



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-A41-CB-2
Date of issue : 2017-06-29
Total number of pages : 76

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
DEVON
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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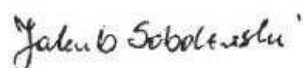
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Test item description	Switch Mode Power Supply
Trade Mark	
Manufacturer	TDK-LAMBDA UK LTD KINGSLEY AVE ILFRACOMBE DEVON EX34 8ES UNITED KINGDOM
Model/Type reference	XMS350 or XMS-350 and XMS500 or XMS-500 series switch mode power supplies (see report Model Differences for details of nomenclature)
Ratings	XMS350, XMS-350: 100-240Vac nom, 47-63Hz, 5.3A rms max. XMS500, XMS-500: 100-240Vac nom, 47-63Hz, 7A rms max. (see report Model Differences for details of nomenclature)

Testing procedure and testing location:	
<input type="checkbox"/> CB Testing Laboratory	Testing location / address..... :
<input type="checkbox"/> Associated CB Test Laboratory	Testing location / address..... :
	Tested by (name + signature) :
	Approved by (name + signature) ... :
<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 checked="" type="checkbox"/> Testing Procedure: SMT/CTF Stage 3 or 4	
Tested by (name + signature) :	N. S. Marsh / Tester 
Approved by (+ signature) :	Hashan Dias / Reviewer 
Supervised by (+ signature) :	Jakub Sobolewski / Reviewer 
Testing location / address..... :	TDK-Lambda UK Ltd, Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United Kingdom
<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 (40 pages)
Summary Of Testing
Unless otherwise indicated, all tests were conducted at TDK-Lambda UK Ltd, Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United Kingdom.

Tests performed (name of test and test clause)	Testing location / Comments
Voltage Limitation - Part 1 (15B)	Only considered tests between line and neutral pins as this is where the additional resistors have been fitted to discharge the X-capacitors.
Working Voltage Measurement (20.3)	
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, SI, SK, UA, US	
The product fulfills the requirements of: EN60601-1:1990 + A1:1993 + A2:1995, UL60601-1, 1st Edition 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601-1-M90 (R2005) (includes National Differences for Canada)	

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

Test item particulars :	
Classification of installation and use	Component part of host equipment
Supply connection	Component part of host equipment
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	2017-04-04
Date(s) of Performance of tests	2018-04-25 to 2018-05-03
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 IEC60061-1:	
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 DEVON 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 2018-06-15 to include the following changes/additions:

The original report was modified on to include the following changes/additions:

This report is a technical amendment to CBTR Ref. No. E349607-A41-CB-2 dated 2017-06-29; E349607-A41-CB-2-Correction-1 dated 2017-07-06 including E349607-A41-CB-2 Amendment 1 dated 2017-12-27 with CB Test Certificates DK-64715-UL dated 2017-07-06 and DK-64715-A1-UL dated 2017-12-27.

Based on previously conducted testing and the 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 and only limited testing was required.

The original report was modified to include the following changes/additions:

1. Addition of alternates to the CCL.
2. Corrections to CCL.
3. Testing of alternate discharge resistors
4. Enclosures updated where applicable

Product Description

XMS350 or XMS500 series switch mode power supplies
(See Model Differences for details of nomenclature)

The series consists of two power outputs, a 350W and 500W, these use the same topology with some component variations.

The XMS series switch mode power supply consists of:

1. Input filter, consisting of the input fuse(s), X and Y capacitors, common mode chokes up to the bridge and series choke after the bridge.
2. PFC (boost circuit), consisting of the boost choke and associated switching FETs/circuitry.
3. Forward converter, consisting of the main transformer and switching FETs/circuitry supplying channel 1 and fan supply outputs.
4. Standby circuit, consisting of the standby transformer and switching IC/circuitry supplying the standby output.
5. Secondary circuits (SELV), consisting of channel 1 output, standby output, fan supply, power OK and inhibit/enable.

Model Differences

XMS350 or XMS500 series (may also be marked as XMS-350 or XMS-500) as described below:

Units may be marked with a Product Code: Xy where y may be any number of characters.

Unit Configuration Code (Description): may be prefixed with NS # followed by / or - (where # may be any number of characters indicating non-safety related model differences).

Unit Configuration (Description)

XMSxy-a-bc-defghijklm

where:

- x = 350 for 350W model
500 for 500W model
500P for 576W peak power models (36V, 40V and 48V output models only)
- y = Blank for Class I
D for Class II
- a = Channel 1 Output Voltage (see Ch1 in the table below, adjustment range column).
- b = Standby Output Voltage: see standby voltage in table below
N for no supply
5 for 5 volt
12 for 12 volt
- c = Standby Output Current:
C for 0.5A
M for 1.0A
H for 2.0A
N for no supply or 0 amps output
- d = Fan Supply:
N for no fan supply (customer cooling)
N1 for 24V fan supply (customer cooling)
N2 for 12V variable supply
N3 for 12V fixed supply
KF for non-standard top fan
TF for top-fan
- e = U for non-standard U chassis
P for perforated frame
N for Open Frame
C for custom chassis/covers for non-standard models
S for standard U chassis
B for standard U chassis with perforated cover
- f = Touch (Enclosure) current:
B for <100uA
T for <75uA
- g = Earth leakage current:
D for Class II (no Earth)
L for <300uA
R for <150uA
T for <100uA
- h = E or In for inhibit
T or En for enable
- i = A for AC OK option
N for no AC OK option
- j = Blank for dual fuses fitted

FL for single fuse fitted in the Live line

klm = Blank for standard output settings

May be three numbers from 0 to 9 (preceded by -) which denotes various output voltage/current settings within the specified ranges of each output for a particular unit. (may define non-safety related parameters/feature, e.g. reduced primary current limit, reduced OVP)

Input Parameters

Nominal input voltage 100 - 240 Vac
 Input voltage range 90 - 264 Vac
 Input frequency range 47 - 63 Hz
 Maximum input current 7A (5.3A*) rms

* Input for 350W models.

