

DE 3 - 4231

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

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

Rating and principal characteristics Valeurs nominales et caractéristiques principales

Trade mark (if any)

Marque de fabrique (si elle existe)

Model/type Ref.

Ref. de type

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

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 form part of this certificate comme indiqué dans le Rapport d'essais numéro de référence qui constitue une partie de ce

Power supplies

XP Power

305 Foster Street

Littleton MA 01460, USA

XP Power, 305 Foster Street, Littleton MA 01460, USA

4th Fl., No.76, Chen-Kong Rd., Sec.1, Nan Kann Distr., Talpei, TAlWAN

Rated voltage: Rated frequency: Rated input current:

50-60Hz 1.5-0.75A No applied part

100-240VAC

XP Power

Type:

Class:

PDM60US12, PDM60US15, PDM60US18, PDM60US24,

PSM60US30, PDM60US36 and PDM60US48

N/A

IEC 60601-1/A2:1995

TÜV SÜD Product Service

091-307656-000

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,

2006-07-25

CB 06 07 57271 009

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstrasse 65 · D-80339 München



Product Service



Project Number: 091-307656-000

Applicant:

XP Power

305 Foster Street

Littleton MA 01460

Manufacturing

location:

XP Power

305 Foster Street

Littleton MA 01460

Project Number:

091-307656-000

Date:

25 July 2006

Equipment:

Brick Style Power Supplies

Type /Model:

Models: PDM60US12, PDM60US15, PDM60US18, PDM60US24,

PDM60US 30, PDM60US36 and PDM60US48 (Hereinafter referred to as the 'Equipment')

Specifications:

IEC601-1/A2:1995

Selected requirements as detailed in Section 1

Purpose of

Inspection:

See section 7

Test results:

The above mentioned Equipment has been assessed with respect to

the above Specifications and has been found to comply with the

requirements.



Project Number: 091-307656-000

1. Description of test sample

The PDM60US series of power supplies are 'Brick Style' power supplies intended for use with medical devices.

The power supplies are contained in plastic enclosures of nominal dimensions 133m x 64mm x 44mm and are fitted with a Class II appliance inlet, in accordance with IEC320, for connection to the mains supply. The input is multi ranging from 100 to 240VAC and the output voltages are 12, 15, 18, 24, 30, 36 and 48 VDC at up to 60 Watts.

As the power supplies are not medical devices in their own right they cannot fully comply with all of the requirements of the listed Specifications and have, therefore, been subjected only to the applicable requirements of selected sub-clauses as listed below:

- 6.1 External marking
- 6.4 Symbols
- 7.1 Power Input
- 14.4 Class I and Class II Equipment
- 15 Limitation of Voltage and/or Energy
- 16 Enclosures and Protective Covers
- 17 Separation
- 19 Continuous Leakage Current
- 20 Dielectric Strength
- 21 Mechanical Strength
- 23 Surfaces, Corners and Edges
- 24 Stability in Normal Use
- 42 Excessive temperatures
- 43 Fire Prevention
- 44.5 Humidity
- 49 Interruption of the Power Supply
- 52 Abnormal operation and fault conditions
- 56 Components and General Assembly
- 57.10 Creepage distances and air clearances
- 59 Construction and Layout



Project Number: 091-307656-000

2. Technical data

Classification/rating:

Rated input voltage: 100-240VAC
Rated input frequency: 50/60Hz
Rated input current: 1.5-0.75A
Input power (Nominal) 60Watts
Output voltage: 12-48VDC

Output current: Varies by model

Type of protection against electric shock: Class II

Degree of protection against electric shock: N/A – No applied part

Degree of protection against ingress of liquids: Not protected Protection against flammable anaesthetics: Not protected Mode of operation: Continuous

3. Clients purchase order

For the purpose of this investigation the client provided partial pre-payment dated 04/03/2006.

4. Date of receipt of test sample

04/03/2006.

5. Date of inspection

04/03/2006 to 07/25/2006.

