


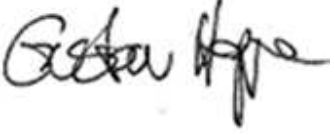



Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance	
Report Reference No:	E349607-D1003-2/A1/C0-ULCB
Date of issue	2020-06-17; 2021-03-15 (A1)
Total number of pages:	201
CB Testing Laboratory:	UL International Polska Sp. z o.o. Równoległa 4 PL-02-235 Warszawa Poland
Applicant's name:	TDK-Lambda UK Ltd
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 supplies
Trade Mark.....:	Trademark image(s): 
Original Product/Equipment Manufacturer.....:	Same as Applicant
Branding Manufacturer(s).....:	
Model/Type reference.....:	CUS150M (may be prefixed and followed by alphanumeric characters - See model differences section for details of nomenclature). CUS100ME (may be prefixed and followed by alphanumeric characters - See model differences section for details of nomenclature). KCUS100ME-32/0001# (where # can be any letter or character indicating non-safety related changes).
Ratings.....:	Input: CUS150M-xxVx/yyyy 100-240Vac; 47-63Hz; 2.2Arms Max. CUS150MD-xxVx/yyyy 133-318Vdc, 1.8A CUS100ME-xxVx/yyyy 100-240Vac; 47-63Hz; 1.4Arms Max. KCUS100ME-32/0001# 100-240Vac +10%/-20%; 47-63Hz; 1.4Arms Max. Output: CUS100ME-12/yyyy output: 12-13.2Vdc 8.33A CUS100ME-15/yyyy output: 15-16.5Vdc 6.66A CUS100ME-18/yyyy output: 18-19.8Vdc 5.55A CUS100ME-24/yyyy output: 24-26.4Vdc 4.16A CUS100ME-28/yyyy output: 28-30.8Vdc 3.57A CUS100ME-36/yyyy output: 36-39.6Vdc 2.77A CUS100ME-48/yyyy output: 48-50Vdc 2.08A KCUS100ME-32/0001# output: 32.2Vdc 3.11A CUS150M-12/yyyy output: 12-13.2Vdc 12.5A CUS150M-15/yyyy output: 15-16.5Vdc 10A CUS150M-18/yyyy output: 18-19.8Vdc 8.33A CUS150M-24/yyyy output: 24-26.4Vdc 6.25A CUS150M-28/yyyy output: 28-30.8Vdc 5.4A CUS150M-36/yyyy output: 36-39.6Vdc 4.2A

		CUS150M-48/yyyy output: 48-50Vdc 3.125A
		Each output has a range shown in the table above which is factory configurable only.
		For further details please see model differences section.
Testing procedure and testing location:		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	
Testing location/ address		UL International Polska Sp. z o.o. Równoległa 4 PL-02-235 Warszawa Poland
Tested by (name, function, signature)		Gustav Hoppe, Project Handler 
Approved by (name, function, signature) ..		Shahab Musavian, 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 LTD KINGSLEY AVE ILFRACOMBE EX34 8ES UNITED KINGDOM
Tested by (name, function, signature)		Nick Marsh (Safety Engineer) See the original CBTR for signature
Witnessed by (name, function, signature) ..		Maciej Gryczan (Project Handler) See the original CBTR for signature

Approved by (name, function, signature) .. :	Dennis Butcher (Reviewer)	See the original CBTR for signature
Supervised by (name, function, signature) :	Dennis Butcher (Reviewer)	See the original CBTR 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 D 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, 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:	Component part of host equipment
Device type (component/sub-assembly/ equipment/ system):	Component Switch Mode Power Supply
Intended use (Including type of patient, application location):	To supply regulated power
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)	2017-01-12, 2017-01-19, 2017-01-27; 2017-07-11 (A1); 2018-01-03, 2018-01-12, 2018-01-15 (A2); N/A (A3); 2020-06-10 (R2);
Dates tests performed	2017-02-17 to 2017-02-28, 2017-03-3 to 2017-03-06, 2017-04-04; 2017-07-20 (A1); 2018-02-22 to 2018-03-14 (A2); N/A (A3); 2020-06-12 (R2)
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.
- means of Operator protection	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection	MOPP
General remarks:	
<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>Throughout this report a point is used as the decimal separator.</p>	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60060-2:2012	
<p>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</p> <p>.....: Yes</p>	
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

