider the need for simultaneous fault condition testing.
- For Power Supplies with No RM: End product Risk Management Process to consider the need for different orientations of installation during testing.

- For Power Supplies with No RM with Exposure Condition outside of Humidity Range: Power Supply tested in 50°C, 40%RH. End product Risk Management Process to determine risk acceptability criteria.
- For Power Supplies with No RM and Insulating Materials: End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- For Power Supplies with No RM and Not tested with Test Corner: Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.
- For Power Supplies with No RM or Units without Cleaning/Disinfection Methods: End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as part of the power supply.
- For Power Supplies with No RM or Units with Liquids: End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply.
- For Power Supplies with No RM or Units with Indicators: End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators as part of the power supply.
- For Power Supplies with No RM or Units with Enclosures: End product to determine the acceptability of risk in conjunction to the results of Mechanical Testing conducted as part of the power supply
- For Power Supplies with No RM: End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions as part of the power supply
- For Power Supplies with Thermal Cut-off and No RM: End product to determine the acceptability of risk in conjunction to the use of Thermal Cut-off and Overcurrent releases as part of the power supply
- For Power Supplies with Pre-set components and No RM: End product to determine the acceptability of risk in conjunction to the use of Pre-set controls as part of the power supply.

Report Modifications

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By
2019-10-06	<p>This report is reissued on the basis of report E349607-D6-CB-1 issued on 2015-05-12 by UL International Demko A/S certificate DK-45751-UL to assess AM1 of 60601-1 3rd Edition. Based on the previously conducted testing, limited testing for this report and the review of product technical documentation including photos, schematics, wiring diagrams and similar, it has been determined that the product complies with the standard.</p> <p>The original report has been modified for the following:</p> <ol style="list-style-type: none"> 1. Modification of base PWBs to accommodate 2x additional discharge resistors with relevant testing to show continued compliance. 2. Updates to the CCL. 3. Updates to the enclosures. 	Hedieh Naderi
2019-03-31	<p>This report is a technical amendment of CBTR Ref. No.: E349607-D1013-1/A0/C0-CB , CB Test Certificate Ref. No. DK-88634-UL. Based on the previously conducted testing and a review of product technical documentation including photos, schematics, wiring diagrams and similar, it has been determined that the product continues to comply with the standard.</p> <p>Within this project (4789388532) the EN standard has been added to the report. Austria, United Kingdom, Sweden and</p>	Hedieh Naderi

	Korea have been added in the country differences section.	
2020-11-18	Administrative Amendment to add new Manufacturer Location Trio-Tronics (Thailand) Ltd. (E349607-D1013-1/A2/C0)	Gustav Hoppe