



Test Report issued under
the responsibility of:



TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1:General requirements for safety

Report Reference No : E349607-A44-CB-1
Date of issue : 2017-04-28
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CB Testing Laboratory : UL International Polska Sp. z o.o.
Address : Aleja Krakowska 81, 05-090 Sekocin Nowy, Poland

Applicant's name : TDK-LAMBDA UK LTD
KINGSLEY AVE
Address : ILFRACOMBE
EX34 8ES UNITED KINGDOM

Test specification:

Standard : IEC 60601-1:1988 + A1:1991 + A2:1995
Test procedure : CB Scheme
Non-standard test method : N/A

Test Report Form No. : IEC60601_1c/97-04
Test Report Form originator : UL LLC
Master TRF : dated 97-04

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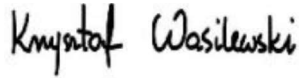

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Test item description	Switch mode power supply
Trade Mark	
Manufacturer	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE EX34 8ES UNITED KINGDOM
Model/Type reference	CUS150M (may be prefixed and followed by alphanumeric characters - See model differences section for details of nomenclature) CUS100M (may be prefixed and followed by alphanumeric characters - See model differences section for details of nomenclature)
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. 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 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. Aleja Krakowska 81, 05-090 Sekocin Nowy, Poland
<input type="checkbox"/> Associated CB Test Laboratory	Testing location / address..... :
	Tested by (name + signature) : Krzysztof Wasilewski (handler) 
	Approved by (name + signature) ... : Bruno Motta (Reviewer) 
<input type="checkbox"/> Testing Procedure: TMP/CTF Stage 1	
	Tested by (name + signature) : _____
	Approved by (+ signature) : _____
	Testing location / address..... : _____
<input type="checkbox"/> Testing Procedure: WMT/CTF Stage 2	
	Tested by (name + signature) : _____
	Witnessed by (+ signature)..... : _____
	Approved by (+ signature) : _____
	Testing location / address..... : _____
<input type="checkbox"/> Testing Procedure: SMT/CTF Stage 3 or 4	
	Tested by (name + signature) : _____
	Approved by (+ signature) : _____
	Supervised by (+ signature) : _____
	Testing location / address..... : _____
<input type="checkbox"/> Testing Procedure: RMT	
	Tested by (name + signature) : _____
	Approved by (+ signature) : _____
	Supervised by (+ signature) : _____
	Testing location / address..... : _____

List of Attachments
National Differences (0 pages)
Enclosures (25 pages)
Summary Of Testing
Unless otherwise indicated, all tests were conducted at UL International Polska Sp. z o.o. Aleja Krakowska 81, 05-090 Sekocin Nowy, Poland.
Tests performed (name of test and test clause)
Testing location / Comments

Power Input (7.1)	Test performed acc. to IEC 60601-1 Edition 3.1 (2012) and results accepted basing on tests similarity between standard editions.
Voltage Limitation - Part 1 (15B)	Test performed acc. to IEC 60601-1 Edition 3.1 (2012) and results accepted basing on tests similarity between standard editions.
Leakage Current (19)	Test performed acc. to IEC 60601-1 Edition 3.1 (2012) and results accepted basing on tests similarity between standard editions.
Dielectric Voltage Withstand (20.4)	Test performed acc. to IEC 60601-1 Edition 3.1 (2012) and results accepted basing on tests similarity between standard editions.
Temperature (42)	Test performed acc. to IEC 60601-1 Edition 3.1 (2012) and results accepted basing on tests similarity between standard editions.
Humidity Preconditioning Treatment (44.5)	Test performed acc. to IEC 60601-1 Edition 3.1 (2012) and results accepted basing on tests similarity between standard editions.
Abnormal Operation and Fault Conditions (52)	Test performed acc. to IEC 60601-1 Edition 3.1 (2012) and results accepted basing on tests similarity between standard editions.
Transformer Overload and Short-Circuit (57.9.1)	Test performed acc. to IEC 60601-1 Edition 3.1 (2012) and results accepted basing on tests similarity between standard editions.