PANYU TRIO MICROTRONIC CO. LTD
SHIJI INDUSTRIAL ESTATE
DONGYONG, NANSHA, GUANGZHOU
GUANGDONG CHINA

TDK-Lambda Malaysia Sdn. Bhd.
Lot 2 & 3, Batu 9 3/4, Kawasan Perindustrian
Bandar Baru Jaya Gading
26070 Kuantan, Pahang Malaysia

General product information:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.

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

Product Description

The CUS150M is a power supply for building in to end equipment. It is available as open frame, U chassis, U chassis and lid, base plate and with a top fan version.

The power supply can be used as either a Class I or a Class II construction.

- For Class I construction, the power supply will need to be reliably earthed, professionally installed and fixed with suitable, metal screws.
- For Class II construction no earthing connection is required. The power supply needs to be fixed so that it is insulated from any unearthed accessible conductive part by reinforced insulation.

The power supply provides two fuses for input protection. One in the Live line and one in the Neutral line. Option E uses one fuse only. This is fitted in the live line only.

The power supply can be forced air (top fan or customer air), convection or conduction cooled. Due to the fact that air flow for cooling depends on end product use, only convection cooling and top fan configurations were considered during temperature measurement.

The component temperatures listed in the additional information shall not be exceeded.

Model Differences

The CUS has two ranges of 100W and 150W each with seven nominal output voltages of 12, 15, 18, 24, 28, 36 and 48 Volt. Each output has a range shown in the table below which is factory configurable only.

CUS models as described below:

Units may be marked with a Product Code: CUSZ-xxVx/yyyy where Z is 100ME or 150M and x may be any number of numbers or left blank to indicate the output voltage. V represents a decimal place when required or can be left blank. y can be blank or any number of numbers or letters (excluding M, E, U, A, F, B, H) when indicating non-safety related model differences. y can be M, E, U, A, F, B when indicating the standard options as listed below.

Unit Product Code may be prefixed by K, SP # and/or NS # followed by / or - (where # may be any number of characters indicating non-safety related model differences).

Unit Product Code:

CUSZ-xxVx/yyyy

Where:

Z = 150M for 150W model (may be followed by 'D' for DC input), 100ME for 100W model

xxVx = Channel 1 output voltage from within the output voltage adjustment range from the Output Parameters Tables below.

yyyy = Unit options from list of standard unit options below, or non-safety related model differences:

/M = Molex connectors

/E = Single fuse in the live line

/U = U chassis

/A = Cover and U chassis

/F = Top fan, cover and U chassis (CUS150M model only)

/B = Baseplate

Non standards

KCUSZ-xxVx-yyyy/H

Where:

Z = 100ME for 100W model

xxVx = Channel 1 output voltage from within the output voltage adjustment range from the Output Parameters Table below.

yyyy = Unit options from list of standard unit options below, or non-safety related model differences

/M = Molex connectors

/E = Single fuse in the live line

/U = U chassis

/A = Cover and U chassis

/F = Top fan, cover and U chassis (CUS150M model only)

/B = Baseplate

Followed by

/H = alternate link wire and discharge resistors

KCUS100ME-32/0001# is electrically identical to CUS100ME series except for the following:

- model designation

- Input tolerances (see Ratings for details).

- output ratings

- Input (J1)/Output (J100) connectors are placed on the underside of the PCB and J2 not fitted.

