



Ref. Certif. No.

SG-MD-00206

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

Switching power supply unit
(Switching Power Adaptor)

Name and address of the applicant
Nom et adresse du demandeur

XP Power Limited
401 Commonwealth Drive,
Haw Par Technocentre, Lobby B, #02-02 149598, SINGAPORE

Name and address of the manufacturer
Nom et adresse du fabricant

XP Power Limited, 401 Commonwealth Drive,, Haw Par Technocentre,
Lobby B, #02-02 149598, SINGAPORE

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

Dongguan Shilong Fuhua Electronic Co., Ltd., Fuhua Electronic Industrial
Park, Xianglong Road, Huangzhou, New Town District, Shilong Town,
523326 Dongguan, Guangdong Province, PEOPLE'S REPUBLIC OF
CHINA

Rating and principal characteristics
Valeurs nominales et caractéristiques principales

Rated Input : 100-240VAC, 50/60Hz, 0.5A
Rated Output : See test report for details
Protection Class : See test report for details
Degree of Protection : See test report for details

Trade mark (if any)
Marque de fabrique (si elle existe)

XP

Model/type Ref.
Ref. de type

VEP15US series, VCP15US series, VCP15US-E series
(See test report for details of model description.)

Additional information (if necessary)
Information complémentaire (si nécessaire)

See Test Report for National Differences and Group Differences

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 60601-1:2005

as shown in the Test Report Ref. No.
which form part of this certificate
comme indiqué dans le Rapport d'essais numéro
de référence qui constitue une partie de ce
certificat

TÜV SÜD PSB Pte Ltd
211-300735-000

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, 2012-04-26
CBS 12 04 65969 091

(Jimmy Huang)



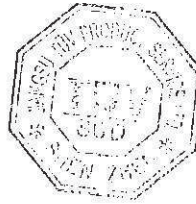
TÜV SÜD PSB Pte Ltd · 1 Science Park Drive · Singapore 118221

PSB Singapore

		Test Report issued under the responsibility of: NCB TÜV SÜD PSB 1 Science Park Drive, 118221 Singapore Singapore	
IEC 60601-1 Medical electrical equipment Part 1: General requirements for basic safety and essential performance			
Report Reference No.: 211-300735-000 Date of issue: 2012-04-19 Total number of pages: 173			
CB Testing Laboratory: Jiangsu TÜV Product Service Ltd. - Shenzhen Branch Address: 6/F, H Hall, Century Craftwork Culture Square, No. 4001, Fuqiang Road, Futian District, 518048 Shenzhen, China			
Applicant's name: XP Power Limited Address: 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02 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: Underwriters Laboratories Inc. Master TRF: Dated 2010-11			
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Test item description	Switching Power Adaptor
Trade Mark	
Manufacturer	XP Power Limited 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02-02 149598, SINGAPORE
Model/Type reference	VEP15US series, VCP15US series, VCP15US-E series (See general product information for details)
Ratings	Input: 100-240VAC, 50/60Hz, 0.5A. DC output: 3.0V-24.0V, 0.01A-2.0A. (See general product information for details)
Testing procedure and testing location:	
<input checked="" type="checkbox"/> CB Testing Laboratory:	Jiangsu TÜV Product Service Ltd. - Shenzhen Branch
Testing location/ address	6/F, H Hall, Century Craftwork Culture Square, No. 4001, Fuqiang Road, Futian District, 518048 Shenzhen, China
Tested by (name + signature).....	Jack Liu
Approved by (+ signature)	Yager Bi





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

Attachment No.1: 10 pages of National Differences for IEC 60601-1 3rd edition as per IEC Bulletin.

Attachment No. 2: 12 pages of AU/EU/KR/US/UK Plug report

Attachment No. 3: 10 pages of photograph.

Summary of testing

Tests performed (name of test and test clause):

Testing location:

The test subject has been assessed for safety with respect to the above test specifications and found to comply with the requirements of IEC 60601-1:2005.

