




Test Report issued under the responsibility of:



| IEC 60601-1 | |
|--|---|
| Medical electrical equipment | |
| Part 1: General requirements for basic safety and essential performance | |
| Report Reference No. | E349607-D1000-2/A2/C1-ULCB |
| Date of issue | 2017-07-24; 2017-12-18(A1); 2018-03-09(C1); 2018-05-21 |
| Total number of pages | 310 |
| CB Testing Laboratory | UL International Polska Sp. z o.o. |
| Address | Aleja Krakowska 81 05-090 Sekocin Nowy k/Warszawy POLAND |
| Applicant's name | TDK-Lambda UK Ltd |
| Address | Kingsley Avenue Ifracombe, Devon, EX34 8ES UNITED KINGDOM |
| Test specification: | |
| Standard | IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) |
| Test procedure | CB Scheme |
| Non-standard test method..... | N/A |
| Test Report Form No..... | IEC60601_1K |
| Test Report Form Originator | UL(US) |
| Master TRF | 2015-11 |
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| This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02. | |
| General disclaimer: | |
| The test results presented in this report relate only to the object tested. | |
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| | | |
|---|--|---|
| Test item description: | Switch Mode Power Supply | |
| Trade Mark: | TDK-Lambda | |
| Manufacturer: | Same as Applicant | |
| Model/Type reference: | XMS350 or XMS-350 and XMS500 or XMS-500 series switch mode power supplies | |
| 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 Testing Laboratory: | | |
| Testing location/ address: | | |
| Tested by (name, function, signature): | | |
| Approved by (name, function, signature): | | |
| <input type="checkbox"/> Testing procedure: CTF Stage 1: | | |
| Testing location/ address: | | |
| Tested by (name, function, signature): | | |
| Approved by (name, function, signature): | | |
| <input type="checkbox"/> Testing procedure: CTF Stage 2 | | |
| Testing location/ address: | | |
| Tested by (name, function, signature): | | |
| Witnessed by (name, function, signature): | | |
| Approved by (name, function, signature): | | |
| <input checked="" type="checkbox"/> Testing procedure: CTF Stage 3: | | |
| <input type="checkbox"/> Testing procedure: CTF Stage 4: | | |
| Testing location/ address: | TDK-Lambda UK Ltd, Kingsley Avenue, Ilfracombe, Devon, EX34 8ES, United Kingdom | |
| Tested by (name, function, signature): | Nick Marsh (Tester) |  |

| | | |
|--|--------------------------------|---|
| Witnessed by (name, function, signature): | | |
| Approved by (name, function, signature): | Jakub Sobolewski (Reviewer) |  |
| Supervised by (name, function, signature): | Hashan Dias (Handler) |  |

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.

Summary of compliance with National Differences

List of countries addressed: Austria, Korea, Republic of, USA, Canada, United Kingdom, Sweden

[X] The product fulfils the requirements of IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012

(or IEC 60601-1: 2012 reprint).

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.

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

| 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: | None |
| Other Options Include: | None |
| Testing | |
| Date of receipt of test item(s) | 2015-06-24 to 2015-08-27, 2015-07-17 to 2015-12-17, 2016-04-21, 2016-04-27, 2016-04-21 to 2016-12-02, 2017-10-18, 2017-04-04 |
| Dates tests performed | 2015-07-01 to 2015-09-21, 2015-11-10 to 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 |
| 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 |
| 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. | |
| Manufacturer's Declaration per sub-clause 4.2.5 of IEC60601-1:2012 | |
| The application for obtaining a CB Test Certificate includes more than one factory location 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 | Yes |
| When differences exist; they shall be identified in the General product information section. | |

| | |
|---|---|
| Name and address of factory (ies) | <p>TDK-LAMBDA UK LTD KINGSLEY AVENUE ILFRACOMBE, DEVON, EX34 8ES UNITED KINGDOM</p> <p>PANYU TRIO MICROTRONIC CO. LTD SHIJI INDUSTRIAL ESTATE DONGYONG NANSHA GUANGZHOU GUANGDONG CHINA</p> |
|---|---|

GENERAL PRODUCT INFORMATION:

Report Summary

The report was modified to include the output ratings table in the Model Differences section and the temperature table in the Additional Information section of the report, typographical correction.

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 # 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 (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

TRF No. IEC60601_1K

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 | 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 |

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

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

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 –TF and KF fan supply)

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) ++ |
|--|---------------------------|-----------------------------|
| 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

Amendment 1 (project #4787185482):

This report is the 1st amendment to the original CBTR Ref. No. E349607-D1000-CB-1 dated 2015-06-11 with CB Test Certificate DK-49679-UL dated 2015-06-11.

This E349607-D1000-1/A1/C0 amending Test Report shall be read and reproduced only in conjunction with Original Test Report.

Based on 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.