Input Parameters

Nominal input voltage: 100 - 240Vac, 133 - 318Vdc*

Input voltage range : 85 - 264Vac, 120 - 350Vdc*

Input frequency range: 47 - 63Hz, DC*

Maximum input current: 2.2A rms (CUS150M), 1.4A rms (CUS100ME) 1.8A*

* 60601-1 2nd ed, 300Vdc input max. DC rating applies for CUS150M family only.

All ratings apply for ambient temperatures up to 50°C. (see Variations and Limitations below)

Output power is reduced linearly by 10% for input voltages from 90 to 85Vac

Output Parameters

There are seven CUS150M and CUS100ME standard models as shown in the tables below. All of these models may be fan(CUS150M model only), forced air, conduction or convection cooled. The output parameters are shown in the tables below.

Outputs are not user adjustable but can be factory set.

CUS150M

Model	Vout Range (V)	*Fan Vnom (V)	Max Iout (A)	Max Pout (W)	*Fan Inom (A)	Output ratings Pnom (W)
12	12-13.2	11.6	12.5	150	0.5	5.8
15	15-16.5	9.8	10	150	0.5	4.9
18	18-19.8	11.6	8.33	150	0.5	5.8
24	24-26.4	11.6	6.25	150	0.5	5.8
28	28-30.8	10.8	5.4	150	0.5	5.4
36	36-39.6	11.6	4.2	150	0.5	5.8
48	48-50	11.6	3.125	150	0.5	5.8

* Fan output tracks Vout Range

Variation and Limitations:

Customer Forced Air Cooling max ambient 85°C (note 1)

Convection and conduction/cold plate Cooling (U chassis with lid-Option A) max ambient 75°C (note

1)

Convection and conduction/cold plate Cooling (U chassis and open frame) max ambient 80°C (note 1)

Fan supplied ratings/Option F max ambient 70°C, from 50°C to 70°C the output power is de-rated by 0.5°C per watt

Note 1. Maximum output power and current ratings are dependent on the ambient used in the end equipment.

CUS100M

Model	Vout Range (V)	Max Iout (A)	Max Pout (W)
12	12-13.2	8.33	100
15	15-16.5	6.66	100
18	18-19.8	5.55	100
24	24-26.4	4.16	100
28	28-30.8	3.57	100
36	36-39.6	2.77	100
48	48-50	2.08	100

Variation and Limitations:

Customer Forced Air Cooling max ambient 85°C (note 1)

Convection and conduction/cold plate Cooling (U chassis with lid-Option A) max ambient 75°C (note

1)

Convection and conduction/cold plate Cooling (U chassis and open frame) max ambient 80°C (note 1)

Note 1. Maximum output power and current ratings are dependent on the ambient used in the end equipment.

Additional Information

Cooling for units with forced air cooling (Except option F)

The product can also operate at input voltage lowered to 85Vac with linear output de-rating to -10%.

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 stabilized.

CUS150M Cooling for Unit Temperature Table:

Circuit Ref.	Description	Max. Temperature (°C)
L1	Common Mode Choke	110 (130)
L2	PFC choke	125 (130)
L3	Differential mode choke	125 (130)
C1	Film capacitor	105
C2, C110	Electrolytic Capacitors	86 (105)
C6, C102, C104, C105	Electrolytic Capacitors	92 (105)
C3	X Capacitor	100
C5, C100, C101, C103,	Y Capacitors	105
TX100	Transformer Winding	110

XU101, XU102	Opto-Coupler	100	(110)
XD8	Diode		130
J1	Input Connector		105
J100	Output Connector		105
CUS100ME Cooling for Unit Temperature Table:			
Circuit Ref.	Description	Max.	Temperature(°C)
L1	Common Mode Choke		110 (130)
L2	PFC choke		125 (130)
L3	Differential mode choke		125 (130)
C1	Film capacitor		105
C2	Electrolytic Capacitors		90 (105)
C104, C105	Electrolytic Capacitors		92 (105)
C6, C102	Electrolytic Capacitors		93 (105)
C3	X Capacitor		100
C5, C100, C101, C103,	Y Capacitors		105
TX100	Transformer Winding		110
XU101, XU102	Opto-Coupler		100 (110)
XD8	Diode		130
J1	Input Connector		105
J100	Output Connector		105

Higher temperature limits (in brackets) may be used but product life may be reduced.

