

US-18397-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

Product Produit

Name and address of the applicant Nom et adresse du demandeur

Name and address of the manufacturer Nom et adresse du fabricant

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

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

Ratings and principal characteristics Valeurs nominales et caractéristiques principales

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

considéré conforme à la

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

Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2^{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

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

CERTIFICAT D'ESSAI OC

DC-DC Converter

XP POWER INC SUITE 150 1241 E DYER RD SANTA ANA CA 92705, USA

XP POWER INC SUITE 150 1241 E DYER RD SANTA ANA CA 92705, USA

CINCON ELECTRONICS CO LTD 8-1 FU KUNG RD FU HSING PARK FU HSING HSIANG CHANGHUA HSIEN 506 TAIWAN

Additional Information on page 2
See Page 2



JHM10XXDYY, JHM10XXSYY

National Differences specified in the CB Test Report.

Additional Information on page 2

IEC 60601-1(ed.3)

E321744-A9-CB-1 issued on 2012-01-26

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



Date: 2012-01-26

Signature:

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

Jolanta M. Wroblewska



US-18397-UL

Model Details:

JHM10XXDYY,JHM10XXSYY (where 'XX' =05, 12, or 24; 'YY' = 05, 12, 15; and maybe provided optional suffix - SG01)

Factories:

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

Ratings:

Input:

For Models JHM1005SYY and JHM1005DYY Series: 4.5-9Vdc, 2700mA; For Models JHM1012SYY and JHM1012DYY Series: 9-18Vdc, 1300mA; For Models JHM1024SYY and JHM1024DYY Series: 18-36Vdc, 650mA

Output: See Model Differences for details.

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

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

Date: 2012-01-26

Signature:

Jolanta M. Wroblewska



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-A9-CB-1

Date of issue: 2012-01-26

Total number of pages: 191

CB Testing Laboratory: UL Camas

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

Applicant's name XP POWER INC

SUITE 150

Address: 1241 E DYER RD

SANTA ANA CA 92705 UNITED STATES

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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Test item description DC-DC Converter

Trade Mark:

Manufacturer: XP POWER INC

SUITE 150 1241 E DYER RD SANTA ANA CA 92705 UNITED STATES

'YY' = 05, 12, 15; and maybe provided optional suffix -SG01)

Ratings: Input:

For Models JHM1005SYY and JHM1005DYY Series: 4.5-9Vdc,

2700mA;

For Models JHM1012SYY and JHM1012DYY Series: 9-18Vdc,

1300mA;

For Models JHM1024SYY and JHM1024DYY Series: 18-36Vdc,

650mA

Output: See Model Differences for details.

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Testing procedure and testing location:							
[]	CB Testing Laboratory						
	Testing location / address::						
[]	Associated CB Test Laboratory						
	Testing location / address::						
	Tested by (name + signature):						
	Approved by (name + signature):						
[]	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::						
[x]	Testing Procedure: SMT						
	Tested by (name + signature):	Chin Chee Siang	68				
	Approved by (+ signature):	Tac Pham	Taulane_				
	Supervised by (+ signature):	Michael J. Howell	Midd Hodel				
	Testing location / address::	XP POWER LTD, 401 COMMO TECHNOCENTRE LOBBY B, # Singapore, XP POWER LLC, S SANTA ANA, CA 92705 UNITE	#02-02, SINGAPORE 149598 SUITE 150, 1241 E DYER RD,				
[]	Testing Procedure: RMT						
	Tested by (name + signature):						
	Approved by (+ signature)::						
	Supervised by (+ signature):						
	Testing location / address::						

List of Attachments

National Differences (9 pages)

Enclosures (89 pages)

Summary Of Testing

Unless otherwise indicated, all tests were conducted at XP POWER LTD, 401 COMMONWEALTH DR HAW PAR TECHNOCENTRE LOBBY B, #02-02, SINGAPORE 149598 Singapore, XP POWER LLC, SUITE 150,

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Tests performed (name of test and test clause)	Testing location / Comments
Power Input Test (4.11)	
Humidity Preconditioning Treatment (5.7)	XP Power LLC, 1241 E. Dyer Rd., Suite 150, Santa Ana, CA 92705
Working Voltage Measurement (8.5.4)	
Dielectric Voltage Withstand (8.8.3)	Also tested at XP Power LLC, 1241 E. Dyer Rd., Suite 150, Santa Ana, CA 92705
Ball Pressure (8.8.4.1)	XP Power LLC, 1241 E. Dyer Rd., Suite 150, Santa Ana, CA 92705
Temperature Test (11)	
Abnormal Operation and Single Fault Conditions (13)	
Power Availability (13.1.2)	
Transformer Overload and Short-Circuit Tests (15.5.1)	
Transformer Dielectric Voltage Withstand (15.5.2)	

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, IT, NL, NO, PL, SE, SI, SK, TR, UA, US

The product fulfills the requirements of: 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), 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)

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)		2011-04-18, 2012-01-10	
Dates tests performed:		2011-06-20 to 2011-06-30, 2012-01-17, 2012-01-10 to 2012-01-12	
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 requirement	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:	МООР	- means of Patient protection:	MOPP
			<u> </u>

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:

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

Yes

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

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

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CHANGHUA HSIEN 506 TAIWAN

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

All applicable tests according to the referenced standard(s) have been carried out.

Product Description

The unit is a DC/DC Converter to be used as part of Medical Electrical Equipment, and is intended to provide Two MOPP between DC input circuits to DC output circuit.

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

Model Differences

Model JHMXXDYY Series is identical to Model JHMXXSYY Series with except it is provided with two output instead of one.

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

See below for Model Output Ratings @ 50°C.

JHM10XXS05: 5 Vdc, 2000mA JHM10XXS12: 12Vdc, 833mA JHM10XXS25: 15Vdc, 666mA

JHM10XXD05: 5Vdc, 1000mA; 5Vdc, 1000mA JHM10XXD12: 12Vdc, 420mA; 12Vdc, 420mA JHM10XXD15: 15Vdc, 333mA; 15Vdc, 333mA

Where XX can be 05, 12, 15 and denotes nominal input voltage ranges as follows:

05 = 4.5-9Vdc 12 = 9-18Vdc 24 = 18-36 Vdc

Additional suffix "-SG01" maybe provided but not related to safety.

Additional Information

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

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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: 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), 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)
- 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: 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:

• This power supply has been judged on the basis of the required creepage and clearances in the Third Edition of the Standard for Medical Electrical Equipment, IEC 60601-1, Sub-clause 8.9, which covers the end-use product for which the component was designed. --

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 The unit is a DC/DC converter and not evaluated for the separation 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 70°C at Full Load. --
- The output circuit has not been evaluated for connecting to Applied Parts. For end products intended to connect to Applied Parts, suitable evaluation should be considered. --
- Considerations to the applied parts requirement, to be conducted as end-product --
- 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-use product shall ensure that the power supply is used within its ratings. --
- 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 on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary. --