6. Purpose of the inspection:

The purpose of this investigation is to determine whether the power supplies are in compliance with the applicable selected requirements of those standards listed on page 1 under "Specifications".



Project Number: 091-307656-000

7. Results

Details of the results of this investigation can be found in the attached document titled:

TEST REPORT IEC 60601 -1

Medical electrical equipment
Part 1: General requirements for safety

and its attachments

and

TEST REPORT National Deviations to IEC 60601-1 (1988) + A1:1991 + A2:1995

Australia, Canada, Denmark, United States, Israel, Korea Medical electrical equipment

8. Test Conditions:

- 1. The outputs were not evaluated as patient connected circuits
- 2. Compliance with EMC requirements needs to be evaluated for the end use product
- This product is investigated only for use as a component in equipment where the suitability of the combination is subject to end product investigation



Project Number: 091-307656-000

9. Conclusion:

The Equipment has been assessed for electrical and mechanical safety with respect to selected requirements of the Specifications as detailed on page one of this report and has been found to comply with the requirements.

Antony C. Young-Taylor MHS East Manager Senior Safety Engineer

Quality System/Technology Auditor



TEST REPORT IEC 60601 -1

Medical electrical equipment Part 1: General requirements for safety

Part 1: General requirements for safety					
Report reference No	091-307656-000				
Compiled by (+ signature)	A C Young-Taylor				
Reviewed by (+ signature)	Nikolaus-Peter Ohl Ltt.				
Additional information	CB reviewed TPS-Munich				
Approved by (+ signature)	Refer to CB certificate				
Date of issue	Refer to CB certificate				
Testing laboratory	TUV Product Service, Ridlerstrasse 65, 80339 Munich, Germany				
Address	[]CBTL []SMT [X]TMP				
Testing location	XP Power, 305 Foster Street, Littleton, MA 01460				
Applicant	XP Power				
Address	305 Foster Street, Littleton, MA 01460				
Standard	IEC 60601-1:1988 + A1:1991 + A2:1995				
Test Report Form No.	IEC 60601-1:1988+A1:1991 + A2:1995 Rev. 01/2003-05				
TRF modified by	TÜV PRODUCT SERVICE GmbH				
Master TRF	Can be obtained by IECEE (see general remarks).				
Copyright blank test report	This report is based on a blank test report that was prepared by KEMA using information obtained from the TRF originator. Copyright reserved to the bodies participating in the Committee of Certification (CCB).				
Test procedure	CB Scheme				
Procedure deviation	N				
Non-standard test method	N				
Type of test object	Component power supplies				
Trademark	XP Power				
Model/type reference	PDM60US12, PDM60US15, PDM60US18, PDM60US24, PDM60US 30, PDM60US36 and PDM60US48				
Manufacturer	XP Power				
Address	305 Foster Street, Littleton, MA 01460				
Rating	Input - 100 - 240VAC, 1.5-0.75A, 50/60Hz				
	Output - 12VDC to 48VDC, 60Watts				



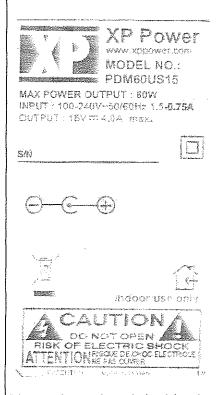
Report No. 091-307656-000

Page 2 of 55

Copy of marking plate: As reflected below or displayed in the attachment (see also attachment overview at the end of this protocol).