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
- Israel: SI 60601 Part 1 (2018-06)

Additional Standards:

EN 60601-1:2006/A1:2013, KS C IEC 60601-1, ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, BS EN 60601:2006 A1, SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

- The following additional investigations were conducted: n/a
- The product was not investigated to the following standards or clauses: Biocompatibility, PESS, EMC, Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product: n/a
- No Other Considerations

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 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: 20A

The investigated pollution degree is: II

Proper bonding to the end product main protective earthing termination is: required in a Class I application

The following magnetic devices (e.g. transformers or inductor) are provided with an OBJ2 insulation system with the indicated rating greater than Class A (105°C): TX100 (class B)

The following end-product enclosures are required: Mechanical, Fire, Electrical

EMC compliance has not been verified nor has it been taken into consideration. An accredited EMC Test Report will be required in conjunction with the Certification of the end product.

All models require component temperatures to be monitored as detailed in the additional information.

The end-product Dielectric Strength Test is to be based upon a maximum working voltage of: Primary-Secondary: 240 Vrms, 480 Vpk, Primary-Earthed Dead Metal: 350 Vrms, 410 Vpk, Secondary outputs-Earthed Dead Metal: 240Vrms, 340Vpk.

Report Modifications

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By
2017-08-29	Amendment 1: measurements of earth leakage current and touch current repeated per client's request (E349607-D1003-1/A1/C0-ULCB)	Hubert Koszewski
2018-03-21	Amendment 2: Technical amendment was issued in order to add CUS100ME, CUS150M-15, CUS150M-18, CUS150M-28, CUS150M-36 and DC rated version of CUS150M series. Due to the modification following report sections were modified: general product information, insulation table, clause list and test tables. Only limited testing was considered necessary due to similarity to previously evaluated construction. This amendment shall be read in conjunction with the Original CB Report No.E349607-D1003-1/A0/C0-ULCB and Amendment-1 issue 2017-08-29.	Krzysztof Wasilewski
2019-11-18	This is an administrative Amendment Report of the original CB Report Ref. No. E349607-D1003-1/A0/C0-ULCB issue 2017-4-14, Certificate CB Test Certificate Ref. No. CB-DK-63107-UL and CB-DK-63108-UL to include a new factory in Malaysia. No tests were considered necessary due to these changes.	Grzegorz Kowalski
2020-06-17	This Reissue 2 of the original CB Report Ref. No. E349607-D1003-1/A0/C0-ULCB issued 2017-4-14, Certificate CB Test Certificate Ref. No. CB-DK-63107-UL and CB-DK-63108-UL contains: - update to the P version of TRF - addition of new model KCUS100ME-32/0001# that is electrically identical to CUS100ME series except for the following: - model designation - Input tolerances (see Ratings for details). - output ratings	Maciej Gryczan

	<p>- Input (J1)/Output (J100) connectors are placed on the underside of the PCB and J2 is not fitted (see List of Critical Components for details)</p> <p>- addition of CTF 3 stage testing laboratory</p> <p>Based on previously conducted testing and the review of product construction, only Power Input, Dielectric Strength, Temperature, Abnormal Operation tests were deemed necessary.</p>	
2021-03-15	<p>Technical Amendment 1 to E349607-D1003-2/A0/C0-ULCB: LOCC to include alternate Input Connector 5273 Series form Molex and change in Manufacturers name for TX100 insulaiton system. No testing was deemed necessary (E349607-D1003-2/A1/C0)</p>	Gustav Hoppe