Jiangsu TÜV Product Service Ltd. - Shenzhen Branch

Exceptions:

The following clauses / collaterals were not part of the manufacturers order and therefore excluded from this testing:

6/F, H Hall, Century Craftwork Culture Square,
No. 4001, Fuqiang Road, Futian District,
518048 Shenzhen, China

Clause 11.7 Biocompatibility, referencing ISO 10993

Clause 12.2 Usability, referencing IEC 60601-1-6

Clause 17 EMC, referencing IEC 60601-1-2

Summary of compliance with National Differences

List of countries addressed: Switzerland, Canda and US.

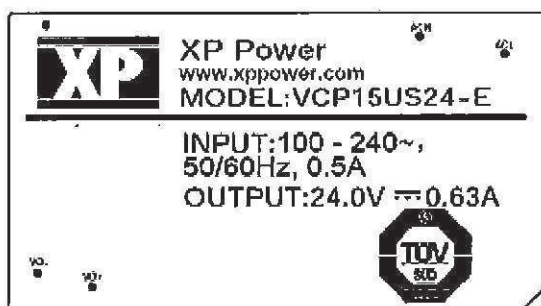
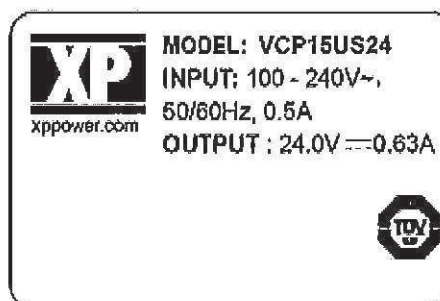
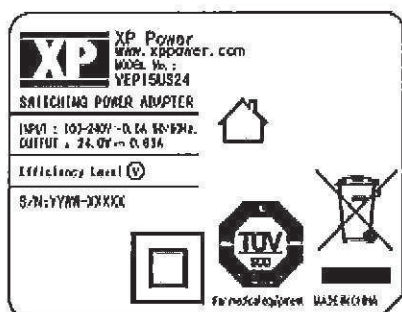
The product fulfils the requirements of SN EN 60601-1:2006, CAN/CSA-C22.2 No. 60601-1:08 and ANSI/AAMI ES60601-1: 2005

The CB report also covers EN 60601-1:2006 for project 682701100701A



Copy of marking plate

These are representative markings for VEP15US24, VCP15US24 and VCP15US24-E.
Marking plates of other models are similar except only the model number and output ratings according to model number listed in general product information.



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.

GENERAL INFORMATION

Test item particulars (see also Clause 6):

Classification of installation and use	:	Portable equipment for VEP15US series; Built-in equipment for VCP15US series and VCP15US-E series.
Device type (component/sub-assembly/ equipment/ system)...	:	Component
Intended use (Including type of patient, application location) ...	:	Power supply to medical device
Mode of operation	:	Continuous
Supply connection	:	Directly plug-in for VEP15US series; Consider in end product for VCP15US series and VCP15US-E series.
Accessories and detachable parts included.....	:	N/A
Other options include	:	N/A

Testing

Date of receipt of test item(s)	:	2012-04-19
Dates tests performed	:	2012-03-30 to 2012-04-19

Possible test case verdicts:

- test case does not apply to the test object	:	N/A
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- 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 <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 6.2.5 of IEC60601-1:	
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:	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> Not applicable
When differences exist; they shall be identified in the general product information section.	
Name and address of factory (ies):	



General product information:

Switching mode power supply, models VEP15US series, VCP15US series, and VCP15US-E series, were manufactured by XP Power Limited

Model VEP15US series is class II direct plug-in equipment with changeable plug portion.

Model VEP15US series is identical with VCP15US series, except for model designation, protection class, and additional enclosure with plug portion.

Model VCP15US-E series is identical with VCP15US series, except for model designation, additional potting material and case for potting.

