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-D1012-1/A1/C0-CB
Date of issue.....:	2019-10-06; 2020-03-31 (A1)
Total number of pages.....:	192
CB Testing Laboratory.....:	UL International Demko A/S
Address.....:	Borupvang 5A, DK-2750 Ballerup, Denmark
Applicant's name.....:	TDK-LAMBDA UK LTD
Address.....:	KINGSLEY AVE, ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM 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

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.

General disclaimer:

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.

Test item description.....:	Medical Switch Mode Power Supply
Trade Mark.....:	Trademark image(s): TDK·Lambda
Original Product/Equipment Manufacturer.....:	Same as Applicant
Branding Manufacturer(s).....:	
Model/Type reference.....:	EFE400M or EFE-400M series (see Model Differences for details of models and nomenclature)
Ratings.....:	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)

Testing procedure and testing location:			
[X]	**CB Testing Laboratory:**		
Testing location/ address ..... :		UL International Demko A/S Borupvang 5A, DK-2750 Ballerup, Denmark	
Tested by (name, function, signature) ..... :		Hedieh Naderi, Handler	
Approved by (name, function, signature) .. :		Mikolaj Krukowski, Reviewer	
[ ]	**Testing procedure: CTF Stage 1:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Approved by (name, function, signature) .. :			
[ ]	**Testing procedure: CTF Stage 2:**		
Testing location/ address ..... :			
Tested by (name, function, signature) ..... :			
Witnessed by (name, function, signature) . :			
Approved by (name, function, signature) .. :			

[X]	**Testing procedure: CTF Stage 3:**		
[ ]	**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) ..... :		Nick Marsh, Tester	See the original report for signature
Witnessed by (name, function, signature) . :		N/A	N/A
Approved by (name, function, signature) .. :		Michael Jespersen, Approver	See the original report for signature
Supervised by (name, function, signature) :		Hedieh Naderi, Handler	See the original report for signature

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, Korea, Republic of, USA, Canada, United Kingdom, Sweden, Japan [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
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
Testing	
Date of receipt of test item(s) .....:	2014-11-21 and 2019-06-03
Dates tests performed .....:	2014-12-01 to 2015-01-15 and 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 [ ] comma / [x] point is used as the decimal separator.

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

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012

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)..... :	Same as Applicant PANYU TRIO MICROTRONIC CO., LTD, SHIJI INDUSTRIAL ESTATE, DONGYONG, NANSHA GUANGZHOU, GUANGDONG CHINA

General product information:

Report Summary

This report is a technical amendment of CBTR Ref. No.: E349607-D1012-1/A0/C0-CB, CB Test Certificate Ref. No.DK-88676-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.

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

Product Description

Medical Switch Mode Power Supply (see Model Differences for details of models and nomenclature)

- 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.

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 (Description :) may be prefixed by SP followed by / or – (SP represents a sales code)

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.
N for no remote signals

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:

	Vout Nom.	Adjustment Range (V)	Output Current (A)	Maximum Power (W)
Output 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
	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 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):

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 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
  - Korea, Republic of: KS C IEC 60601-1
  - USA: AAMI/IEC 60601-1:2005 + AMD 1:2012
  - 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))

  Additional Standards:

  EN 60601- 1:2006/A1:2013/A12:2014 (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 following additional investigations were conducted: None

- 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
- None

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:
- 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 (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: 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.

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By
2019-10-06	This report is reissued based on CBTR Ref. No. E349607-D9-CB-1 dated 2015-04-30, CB Test Certificate Ref. No.DK-	Hedieh Naderi

	46068- UL dated 2015-06-05, with the following changes: 1. Enclosures updated. 2. Extra discharge resistors added 3. Critical Component List updated. Based on previously conducted testing and the review of product construction, only the following additional tests were considered necessary: Clause 8.4.3 Voltage or charge limitation All other required tests were carried out under the original investigation.	
2019-03-31	This report is a technical amendment of CBTR Ref. No.: E349607-D1012-1/A0/C0-CB, CB Test Certificate Ref. No.DK-88676-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, Korea and Japan have been added in the country differences section.	Hedieh Naderi