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

- 1) CH1, 48V unit assessed (CH1 output voltage rated 48V added)
- 2) Standby, 12V, 1A and 5V, 2A assessed (new ratings of standby output)
- 3) Variable speed fan assessed
- 4) Perforated chassis assessed
- 5) Bypass capacitors assessed (C23, C24 added to CCL)
- 6) Critical components updated
- 7) Enclosures updated
- 8) Add standard top fan
- 9) Add standard U chassis
- 10) CBTL changed to CBTL Denmark
- 11) Models designations description revised

Amendment 2 (project #4787424006):

This report is an amendment to CBTR Ref. No. E349607-D1000-1-CB dated 2015-06-11 including E349607-D1000-1/A1/CO-ULCB amendment 1 dated 2016-02-15 with CB Test Certificates DK-49679-UL dated 2015-11-09 and DK-49679-A1-UL dated 2016-02-24.

This E349607-D1000-1/A2/C0 amending Test Report shall be read and reproduced only in conjunction with Original Test Report and previous Amendment.

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 on 2016-06-03 to include the following changes/additions:

- 1) CH1, 12V unit assessed
- 2) Critical components updated/corrected (added C21 and C22 input to chassis Y capacitors)
- 3) Enclosures updated
- 4) XMS350 input current rating corrected to 5.3A
- 5) Added N3 option (as N2 but fixed 12V standby output)
- 6) Added standard 12V top fan
- 7) Clause 15.5.2 corrected
- 8) Table 8.8.3 corrected to include Z primary to secondary

Amendment 3 (project #4787696215):

This report E349607-D1000-1/A3/C0 is the 3rd amendment to CBTR Ref. No. E349607-D1000-1-CB dated 2015-06-11 with amendment 1 dated 2016-02-15 and amendment 2 dated 2016-08-11.

This E349607-D1000-1/A3/C0 amending Test Report shall be read and reproduced only in conjunction with Original Test Report and previous Amendments.

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. Add alternate TX1 flyback transformers
 - 230295 (5V, 0.5A)(winding position changes for EMC)
 - 230294 (5V, 2A), (adding foil for EMC)
 - 230287 (12V, 1A), (winding position changes for EMC)
4. Add alternate GUL wing Lexan insulator
5. Nomenclature changes:
 - g = T for <100uA
 - h = T or En for enable
 - E or In for inhibit
6. XMS500 40V and 48V models add peak power of 576W up to 2 mins
7. C7 X capacitor value increased to 470nF max
8. Add alternate L2 common mode choke

Amendment 1 (Project# 4788143479)

This report is an amendment to CBTR Ref. No. E349607-D1000-2/A0/C0-ULCB dated 2017-07-24 with CB Test Certificates DK-65446-UL dated 2017-06-25.

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 on 2017-11-09 to include the following changes/additions:

1. Addition of alternates to the CCL, add L4 to alternate L2 common mode choke and Rynite base E41938
2. Corrections to CCL. (Rynite UL CCN code)
3. Add X00073# (where # may be any letter) to non-standard models.
4. Add X00073# Gap-pad to CCL

5. Add Nomenclature change:
e = B for standard U chassis with perforated cover
6. Add X00073# Gap-pad drawings to Enclosures
7. Add X00073# chassis and cover drawings to Enclosures
8. Replace the following Enclosures with updated Enclosures:
diagrams 01, 04, 09
manuals 01
miscellaneous 07
9. Add new Enclosures:
photographs 06, 07
diagrams 10 – 14

Technical Considerations

- The product was investigated to the following standards:

Main Standard(s):

ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)

From Country Differences:

- Austria: EN 60601-1:2006/A1:2013
- Korea, Republic of: KS C IEC 60601-1
- USA: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012
- Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
- United Kingdom: BS EN 60601:2006 A1
- Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

Additional Standards:

EN 60601-1:2006/ A11:2011/ A1:2013/ A12:2014 (IEC60601-1, Edition 3.1),
ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012,, C1:2009/(R)2012 and A2:2010/(R)2012
Medical Electrical Equipment - Part 1 (IEC 60601-1:2005, Mod),
CAN/CSA-C22.2 NO. 60601-1:14 - Medical electrical equipment - Part 1 (Adopted IEC 60601-1:2005, third edition, 2005-12, incl. Am1:2012, with Canadian deviations), Third Edition

- The following additional investigations were conducted:
- The product was not investigated to the following standards or clauses: Biocompatibility, PESS, EMC, Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product:
- The product was tested for use at the maximum ambient temperature (T_{ma}) 50°C in normal conditions permitted by the manufacturer, see Additional Information for details.
-
- 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.
-
- 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

Open frame models, H3 is connected to the input connector earth (not applicable to XMSxD model)

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 OBJY2 insulation system with the indicated rating greater than Class A (105°C): TX1 (Class F), TX3 (Class B or F) see Critical Component List for details of insulation systems used.

The following end-product enclosures are required: Mechanical, Fire, Electrical

All models require component temperatures monitored as detailed in the Additional Information (except KF and TF fan models)

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.

Output circuits have not been evaluated for direct patient connection (Type B, BF, CF)

Considerations to the applied parts requirement, to be conducted as end-product.

End product Risk Management Process to be performed to include consideration of requirements specific to the Power Supply.

Report Modifications

| Date Modified | Modifications Made (include Report Reference Number) | Modified By |
|---------------|--|-------------|
|---------------|--|-------------|