Example of the rating plate

The subject power supplies are components for use with a medical device



Note: the other label in the range have the same format and content



Report No. 091-307656-000

Page 3 of 55

GENERAL INFORMATION					
Test item particulars (see also clause 5):					
Classification of installation and use	Transportable				
Supply connection	100-240VAC				
Accessories and detachable parts included in the evaluation	None				
Options included	PDM60US12, PDM60US15, PDM60US18, PDM60US24, PDM60US, PDM60US 30, PDM60US, PDM60US36 and PDM60US48				
Possible test case verdicts:					
- test case does not apply to the test objectN/A	N				
- test object does meet the requirement	P				
- test object does not meet the requirementFail	F				
Abbreviations used in the report:					
- normal condition	- single fault conditionS.F.C basic insulation:Bl - supplementary insulation:SI - reinforced insulation:Rl				

General remarks:

"This report is not valid as a CB Test Report unless appended to a CB Test Certificate issued by a NCB, in accordance with IECEE 02".

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

"(see appended table)" refers to a table appended to the report.

Throughout this report a point or a comma is used as the decimal separator.

Master TRF: UL Inc. dated 97-04.

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.

Summary of contents provided on the last page of this report.

General product information and considerations:

The power supplies are contained in plastic enclosures of nominal dimensions 133m x 64mm x 44mm and are fitted with a Class II appliance inlet, in accordance with IEC320, for connection to the mains supply. The input is multi ranging from 100 to 240VAC and the output voltages are 12, 15, 18, 24, 30, 36 and 48 VDC at up to 60Watts

As the power supplies are not medical devices in their own right they cannot fully comply with all of the requirements of the listed Specifications and have, therefore, been subjected only to the applicable requirements of selected sub-clauses as follows: 6.1 External marking, 6.4 Symbols, 7.1 Power input, 14.4 Class I and Class II equipment, 15 Limitation of voltage and/or energy, 16 Enclosures and protective covers, 17 Separation, 19, Continuous leakage currents, 20 Dielectric strength, 21 Mechanical strength, 23 Surfaces, corners and edges, 24 Stability in normal use, 42 Excessive temperatures, 43 Fire prevention, 44.5 Humidity, 49 Interruption of the power supply, 52 Abnormal operation and fault conditions, 56 Components and general assembly, 57.10 Creepage distances and air clearances, 59 Construction and layout.

Clauses 36 (IEC 60601-1-2) was not part of the manufacturers order.



DE 3 - 54824

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'ESSA! OC

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

Rating and principal characteristics
Valeurs nominales et caractéristiques principales

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

Model/type Ref. Ref. de type

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

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 form part of this certificate comme indiqué dans le Rapport d'essais numéro de référence qui constitue une partie de ce certificat

Power supplies Brick Style Power Supplies

XP Power 305 Foster Street Littleton MA 01460, USA

XP Power, 305 Foster Street, Littleton MA 01460, USA

XP Power, 305 Foster Street, Littleton MA 01460, USA

Rated Input Voltage: Rated Frequency:

100-240 V AC 50/60 Hz 1.5-0.75 A

Rated Input Current: Rated Output Voltage:

12 V DC to 48 V DC

Rated Output Power: Protection Class: 60 W

XP Power

PDM60US12, PDM60US15, PDM60US18, PDM60US24, PDM60US30, PDM60US36, PDM60US48

CBTL Procedure

IEC 60950-1:2001

TÜV SÜD Product Service 090-602005-000

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.

2006-07-25

CB 06 07 57271 008

Joseph Janelinnan

Joseph Janeliunas

TÜV SÜD Product Service GmbH · Certification Body · Ridlerstrasse 65 · D-80339 München



Product Service



Technical Report No. 090-602005-000 Rev. 0 Dated 2006-07-05

Client: XP Power

305 Foster Street, Littleton, MA 01460

USA

Manufacturing XP Power

place: 305 Foster Street,

Littleton, MA 01460

USA

Test subject: Product: Brick Style Power Supplies

Type: PDM60US12, PDM60US15, PDM60US18, PDM60US24,

PDM60US 30, PDM60US36 and PDM60US48

Test EN 60950-1:2001, IEC 60950-1 2001

specification:

Purpose of Test according to the test specification

examination:

Test result: Positive: The test subject was found to be in compliance with

the mentioned test specification

.