Model list:

No	Model No.	Output Voltage (V)	Max Load Current (A)	Max Output Power (W)
1	VEP15US03 VCP15US03 VCP15US03-E	3.00	0.01-2.00	6.00
2	VEP15US033 VCP15US033 VCP15US033-E	3.30	0.01-2.00	6.60
3	VEP15US036 VCP15US036 VCP15US036-E	3.60	0.01-2.00	7.20
4	VEP15US04 VCP15US04 VCP15US04-E	4.00	0.01-2.00	8.00
5	VEP15US042 VCP15US042 VCP15US042-E	4.20	0.01-2.00	8.40
6	VEP15US045 VCP15US045 VCP15US045-E	4.50	0.01-2.00	9.00
7	VEP15US05 VCP15US05 VCP15US05-E	5.00	0.01-2.00	10.00
8	VEP15US052 VCP15US052 VCP15US052-E	5.20	0.01-2.00	10.40
9	VEP15US055 VCP15US055 VCP15US055-E	5.50	0.01-2.00	11.00
10	VEP15US059 VCP15US059 VCP15US059-E	5.99	0.01-2.00	11.98
11	VEP15US06 VCP15US06 VCP15US06-E	6.00	0.01-2.00	12.00
12	VEP15US065 VCP15US065 VCP15US065-E	6.50	0.01-2.00	13.00
13	VEP15US07 VCP15US07 VCP15US07-E	7.00	0.01-1.70	11.90



14	VEP15US075 VCP15US075 VCP15US075-E	7.50	0.01-1.50	11.25
15	VEP15US08 VCP15US08 VCP15US08-E	8.00	0.01-1.50	12.00
16	VEP15US085 VCP15US085 VCP15US085-E	8.50	0.01-1.40	11.90
17	VEP15US09 VCP15US09 VCP15US09-E	9.00	0.01-1.40	12.60
18	VEP15US10 VCP15US10 VCP15US10-E	10.0	0.01-1.40	14.00
19	VEP15US105 VCP15US105 VCP15US105-E	10.5	0.01-1.30	13.65
20	VEP15US12 VCP15US12 VCP15US12-E	12.0	0.01-1.25	15.00
21	VEP15US138 VCP15US138 VCP15US138-E	13.8	0.01-1.05	14.49
22	VEP15US15 VCP15US15 VCP15US15-E	15.0	0.01-1.00	15.00
23	VEP15US16 VCP15US16 VCP15US16-E	16.0	0.01-0.85	13.60
24	VEP15US175 VCP15US175 VCP15US175-E	17.5	0.01-0.80	14.00
25	VEP15US18 VCP15US18 VCP15US18-E	18.0	0.01-0.80	14.40
26	VEP15US19 VCP15US19 VCP15US19-E	19.0	0.01-0.75	14.25
27	VEP15US20 VCP15US20 VCP15US20-E	20.0	0.01-0.75	15.00
28	VEP15US22 VCP15US22 VCP15US22-E	22.0	0.01-0.65	14.30
29	VEP15US23 VCP15US23 VCP15US23-E	23.0	0.01-0.65	14.95
30	VEP15US24 VCP15US24 VCP15US24-E	24.0	0.01-0.63	15.12



The following representative models were selected for test.

Maximum output voltage and power in series

- VEP15US24, VCP15US24, VCP15US24-E

Maximum output current in series

- VEP15US065, VCP15US065, VCP15US065-E

Maximum output power in series

- VEP15US12, VCP15US12, VCP15US12-E

Maximum output power in series

- VEP15US15

Remarks:

1. When installing the equipment, all requirements of the mentioned standard must be fulfilled.
2. For VCP15US series and VCP15US-E series, a suitable electrical, mechanical and fire enclosure shall be provided by the end system.
3. The maximum operating temperature is 40°C for VEP15US series, and is 50°C for VCP15US series and VCP15US-E series.
4. VCP15US series, and VCP15US-E series are intended to be built into an end use equipment.
5. VCP15US series, and VCP15US-E series must be installed in accordance with the instruction manual.
6. The output was not evaluated as patient connected circuits.
7. Compliance with the requirements for EMC shall be evaluated for the end use product.
8. These products have been investigated only as a component part for use in equipment where the suitability of the combination is subject to end product investigation.
9. The leakage current test shall be checked in end product.
10. For direct plug-in adaptor VEP15US series, plug is changable, including EU, UK, US, AU, KR types. Each of the corresponding plug portions was tested with relevant national standard:
 - EU plug: EN50075,
 - UK plug: BS1363,
 - US plug: UL1310,
 - AU plug: AS/NZS 3112,
 - KR plug: KSC 8305.

Important:

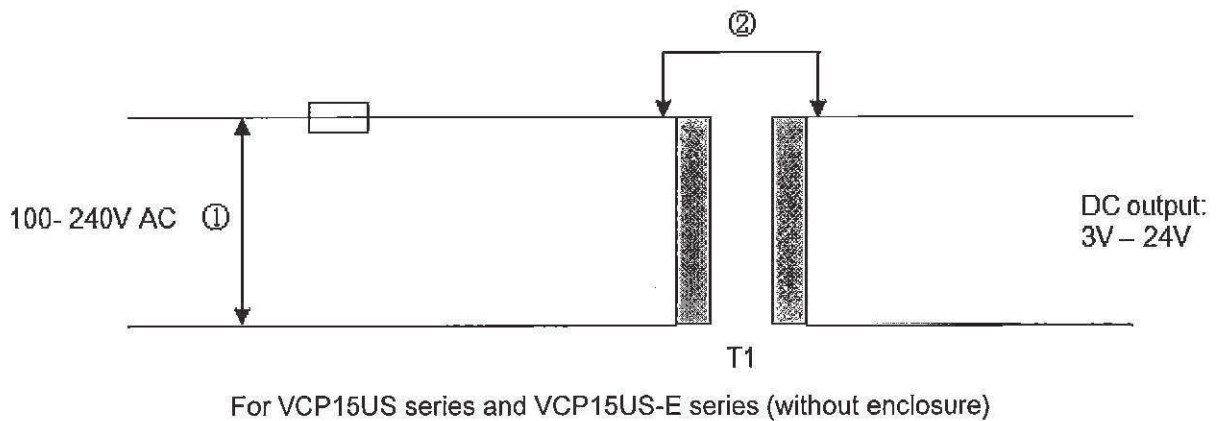
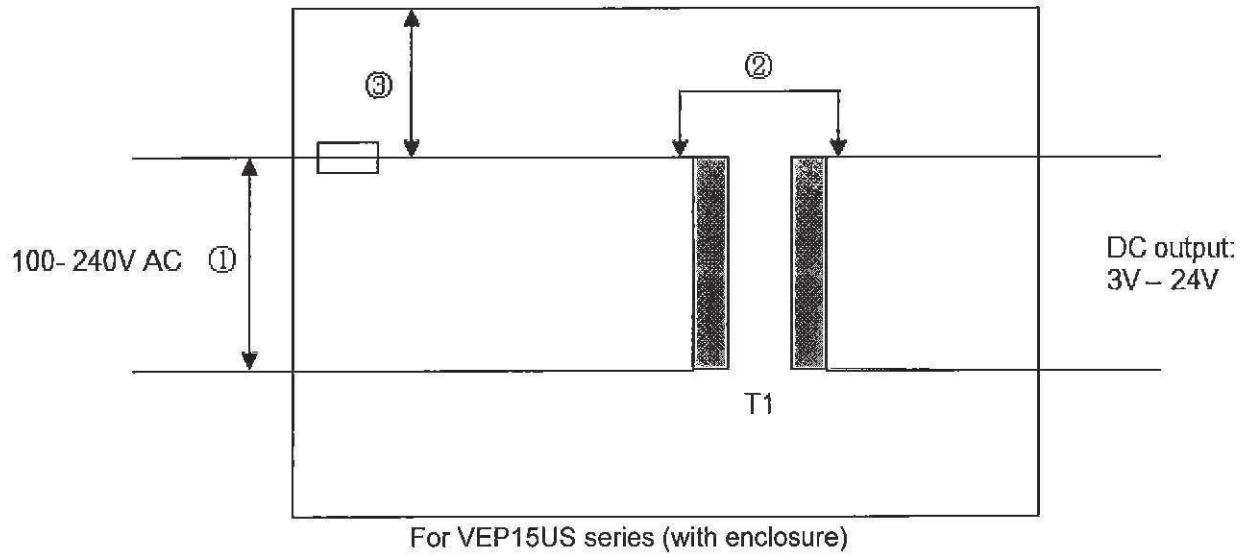
- Differences between IEC 60601-1: 2005 and EN 60601-1: 2006: Annex ZA and Annex ZZ of EN 60601-1: 2006 have been considered.
- Risk management has been considered for the relevant clause in this power supply. When using this power supply for a medical device, compliance with the relevant requirements of the risk management for the complete system has to be considered.
- According to the EU decision 768/2008/EC and German product safety law (ProdSG), the name and address of manufacturer (an EU-based importer or authorized representative if the manufacturer is not based in EU) shall be affixed on the product or, where that is not possible, on its packaging or in a document accompanying the product before the product is placed on EU market.



