

IEC SYSTEM FOR MUTUAL RECOGNITION OF TEST
CERTIFICATES FOR ELECTRICAL EQUIPMENT
(IECEE) CB SCHEME

SYSTEME CEI D'ACCEPTATION MUTUELLE DE
CERTIFICATS D'ESSAIS DES EQUIPEMENTS
ELECTRIQUES (IECEE) METHODE OC

CB TEST CERTIFICATE**CERTIFICAT D'ESSAI OC**

Product
Produit

Component Switching Power Supply

Name and address of the applicant
Nom et adresse du demandeur

XP Power LLC,
15641 Red Hill Ave., Suite 100
Tustin, CA 92780 USA

Name and address of the manufacturer
Nom et adresse du fabricant

XP Power LLC,
15641 Red Hill Ave., Suite 100
Tustin, CA 92780 USA

Name and address of the factory
Nom et adresse de l'usine

XP Power LLC
990 Benecia Ave, Sunnyvale CA 94085
USA

Note: When more than one factory, please report on page 2
Note: Lorsque il y plus d'une usine, veuillez utiliser la 2^{eme} page

Additional Information on page 2

Ratings and principal characteristics
Valeurs nominales et caractéristiques principales

100-240 Vac, 50/60 Hz, 1.2 A
Output Rated: See test report for additional details

Trademark (if any)
Marque de fabrique (si elle existe)



Type of Manufacturer's Testing Laboratories used
Type de programme du laboratoire d'essais
constructeur

Model / Type Ref.
Ref. De type

ECS65USXX
See Page 2

Additional information (if necessary may also be
reported on page 2)
Les informations complémentaires (si nécessaire,,
peuvent être indiqués sur la 2^{eme} page

National Differences specified in the CB Test Report.
 Additional Information on page 2

A sample of the product was tested and found
to be in conformity with
Un échantillon de ce produit a été essayé et a été
considéré conforme à la

IEC 60601-1(ed.3), IEC 60601-1(ed.3);am1

As shown in the Test Report Ref. No. which forms part
of this Certificate
Comme indiqué dans le Rapport d'essais numéro de
référence qui constitue partie de ce Certificat

4786488107-20111012 issued on 2015-01-14

This CB Test Certificate is issued by the National Certification Body
Ce Certificat d'essai OC est établi par l'Organisme **National de Certification**



- UL (US), 333 Pfingsten Rd IL 60062, Northbrook, USA
- UL (Demko), Borupvang 5A DK-2750 Ballerup, DENMARK
- UL (JP), Marunouchi Trust Tower Main Building 6F, 1-8-3 Marunouchi, Chiyoda-ku, Tokyo 100-0005, JAPAN
- UL (CA), 7 Underwriters Road, Toronto, M1R 3B4 Ontario, CANADA

For full legal entity names see www.ul.com/nbnames

Date: 2015-03-18
Original Issue Date: 2014-08-26

Signature:

Jolanta M. Wroblewska



Ref. Certif. No.

US-23822-A1-M1-UL

Model Details:

ECS65USXX (where XX can be any number between 12 and 48 designating the output voltage), may also be provided with suffix "SF" and/or "B", with or without ""

Factories:

XP Power (Kunshan) Limited.
230, Bin Jiang Nan Road, Zhang Pu Town, Kunshan, Jiangsu 215300
China

Additional Information:

Additionally evaluated to EN 60601-1:2006/ A1:2013

Reason for correction:

Correct EN standard

Additional information (if necessary)

Information complémentaire (si nécessaire)



- UL (US), 333 Pfingsten Rd IL 60062, Northbrook, USA
- UL (Demko), Borupvang 5A DK-2750 Ballerup, DENMARK
- UL (JP), Marunouchi Trust Tower Main Building 6F, 1-8-3 Marunouchi, Chiyoda-ku, Tokyo 100-0005, JAPAN
- UL (CA), 7 Underwriters Road, Toronto, M1R 3B4 Ontario, CANADA

For full legal entity names see www.ul.com/ncbnames

Date: 2015-03-18

Original Issue Date: 2014-08-26

Signature:




Jolanta M. Wroblewska



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.:	4786488107-20111012
Date of issue	2014 August 19, Correction 1: 2015 January 28
Total number of pages	17
CB Testing Laboratory	UL Camas
Address	2600 NW Lake Rd., Camas, WA 98607, USA
Applicant's name	XP Power LLC
Address	15641 Red Hill Ave., Suite 100 Tustin, CA 92780 USA
Test specification:	
Standard	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure	CB Scheme
Non-standard test method	
Test Report Form No.:	IEC60601_1J
Test Report Form Originator	UL(US)
Master TRF	2014-07
Copyright © 2014 Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE), Geneva, Switzerland. All rights reserved.	
This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.	
If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.	
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.	
This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	

Test item description:	Component Switching Power Supply	
Trade Mark		
Manufacturer	XP Power LLC, 15641 Red Hill Ave., Suite 100 Tustin, CA 92780 USA	
Model/Type reference:	ECS65USXX (where XX is any number between 12-48 designating output voltage), may also be provided with suffix "SF" and/or "B", with or without ""	
Ratings	100-240 Vac, 50/60 Hz, 1.2 A Output Rated: See Model Differences for additional details	
Testing procedure and testing location:		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	
	Testing location/ address:	UL Camas 2600 NW Lake Road Camas, WA 98607 USA
<input type="checkbox"/>	Associated CB Testing Laboratory:	
	Testing location/ address:	
	Tested by (name + signature)	Melissa DeGuia 
	Approved by (name + signature)	Timothy L. Gambrell 
<input type="checkbox"/>	Testing procedure: TMP/CTF Stage 1:	
	Testing location/ address:	
	Tested by (name + signature)	
	Approved by (name + signature)	
<input type="checkbox"/>	Testing procedure: WMT/CTF Stage 2:	
	Testing location/ address:	
	Tested by (name + signature)	
	Witnessed by (name + signature)	
	Approved by (name + signature)	
<input type="checkbox"/>	Testing procedure:	

	SMT/CTF Stage 3 or 4:	
Testing location/ address..... :		
Tested by (name + signature) :		
Witnessed by (name + signature) :		
Approved by (name + signature) :		
Supervised by (name + signature)..... :		

List of Attachments (including a total number of pages in each attachment):**Summary of testing:**

Unless otherwise indicated, all tests were conducted at XP Power LLC, 1241 E. Dyer Rd #150, Santa Ana, CA 92705, USA

All testing conducted under the Applicant's IEC 60601-1, 3rd Ed under CB Test Report 11CA34108 and CB Certificate US-17857-UL, dated 2011-10-14. The tests conducted per 3rd ed of IEC 60601-1 were considered representative of the corresponding tests required by 3rd ed of IEC 60601-1+AM1

Tests performed (name of test and test clause):**Testing location:**

Input Test (4.11)
Humidity Preconditioning Treatment (5.7)
Limitation of Voltage, Current or Energy (8.4.3 & 8.4.4)
Earth Leakage Current (8.7)
Working Voltage Measurement (8.5.4)
Dielectric Voltage Withstand (8.8.3)
Ball Pressure (8.8.4.1)
Temperature Test (11.1)
Abnormal Operation and Single Fault Conditions (13.2)
Mains Transformers (short and overload) (15.5, 13.2.3)

XP Power LLC, 1241 E. Dyer Rd
#150, Santa Ana, CA 92705, USA

Summary of compliance with National Differences

List of countries addressed:

US, CAN, AUSTRIA, REPUBLIC OF KOREA, SWEDEN and UNITED KINGDOM

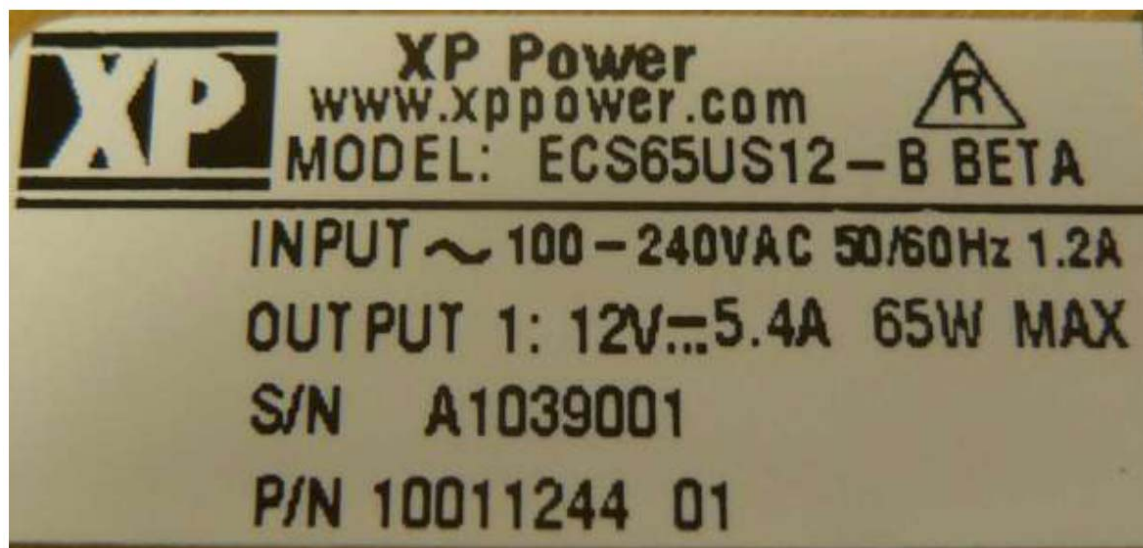
The product fulfils the requirements of IEC 60601-1, Edition 3.1 (2012)

Correction 1: 2015-01-28

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.

Labels provided are considered representative of the entire series



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
Classification of installation and use	: Building-in
Device type (component/sub-assembly/ equipment/ system):	: Component 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.....	: N/A
Other options include.....	: N/A
Testing	
Date of receipt of test item(s).....	: 2010-06-23
Dates tests performed	: 2010-07-01 to 2010-10-13; 2011-07-18, 2011-09-15 to 2011-09-21
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 (collateral standards only)
- test object does not meet the requirement.....	: Fail (F)
Abbreviations used in the report:	
- normal condition	: N.C.
- means of Operator protection	: MOOP
- single fault condition	: S.F.C.
- means of Patient protection	: MOPP
General remarks:	
<p>"(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.</p>	
<p>Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.</p>	
Manufacturer's Declaration per sub-clause 4.2.5 of IEC60060-1	
<p>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</p>	
	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> Not applicable
<p>When differences exist; they shall be identified in the General product information section.</p>	

Name and address of factory (ies) :	XP Power LLC, 990 Benecia Ave, Sunnyvale CA 94085, USA
	XP Power (Kunshan) Limited., 230, Bin Jiang Nan Road, Zhang Pu Town, Kunshan, Jiangsu 215300 China

General product information:

Report Summary

Correction 1 Report:

The original report was modified on 2015-01-28 to include the following changes/additions:

1. Correction to Table 8.10 to add in alternate components which were left out of Amendment 1. No testing deemed necessary based on the similarities to previously evaluated construction.

Amendment 1 Report:

The original report was modified on 2015-01-14 to include the following changes/additions:

1. No additional testing was deemed necessary to add alternate PWB layout for Model ECS60US24 which is a larger size PWB and addition of a plastic post located adjacent to components designated, RT1 and C9.
2. No additional testing was needed to add alternate Connector (J1) by Molex, Type 41791 series (P/N 26-60-4030) and alternate Connector (J2) by Molex, Type 41791 series (P/N 26-60-4060) based on similarities to previously evaluated components.
3. Update Applicant and Manufacturer address from Santa Ana, CA to Tustin, CA.

Product Description

Products covered are open frame power supplies intended for building-in to be used with Medical Electrical Equipment. Units are intended for use with Class I or Class II end-products.

