

	Test Report issued under the responsibility of:	
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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
Total number of pages	13

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
Address	KINGSLEY AVE 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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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 switch mode power supplies (see model differences for details of nomenclature)
Ratings	Input: 100-240Vac; 47-63Hz; 2.2Arms Max. Output: (see model differences for details)

Testing procedure and testing location:	
<input checked="" type="checkbox"/>	<p>CB Testing Laboratory Testing location / address..... : UL International Polska Sp. z o.o. Aleja Krakowska 81, 05-090 Sekocin Nowy, Poland</p> <p><input type="checkbox"/> Associated CB Test Laboratory Testing location / address..... : Tested by (name + signature) : Hubert Koszewski, Handler  Approved by (name + signature) ... : Dennis Butcher, Reviewer </p>
<input type="checkbox"/>	<p>Testing Procedure: TMP/CTF Stage 1 Tested by (name + signature) : _____ Approved by (+ signature) : _____ Testing location / address..... : _____</p>
<input type="checkbox"/>	<p>Testing Procedure: WMT/CTF Stage 2 Tested by (name + signature) : _____ Witnessed by (+ signature)..... : _____ Approved by (+ signature) : _____ Testing location / address..... : _____</p>
<input type="checkbox"/>	<p>Testing Procedure: SMT/CTF Stage 3 or 4 Tested by (name + signature) : _____ Approved by (+ signature) : _____ Supervised by (+ signature) : _____ Testing location / address..... : _____</p>
<input type="checkbox"/>	<p>Testing Procedure: RMT Tested by (name + signature) : _____ Approved by (+ signature) : _____ Supervised by (+ signature) : _____ Testing location / address..... : _____</p>

List of Attachments	
National Differences (0 pages)	
Enclosures (0 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

Leakage Current (19)

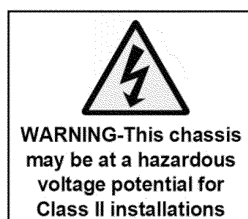
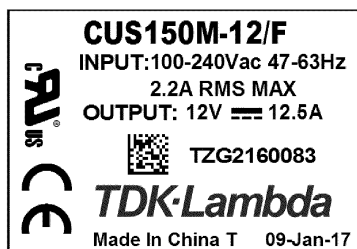
Summary of Compliance with National Differences:

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

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.



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	2017-07-11
Date(s) of Performance of tests	2017-07-20
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 IEC60067-2:	
	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 2017-09-25 to include the following changes/additions:

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.

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, 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) or convection 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

There are three different transformers used. One each for the 12, 24 and 48 Volt models. The secondary output windings have a different amount of turns to get different secondary output voltages. Each output has a range which is set via resistors and non-adjustable for the end user.

CUS150M models as described below:

Units may be marked with a Product Code: CUS150M-xxVx/y where 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 any number of numbers or letters (excluding M, E, U, A, F) when indicating non-safety related model differences. y can be M, E, U, A, F when indicating the standard options as listed below.

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

Unit Product Code:

CUS150M-xxVx/y

Where

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

y = 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

See Enclosure 7-01 for the output parameters tables.

Variations and limitations of use:

1. Component temperatures, for customer air or convection cooled models, must be monitored in the end use application as described in the "Cooling for Unit Temperature Table".

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.

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.

Cooling for unit temperature table:

Circuit Ref.	Description	Max. Temperature (°C)
L1	Common Mode Choke	130
L2	PFC choke	130

L3	Differential mode choke	130
C2, C6, C102, C104, C105	Electrolytic Capacitor	105
C3	X Capacitor	100
C5, C8, C100, C101, C103	Y Capacitor	105
TX100	Transformer Winding	110
XU101, XU102	Opto-Coupler	110
XQ3	FET	130
J1	Input Connector	105
J2	Output Connector	105

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 --

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

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- 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. --