Page 1 of 351 Report No.: E349607-D1000-2/A3/C1-UL

Test Report issued under the responsibility of:



IEC 60601-1 Medical electrical equipment

Part 1: General requirements for basic safety and essential performance

2017-07-24; 2017-12-18(A1); 2018-03-09(C1); 2018-05-21

(A2); 2020-08-19 (A3)

Total number of pages: 351

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 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: UL Certification

Non-standard test method.....: N/A

Test Report Form No.....: IEC60601 1P

General disclaimer:

The test results presented in this report relate only to the object tested.

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Page 2 of 351 Report No.: E349607-D1000-2/A3/C1-UL

Test item description:	Switch Mode Power Supply				
Trade Mark:	TDK-Lambda				
Manufacturer:	Same as Applicant				
Model/Type reference: Ratings:	XMS350 or XMS-350 and XMS500, XMS-500, XMS500P, XMS-500P, XMS500AP series switch mode power supplies XMS350, XMS-350: 100-240Vac nom., 47-63Hz, 5.3A rms max. XMS500, XMS-500, XSM500A, XMS500P, XMS-500P, XMS500AP: 100-240Vac nom., 47-63Hz, 7A rms max. (see report Model Differences for details of nomenclature)				
Testing procedure and testing location	:				
[X] UL/DAP Testing Laboratory:					
Testing location/ address:		UL International Polska Sp. z o.o. Aleja Krakowska 81 05-090 Sekocin Nowy, POLAND			
Tested by (name, function, signature):		Maciej Gryczan (Project Handler)	Heitej Gagnen		
Approved by (name, function, signature):		Mona Nielsen (Reviewer)	Michan		
[] Testing procedure: WMT:					
Testing location/ address:					
			T		
Tested by (name, function, signature):					
Approved by (name, function, signature):					
		1			

Page 3 of 351 Report No.: E349607-D1000-2/A3/C1-UL

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.							

Page 4 of 351 Report No.: E349607-D1000-2/A3/C1-UL

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 owners of these marks.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a сору.

Page 5 of 351 Report No.: E349607-D1000-2/A3/C1-UL

GENERAL INFORMATION

Test item particulars(see also Clause 6):

Classification of Installation and Use: For building-in

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: To be determined in the end-product

Accessories and detachable parts included:

Other Options Include:

None

Testing

2015-12-17, 2016-04-21, 2016-04-27, 2016-04-21 to 2016-12-02, 2017-10-18, 2017-04-04, 2018-05-25, 2018-05-30, 2020-04-27, 2020-04-28, 2020-05-19,

2020-06-17

2015-12-17, 2016-04-26 to 2016-05-16, 2016-09-27 to 2016-12-09, 2017-04-07 to 2017-04-27, 2017-10-19 to 2017-11-06, 2018-04-25 to 2018-05-03, 2020-04-28 to

2020-07-07

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

- test object does not meet the requirement...... Fail (F)

Abbreviations used in the report:

- normal condition: N.C. - single fault condition: S.F.C.

- means of Operator protection: MOOP - means of Patient protection: MOPP

Page 6 of 351 Report No.: E349607-D1000-2/A3/C1-UL

General remarks:

"(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.

Throughout this report a point is used as the decimal separator.

GENERAL PRODUCT INFORMATION:

Report Summary

This report was modified to include the addition of XMS500A models, verification of 85V input rating, the addition of an alternate fuse (Conquer UBM-A010) and the addition of an alternate factory address Refer to the Report Modifications for any modifications made to this report.

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 # or K # followed by / or - (where # may be any number of characters indicating non-safety related model differences).

Unit Configuration Code (Description): may be prefixed by SP followed by / or – (SP represents a sales code)

Unit Configuration (Description)

XMSxy-a-bc-defghijklm

where:

x = 350 for 350W model 500 for 500W model

500A for enhanced 500W model (less than 1W inhibited)

500P for 576W peak power models (36, 40V and 48V output models only)

500AP for enhanced 500W model with 576W peak power (36V, 40V, 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

P for Power Good Option (XMS500A or XMS500AP models only)

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 (proceeded 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 85 - 264 Vac

Report No.: E349607-D1000-2/A3/C1-UL

Input frequency range 47 - 63 Hz Maximum input current 7A (5.3A*) rms

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

At 85Vac input the following deratings apply to all XMS500 TF models: 500W output power at 40°C ambient or 400W output power at 50°C ambient

Output Parameters

†Output ratings are in accordance with the following table:

Standard models:

Output Channel	Voltage	Vout	Adjustment	Output	Output
	Designation	nom.(V)	Range (V)	Current (A)	Power (W)
CH1 (500W)	12	12	11.6 - 13.2	41.6	500
	24	24	23.8 - 25.2	20.8	500
	36	36	36	13.8(16*)	500(576*)
	40	40	38 - 42	12.5(15.16	*) 500(576*)
	48	48	47-50	10.4(12*)	500(576*)
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
Fan Supply	N	-	-	-	-
	N1	24	Fixed	0.2	4.8
	N2	12	6-12	-	3.0
	N3	12	Fixed	0.25	3.0
CH1 (350W)	24	24	23.8 - 25.	2 14.6	350
Standby Option	N	10	5 - 15	0	0
Fan Supply	N	-	-	-	-
	N1	24	Fixed	0.2	4.8

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

500Wrms = $((peakpower^2 x T1 + reducedpower^2 x T2)/(T1 + T2))^1/2$

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 -TF and KF fan supply)

^{*} Input for 350W models.