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Report Reference #

E349607-A44-UL

UL TEST REPORT AND PROCEDURE

Standard: UL 60601-1, 1st Edition, 2006-04-26 (Medical Electrical Equipment,

Part 1: General Requirements for Safety)

CAN/CSA-C22.2 No. 601.1-M90, 2005 (Medical Electrical Equipment -

Part 1: General Requirements for Safety)

Certification Type:

CCN:

Component Recognition

QQHM2, QQHM8 (Power Supplies, Medical and Dental)

Product: Switch mode power supply

Model: 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)

Rating:

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.

Applicant Name and Address: TDK-LAMBDA UK LTD

KINGSLEY AVE

EX34 8ES UNITED KINGDOM

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This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Krzysztof Wasilewski (handler)

Reviewed by: Bruno Motta (Reviewer)

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Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

- A. Authorization The Authorization page may include additional Factory Identification Code markings.
- B. Generic Inspection Instructions -
 - Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.
 - ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.
 - iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

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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*

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Input voltage range:

85 - 264Vac,

120 - 350Vdc*

Input frequency range:

47 - 63Hz.

DC*

18A*

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

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

Vout *Fan Max Max		Max	*Fan Output ratings			
Model	Range (V)	Vnom (V)	lout (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

	Vout	Max	Max
Model	Range (V)	lout (A)	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.

Technical Considerations

Classification of installation and use: Switch mode power supply for building into end medical equipment

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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
- 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

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. 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.

Additional Information

Amendment1

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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

C104, C105 C6, C102

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.

CUS	JS150M Cooling for Unit Temperature Table:				
Circ	cuit 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		
TX1	100	Transformer Winding	110		
XU	101, XU102	Opto-Coupler 100	(110)		
XD	8	Diode	130		
J1		Input Connector	105		
J10	00	Output Connector	105		
11	JS100ME Cooling for Unit Temperature Table:				
		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)		
C1	04, C105	Electrolytic Capacitors	92 (105)		

93 (105)

Electrolytic Capacitors

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100 X Capacitor C3 Y Capacitor
Y Capacitors
Transformer Winding
Opto-Coupler
Diode 105 C5, C100, C101, C103, 110 TX100 100 (110) XU101, XU102 130

XD8

Input Connector Output Connector

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

105

105

J100

J1