

US-18989-A1-UL

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 DC-DC Converter

Name and address of the applicant Nom et adresse du demandeur XP POWER LTD
401 COMMONWEALTH DR
HAW PAR TECHNOCENTRE
LORBY B. #02-02 SINGAPOR

LOBBY B, #02-02, SINGAPORE 149598 SINGAPORE

Name and address of the manufacturer Nom et adresse du fabricant

XP POWER LTD

401 COMMONWEALTH DR HAW PAR TECHNOCENTRE

LOBBY B, #02-02, SINGAPORE 149598

SINGAPORE

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

CINCON ELECTRONICS CO LTD

8-1 FU KUNG RD, FU HSING PARK FU HSING HSIANG, CHANGHUA HSIEN 506

TAIWAN

Note: When more than one factory, please report on page 2 Note: Lorsque il y plus d'une usine, veuillez utiliser la $2_{\theta me}$ page

Additional Information on page 2

Input:

Ratings and principal characteristics Valeurs nominales et caractéristiques principales

JHM0312YZZ and JHM0612YZZ Series: 10-17 VDC JHM0324YZZ and JHM0624YZZ Series: 20-30 VDC

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

JHM03XXYZZ, JHM06XXYZZ Series: See Page 2

Additional information (if necessary may also be reported on page 2)

Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la $2_{\text{ème}}$ page

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

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

Additionally evaluated to EN 60601-1:2006. National Differences specified in the CB Test Report. The risk management requirements of the Standard were not addressed and must be considered in the end product investigation.

Additional Information on page 2 IEC 60601-1(ed.3)

E321744-A10-CB-1 issued on 2013-05-16 E321744-A10-CB-1 issued on 2013-05-16

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



Original Issue Date: 2012-05-18

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: 2013-05-16 Signature:

Jolanta M. Wroblewska



US-18989-A1-UL

Model Details:

JHM0312YZZ, JHM0612YZZ (where XX can be 12 or 24, Y can be S or D, ZZ can be 05, 12, 15)

Factories

DONGGUAN DONGCHENG ZHUSHAN CINCON ELECTRONICS FACTORY 1 JING XIANG RD DONGCHENG

FOREIGN TRADE, INDUSTRIAL PARK ZHUSHAN DONGCHENG DISTRICT DONGGUAN 523128 GUANGDONG CHINA

Additional Information:

The original report was modified to include the following changes/additions: Update Critical Component List. See test report.

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

Jolanda Phy love

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

Date: 2013-05-16

Original Issue Date: 2012-05-18

Signature:

Jolanta M. Wroblewska

Correction 2 2013-05-16



Test Report issued under the responsibility of:



TEST REPORT IEC 60601-1

Medical Electrical Equipment

Part 1:General requirements for basic safety and essential performance

Report Reference No E321744-A10-CB-1

Date of issue: 2012-05-15

Total number of pages: 13

CB Testing Laboratory: UL Camas

Address 2600 N.W. Lake Road, Camas, WA, 98607, USA

Applicant's name XP POWER LTD

401 COMMONWEALTH DR
Address HAW PAR TECHNOCENTRE

LOBBY B, #02-02

SINGAPORE 149598 SINGAPORE

Test specification:

Standard IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)

Test procedure: CB Scheme

Non-standard test method: N/A

Test Report Form No. IEC60601 1G

Test Report Form originator: UL LLC

Master TRF Dated 2010-11

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If this test Report 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.

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Correction 2 2013-05-16

Test item description DC-DC Converter

Trade Mark:

XP

Manufacturer: XP POWER LTD

401 COMMONWEALTH DR HAW PAR TECHNOCENTRE

LOBBY B, #02-02

SINGAPORE 149598 SINGAPORE

Y can be S or D, ZZ can be 05, 12, 15)

Ratings: Input:

JHM0312YZZ and JHM0612YZZ Series: 10-17 VDC JHM0324YZZ and JHM0624YZZ Series: 20-30 VDC

Output: See Model Differences for details.