Summary of Compliance with National Differences:

Countries outside the CB Scheme membership may also accept this report.

List of countries addressed: AT, AU, BE, BR, CA, CH, CZ, DE, DK, FI, FR, GB, GR, HU, IL, IN, IT, JP, KR, NL, NO, PL, RU, SE, SG, SI, SK, UA, US

Copy of Marking Plate - Refer to Enclosure titled Marking Plate for copy.

Test item particulars :	
Classification of installation and use	Switch mode power supply for building into end medical equipment
Supply connection	Power supply for building in. Not for direct connection to mains supply.
Accessories and detachable parts included in the evaluation	None
Options included	None
Possible test case verdicts:	
- test case does not apply to the test object	N / A
- test object does meet the requirement	P(Pass)
- test object does not meet the requirement	F(Fail)
Abbreviations used in the report:	
- normal condition	N.C. - single fault condition
- operational insulation	OP - basic insulation
- basic insulation between parts of opposite polarity:	BOP - supplementary insulation
- double insulation	DI - reinforced insulation
Testing:	
Date(s) of receipt of test item	2018-01-03, 2018-01-12, 2018-01-15
Date(s) of Performance of tests	2018-02-22 to 2018-03-14
General remarks:	
List of test equipment must be kept on file and be available for review.	
"(see Enclosure #)" refers to additional information appended to the report.	
"(see appended table)" refers to a table appended to the report.	
Throughout this report a point is used as the decimal separator.	
Manufacturer's Declaration per Sub Clause 4.2.5 of IECEE 02:	
	Yes
The application for obtaining a CB Test Certificate includes more than one factory 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	
When differences exist, they shall be identified in the General Product Information section.	
Name and address of Factory(ies):	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE EX34 8ES UNITED KINGDOM PANYU TRIO MICROTRONIC CO LTD SHIJI INDUSTRIAL ESTATE DONGYONG NANSHA

GUANGZHOU
GUANGDONG CHINA

GENERAL PRODUCT INFORMATION:

Report Summary

The original report was modified on 2018-03-28 to include the following changes/additions:
Technical amendment was issued in order to add CUS100ME, CUS150M-15, CUS150M-18, CUS150M-28, CUS150M-36 and DC rated version of CUS150M series. Only limited testing was considered necessary due to similarity to previously evaluated construction. Tests performed acc. IEC 60601-1:2005 +A1:2012 were accepted based on similarity in test conditions.

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 left 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

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*

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.

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 Max Max		*Fan Output ratings		
		Vnom (V)	Iout (A)	Pout (W)	Inom (A)	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

Amendment1

The original test report was modified due to the following changes:

- leakage current test repeated per the client's request, new measurements replaced the previous test results.

No construction changes in the product.

Based on the new test results and the results from the previous investigation the product continues to comply with the requirements of the Standard.

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. Only limited testing was considered necessary due to similarity to previously evaluated construction.

Cooling for units with forced air cooling

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 stabilised.

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 additional standards: EN 60601-1: 1990 + A1:1993 + A2:1995, (except EMC limitations, EN 60601-1-2, Biocompatibility, EN 10993-1, Programmable Electronic Systems, IEC 60601-1-4), CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada)
- The product was not investigated to the following standards or clauses: Clause 52.1, Programmable Electronic Systems (IEC 601-1-4), Clause 48, Biocompatibility (ISO 10993-1), Clause 36, Electromagnetic Compatibility (IEC 601-1-2)
- The product is Classified only to the following hazards: Shock, Fire
- The degree of protection against harmful ingress of water is: Ordinary
- The following accessories were investigated for use with the product: No accessories
- The mode of operation is: Continuous
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No
- Above 50°C the total output power and current ratings are both de-rated to ensure power curves are met. The following maximum temperatures are allowed with the output de-rated: 70°C with top fan supplied, 75°C with top cover, 80°C open frame and U chassis, 85°C customer forced air cooling --
- 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. --

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, Earth 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 OBJY2 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 --
- All models require component temperatures to be monitored as detailed in the additional information --
- 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. --