All ratings apply for ambient temperatures up to 50°C.

Output Parameters

Output ratings are in accordance with the following table:

Standard models:

Output Channel	Voltage Designation	Vout nom.(V)	Adjustment Range (V)	Output Current (A)	Output Power (W)
CH1 (500W)	12	12	11.6 - 13.2	41.6	500
	24	24	23.8 - 25.2	20.8	500
	36	36	35.4 - 37.8	13.8(16*)	500(576*)
	40	40	38 - 42	12.5(15.16*)	500(576*)
	48	48	47-50	10.4(12*)	500(576*)
CH1 (350W)	24	24	23.8 - 25.2	14.6	350
Standby Option	5	5	5 - 5.5	0.5	2.75
	5	5	5 - 5.5	2.0	11.0
	12	12	12-13.2	1	13.2
	N	10	5 - 15	0	0
Fan Supply	N	-	-	-	-
	N1	24	Fixed	0.2	4.8
	N2	12	6-12	-	3.0
	N3	12	Fixed	0.25	3.0

*576W peak power up to 2 minutes with 500Wrms power using the following formula:

$$500Wrms = ((peakpower^2 \times T1 + reducedpower^2 \times T2)/(T1 + T2))^{1/2}$$

Where T1 = peakpower time on in seconds
 T2 = reducedpower time on in seconds

Non-Standard Models:

X00011#	XMS350-24-NN-N1CBLEN	Customer specific chassis
X00023#	XMS500D-24.5-5C-KFCBDEN	Customer specific top fan/chassis model
X00073#	XMS500-24-NN-NCBRInA	Customer specific chassis/cover

Where # can be any letter denoting non-safety related changes.

Output Limitations:

All outputs are SELV
 Channel 1 is hazardous energy

Additional Information

Cooling for units with customer supplied air (all models except KF and TF fan supplies)

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.

Cooling for unit temperature table:

Circuit Ref:	Description	Max. Temperature (??C) ++
J1	Input Connector	105
C7, C8	X Capacitor	100
L2, L4	Common Mode Choke Winding	130 (145)
L6	Series Mode Choke Winding	130
ASY5 D7	Bridge Diode	125 (130)
C14, C11, C21, C22, C10, C23, C24, C6, C18 (++)	Y Capacitors	100
C26	Capacitor	85 (105)
RLY1	Relay	100
U1, U2, U5, U6, U7 (++)	Opto-Coupler	100
TX1 (Standby)	Windings and core	120 (130)
TX3 500W	Windings and core	120 (130)
TX3 350W	Windings and core	100 (110)
ASY6 Q3	Boost FET	127 (130)
ASY4 Q1	Forward FET	127 (130)
ASY3 Q4	Output FET	127 (130)
C13	Boost Capacitor	80 (105)
C9	Boost Capacitor	70 (105)
L3, L5	Boost Choke Winding	130 (140)
L7	Channel 1 Output Choke	130 (140)

C4, C5, C15, C16, C17
C19, C20 (++)

Electrolytic Capacitors

80 (105)

+ The higher temperature limits in brackets may be used but product life may be reduced.
++ When fitted

ADDITIONAL STANDARDS

EN60601-1:1990 + A1:1993 + A2:1995, UL60601-1, 1st Edition 2006-04-26 (includes National Differences for USA), CAN/CSA-C22.2 No. 601-1-M90 (R2005) (includes National Differences for Canada)

Technical Considerations

- The product was investigated to the following additional standards: EN 60601-1: 1990 + A1:1993 + A2:1995, CAN/CSA-C22.2 No. 601-1-M90 (R2005) (includes National Differences for Canada), UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA),
- 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 (IPX0)
- 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
- Multilayer PWB's accepted under CBTR Ref No. E349607-A23 dated 2014-07-31 and letter report in Enclosure 8-07 of this report. --

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 (except XMSxD model) --
- 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 output, 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: 20A --
- The investigated Pollution Degree is: 2 --
- Proper bonding to the end-product main protective earthing termination is: Required (except XMSxD model) --
- The following magnetic devices (e.g. transformer or inductor) are provided with an OBJ2 insulation system with the indicated rating greater than Class A (105°C): TX1 (Class F), TX3 (Class B or F). --
- The following end-product enclosures are required: Mechanical, Fire, Electrical --

- The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-SELV: 405Vrms, 655Vpk, Primary-Earthed Dead Metal: 365Vrms, 632Vpk --
- An investigation of the protective bonding terminals has: been conducted. --
- Open frame models, H3 is connected to the input connector earth (not applicable to XMSxD model) -
-
- All models require component temperatures monitored as detailed in the Additional Information (except -KF and TF fan models) --
- The product was tested for use at maximum ambient temperature (Tma) 50°C in normal conditions permitted by the manufacturer, see Additional Information for details. --
- The chassis/cover when fitted to the XMSxD (Class II) has basic/supplementary insulation to primary and basic/supplementary insulation to secondary. --
- The Customer fixings screw penetration require special attention: see handbook in enclosures for details. --