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Testing procedure and testing location:					
[x]	CB Testing Laboratory				
	Testing location / address:	UL Camas 2600 N.W. Lake R	load, Camas, WA, 98607, USA		
[]	Associated CB Test Laboratory				
	Testing location / address:				
	Tested by (name + signature):	Melissa DeGuia	melissa 1. de		
			0 0		
	Approved by (name + signature) :	Bernadette Matsuoka	Belitt Matsucke		
[]	Testing Procedure: TMP				
	Tested by (name + signature):				
	Approved by (+ signature):				
	Testing location / address:				
[]	Testing Procedure: WMT				
	Tested by (name + signature):				
	Witnessed by (+ signature):				
	Approved by (+ signature):				
	Testing location / address::				
[]	Testing Procedure: SMT				
	Tested by (name + signature):				
	Approved by (+ signature)::				
	Supervised by (+ signature):				
	Testing location / address:				
[]	Testing Procedure: RMT				
	Tested by (name + signature):				
	Approved by (+ signature)::				
	Supervised by (+ signature):				
	Testing location / address:				
l int of	Attachments				
National Differences (0 pages)					
Enclosures (0 pages)					
Summary of Testing:					
No tests were conducted Summary of Compliance with National Differences:					
Summary of Compliance with National Differences: Countries outside the CB Scheme membership may also accept this report.					
List of countries addressed: AT, BE, CA, CH, CZ, DE, DK, FI, FR, GB, HU, IL, IT, NL, NO, PL, SE, SG, SI,					
SK, TR, UA, US					

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The product fulfills the requirements of: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada) EN 60601-1: 2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)

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

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Test item particulars (see also Clause 6):				
Classification of installation and use		Building In		
Device type (component/sub-assembly/ equipment/system):		Component		
Intended use (Including type of patient, application location):		Component DC-DC converter for use in medical power supplies		
Mode of operation		Continuous		
Supply connection:		Isolated Secondary		
Accessories and detachable parts included:		None		
Other options include:		None		
Testing:				
Date of receipt of test item(s)		N/A		
Dates tests performed		N/A		
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 was not evaluated for the requiremer	N/E			
- test object does not meet the requirement:		F(Fail)		
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		
On and noncolor				

General remarks:

"(see Attachment #)" refers to additional information appended to the report.

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 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 6.25 of IECEE 02:

Yes

The application for obtaining a CB Test Certificate includes more than one factory and a declaration form 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): CINCON ELECTRONICS CO LTD

> 8-1 FU KUNG RD FU HSING PARK FU HSING HSIANG CHANGHUA HSIEN **506 TAIWAN**

[&]quot;(see appended table)" refers to a table appended to the report.

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DONGGUAN DONGCHENG ZHUSHAN CINCON ELECTRONICS FACTORY 1 JING XIANG RD DONGCHENG FOREIGN TRADE INDUSTRIAL PARK ZHUSHAN DONGCHENG DISTRICT DONGGUAN 523128 GUANGDONG CHINA

GENERAL PRODUCT INFORMATION:

Report Summary

The original report was modified on 2013-05-16 to include the following changes/additions:

Add the following alternate components to the critical component table for clarification to the alternate T1 insulation manufacturer:

- 1) Bobbin by SUMITOMO CHEMICAL CO LTD, Type LCP E4008
- 2) Triple Insulated Wire by FURUKAWA ELECTRIC CO LTD, Type TEX-E
- 3) Triple Insulated Wire by TOTOKU ELECTRIC CO LTD, Type TIW-2

Product Description

Model JHM03 and JHM06 Series units are DC/DC Converters to be used as part of Medical Electrical Equipment, and are intended to provide Two MOPP between DC input circuits to DC output circuit. They have two input ranges: 10-17 VDC (12 VDC nominal) and 20-30 (24 VDC nominal).

The units are provided with top and bottom plastic enclosure. All components inside the unit are mounted on PWB.

Model Differences

Model JHM03XXYZZ Series:

The number "03" represents a maximum output of 3 W, while "XX" is the Nominal Input Voltage, 12 VDC or 24 VDC; and Y represents either S for single output or D for a dual output unit and where ZZ represents the output voltage: 05 = 5 VDC, 12 = 12 VDC, 15 = 15 VDC.

Model JHM06XXYZZ Series:

The number "06" represents a maximum output of 6 W, while "XX" is the Nominal Input Voltage, 12 VDC or 24 VDC; and Y represents either S for single output or D for a dual output unit and where ZZ represents the output voltage: 05 = 5 VDC, 12 = 12 VDC, 15 = 15 VDC.