IEC 60601-1			
Clause	Requirement + Test	Result - Remark	Verdict

Insulation Diagram

(As reflected below or displayed in the attachment. See also attachment overview at the end of this protocol)





IEC 60601-1									
Clause		Requirement + Test				Result - Remark			Verdict
TABLE: To insulation diagram									P
Pollution degree		2							—
Overvoltage category		II							—
Altitude		2000							—
Additional details on parts considered as applied parts		<input checked="" type="checkbox"/> None <input type="checkbox"/> Areas _____ (See Clause 4.6 for details)							—
Area	Number and type of Means of Protection: MOOP, MOPP	CTI (IIIb, unless is known)	Working voltage		Required creepage (mm)	Required clearance (mm)	Measured creepage (mm)	Measured clearance (mm)	Remarks
			Vrms	Vpk					
1	Opposite polarity	IIIb	240	339	3.0	1.6	3.5	3.5	Between L and N before fuse
2	Two MOOP	IIIb	266	512	5.6	4.4	8.2	6.3	Primary T1 pin to U2 secondary pin via PCB and T1 bottom
2	Two MOOP	IIIb	266	512	5.6	4.4	15.0	10.5	Between primary and secondary of T1
2	Two MOOP	IIIb	240	375	4.8	4.0	8.0	6.3	Between primary and secondary of U2
2	Two MOOP	IIIb	240	344	4.8	4.0	8.0	6.7	Between primary and secondary of CY1
3	Two MOOP	IIIb	240	339	5.4	4.4	9.9	9.9	Between primary pin of CY1 and accessible enclosure
3	Two MOOP	IIIb	240	339	4.8	4.0	11.5	11.5	Between pin of plug connector and accessible enclosure

INSULATION DIAGRAM CONVENTIONS and GUIDANCE:

A measured value must be provided in the value columns for the device under evaluation. The symbol > (greater than sign) must not be used. Switch-mode power supplies must be re-evaluated in the device under evaluation therefore N/A must not be used with a generic statement that the component is certified.

Insulation diagram is a graphical representation of equipment insulation barriers, protective impedance and protective earthing. If feasible, use the following conventions to generate the diagram:

- All isolation barriers are identified by letters between separate parts of diagram, for example separate transformer windings, optocouplers, wire insulation, creepage and clearance distances.
- Parts connected to earth with large dots are protectively earthed. Other connections to earth are functional
- Applied parts are extended beyond the equipment enclosure and terminated with an arrow.
- Parts accessible to the operator only are extended outside of the enclosure, but are not terminated with an arrow.