Model Differences

All models in the Model ECS65USXX series are identical with exception to the Mains Transformer, T1, and minor secondary components that allow for different output voltage ratings. See below for Model Ratings for up to 50°C ambient:

Model ECS65US12: Output Rated: 10.1 Vdc to 13.5 Vdc, 5.4 A Max (65W Max)
Model ECS65US15: Output Rated: 13.6 Vdc to 17 Vdc, 4.3 A Max (65 W Max)
Model ECS65US18: Output Rated: 17.1 Vdc to 21 Vdc, 3.4 A Max (65 W Max)
Model ECS65US24: Output Rated: 21.1 Vdc to 26 Vdc, 2.7 A Max (65 W Max)
Model ECS65US28: Output Rated: 26.1 Vdc to 31 Vdc, 2.3 A Max (65 W Max)
Model ECS65US33: Output Rated: 31.1 Vdc to 33 Vdc, 2.0 A Max (65 W Max)
Model ECS65US36: Output Rated: 33.1 Vdc to 42 Vdc, 1.8 A Max (65 W Max)
Model ECS65US48: Output Rated: 42.1 Vdc to 54 Vdc, 1.4 A Max (65 W Max)

See Enclosures 7-01 and 7-02 for de-rating curve for ambient temperatures up to 70°C.

Suffix "SF" indicates single fuse provided in the line side of the primary.

Suffix "-B" indicates unit provided with optional EMI Inductor, L2.

Additional Information

No additional testing was deemed necessary to evaluate the models covered under this Report to IEC 60601-1, Edition 3 with Am.1. based on previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams, etc. conducted under separate CB Scheme investigation to IEC 60601-1, 3rd ed issued under CBTR No. 11CA34108 and CB Certificate US-17857-UL,

dated 2011-10-14.

The output ranges and the alternate capacitor (C1) by Xiamen Faratronic Co Ltd., Type MKP61R (C40 Series) were also added.

The schematics are kept on file at the CBTL and can be provided by the manufacturer upon request by NCB's/CBTL's.

When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

Manufacturer to provide up to date IEC Licensed for component licenses greater than 3 years upon request. The need for the additional testing and evaluation shall be determined in the end product investigation.

Technical Considerations

- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1:2005/C1:2009 +AM1(R2012) (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:14 (includes National Differences for Canada), EN 60601-1:2006+A1 (2013)
- The product is evaluated only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The power supply was evaluated for use in 50°C ambient at Full Rated Output and 50% of the Rated Output in 70°C ambient. (See De-rating Curve, Enclosure 7-01 for details)

Risk Controls/ Engineering Condition of Acceptability

- The component shall be considered for compliance with the Marking (clause 7) and Separation (clause 8) requirements as part of the end use application evaluation.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage current test (Clause 8.7.3e) shall be considered in the end product application.
- This power supply was evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth/Secondary Reference Conductor; and One MOPP between Secondary and Earth/ Secondary Reference Conductor.
- This power supply has been evaluated as a continuous operation, ordinary equipment and has not been evaluated for use in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The end product shall ensure that the requirements related to accompanying documents, clause 7.9, are met.
- The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
- The following secondary output circuits are at non-hazardous energy levels: All outputs
- The output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.

- The maximum investigated branch circuit rating is: 20 A
- The Electric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 359 Vpk, 244 Vrms; Primary-SEC: 588 Vpk, 249 Vrms.
- When installed in a Class I end product, the power supply shall be mounted in a manner that provides, at a minimum, 2.5 mm Clearance/4 mm Creepage between the primary sides of power supply and protectively earthed accessible conductive parts. In addition, when installed in a Class I end product, the protective bonding terminal of the power supply shall be reliably connected to the main protective earthing terminal of the end product.
- When installed in a Class II end product, the power supply shall be mounted, on insulating posts, in a manner that provides, at a min. 5 mm Clearance/8 mm Creepage between the power supply and any accessible conductive parts.
- An investigation of the protective bonding terminal has: Not been conducted.
- For Class I application: Protective bonding testing shall be considered in the end product application.
- Primary side heat sinks are floating and considered live. They should not be accessible in the endproduct.
- 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): L1-L2 and T1 (Class F, 155°C)
- Printed Wiring Board rated 130°C.
- Cleaning test shall be considered as part of end product evaluation.
- The need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation.
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- Unit provided with additional suffix "-SF" are provided with only one fuse in the line side. Consideration for the need for additional fusing to be provided as part of the end product