All models within a series are identical except for transformer windings, inductance and MOSFETs, and output ratings.

See below for Model Output Ratings @ 60°C.

Output: Single Output Units: JHM0312S05: 5 VDC, 600 mA JHM0312S12: 12 VDC, 250 mA JHM0312S15: 15 VDC, 200 mA Issue Date: 2012-05-15 Page 7 of 13 Report Reference # E321744-A10-CB-1

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JHM0324S05: 5 VDC, 600 mA JHM0324S12: 12 VDC, 250 mA JHM0324S15: 15 VDC, 200 mA JHM0612S05: 5 VDC, 1200 mA JHM0612S12: 12 VDC, 500 mA JHM0612S15: 15 VDC, 400 mA JHM0624S05: 5 VDC, 1200 mA JHM0624S12: 12 VDC, 500 mA JHM0624S15: 15 VDC, 400 mA

Output: Dual Output Units:

JHM0312D12: +/-12 VDC, 125 mA JHM0312D15: +/-15 VDC, 100 mA JHM0324D12: +/-12 VDC, 125 mA JHM0324D15: +/-15 VDC, 100 mA JHM0612D12: +/-12 VDC, 250 mA JHM0612D15: +/-15 VDC, 200 mA JHM0624D12: +/-12 VDC, 250 mA JHM0624D15: +/-15 VDC, 200 mA

Additional Information

Marking label submitted is representative of all models in this Report.

CB Test certificates for components are included in Licenses Enclosure. In accordance with the current rules of CB Scheme, CB Test certificate is effective for 3 years. Recognizing NCB may challenge the CBTC when certificates are more than 3 years old.

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.

Technical Considerations

- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States), CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), EN 60601-1: 2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- The degree of protection against harmful ingress of water is: Ordinary
- The following accessories were investigated for use with the product: None
- The mode of operation is: Continuous
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No
- Scope of this evaluation defers the following clauses to the be determined as part of the end product:

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Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems). --

Scope of this evaluation excludes the following: Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15; Battery related clauses: 7.3.3, 15.4.3; Hand Control related clauses: 8.10.4; Oxygen related clauses: 11.2.2; Fluids related clauses: 11.6.2 – 11.6.4; Sterilization clause: 11.6.7; Biocompatibility Clause: 11.7 (ISO 10993); Motor related clauses: 13.2.13.3, 13.4; Heating Elements related clause: 13.2; Flammable Anaesthetic Mixtures Protection: Annex G. --

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

- The unit is a DC/DC converter intended to be powered by an isolated regulated secondary DC source and has not been evaluated for connection to SUPPLY MAINS; suitable MAINS separation shall be provided during final installation. --
- Temperature, Leakage Current, Protective Earthing Dielectric Voltage Withstand and Interruption of the Power Supply tests should be considered as part of the end product evaluation. --
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 60°C at Full Load. --
- The output circuit has not been evaluated for connecting to Applied Parts. --
- Consideration should be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. --
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met. --
- End product Risk Management Process to include consideration of requirements specific to the Power Supply. --
- End product Risk Management Process to consider the need for simultaneous fault condition testing.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength. --
- End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as part of the power supply. --
- End product to determine the acceptability of risk in conjunction to the selection of components as it
 pertains to the intended use, essential performance, transport, storage conditions as part of the
 power supply. --
- The products were tested using a DC source connected to a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary. --
- The units were evaluated for 2 MOPP from Input to Enclosure and 2 MOPP from Input to Output based on a maximum input voltage of 30Vdc. Additionally evaluated for 1 MOPP for 250 Vrms. --
- Abnormal tests were conducted with the input provided with an external UL Listed fuses of the following values: 1.5 A for the 10-17 VDC (Nominal 12 VDC) Input units and 1.0 A for the 20-30 VDC (Nominal 24 VDC) Input units. Testing conducted with an isolated regulated secondary DC source. --
- The need for Marking durability and label legibility to be determined as part of the end product evaluation. --
- End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply. --
- Overcurrent protection is not provided; the end-product evaluation shall consider compliance to

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Clause 8.11.5. --