This technical report may only be quoted in full. Any use for advertising purposes must be granted in writing. This report is the result of a single examination of the object in question and is not generally applicable evaluation of the quality of other products in regular production.



1 Description of the test subject

1.1 Function

Brick Style Power Supplies

The power supplies are contained in plastic enclosures of nominal dimensions 133m x 64mm x 44mm and are fitted with a Class II appliance inlet, in accordance with IEC320, for connection to the mains supply. The input is multi ranging from 100 to 240VAC and the output voltages are 12, 15, 18, 24, 30, 36 and 48 VDC at up to 60Watts

1.2 Technical Data

Input: 100 - 240VAC, 1.5-0.75A, 50/60Hz

Output: 12VDC to 48VDC, 60Watts

2. Order

2.1 Date of Purchase Order, Customer's Reference

2006-04-03; PO# Pre-payment

2.2 Receipt of Test Sample, Location

2006-04-03: TUV Product Service, 5 Cherry Hill Drive, Danvers, MA 01923, USA

2.3 Date of Testing

2006-04-03 through 2006-06-18

2.4 Location of Testing

TUV Product Service, 5 Cherry Hill Drive, Danvers, MA 01923, USA

2.5 Points of Non-compliance or Exceptions of the Test Procedure

None



3. Test Results

3.1 Positive Test Results

Electrical safety
 EN 60950-1:2001, IEC 60950-1 2001

3.2 Points of non-compliance according to the test specification

None

4. Remark 4.1 Remarks to Factory (necessary)

The assembly of the product has to comply with the documentation (CDF). Before the implementation of safety relevant modifications to the product into the ongoing production the product must be assessed for acceptance. The results must be implemented to the documentation and if necessary the certificate must be updated. The final inspections in the production are described in EN 50116. If fluctuations in production quality in a production facility are to be expected it has to be pondered whether a shorter cycle of factory inspections must be applied. Causes therefore may be up directly to the manufacturer or arise from the environment in the country.

TÜV PRODUCT SERVICE GMBH

Engineer: Bull Him.

Technical Report checked:

Technical Report No. 090-602005-000

De Mild

TUV America inc.

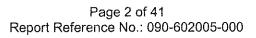


TEST REPORT

IEC 60950-1 and/or EN 60950-1

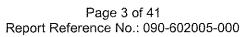
Information technology equipment – Safety – Part 1: General requirements

r art 1. General requirements					
Report reference No					
Tested by (printed name and signature):	Bill Stinson Bill Manual Stinson Bill Manual Stinson Bill Manual Stinson				
Approved by (printed name and signature)::	Glenn McLaughlin Glenn McLaughlin				
Date of issue:	2006-07-05				
Testing Laboratory Name:	TÜV Product Service				
Address:	5 Cherry Hill, Danvers MA 01923, USA				
Testing location:	CBTL ☑ CCATL ☐ SMT ☐ TMP ☐				
Address	Same as above				
Applicant's Name:	XP Power				
Address:	305 Foster Street, Littleton, MA 01460				
Test specification					
Standard:	IEC 60950-1:2001 (1st Edition) and/or EN 60950-1:2001				
Test procedure:	CB/CCA -scheme				
Non-standard test method:	N/A				
Test Report Form No	IECEN60950_1B				
TRF originator:	SGS Fimko Ltd				
Master TRF:	dated 2003-03				
Copyright © 2003 IEC System for Conf Geneva, Switzerland. All rights reserve	formity Testing and Certification of Electrical Equipment (IECEE), d.				
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.					
Test item description:	Brick Style Power Supplies				
Trademark:	XP FOWER				
Manufacturer:	XP Power , 305 Foster Street, Littleton, MA 01460				
Model and/or type reference::	ence:: PDM60US12, PDM60US15, PDM60US18, PDM60US24, PDM60US 30, PDM60US36 and PDM60US48				
Serial number:	-				
Rating(s)	Input – 100 - 240VAC, 1.5-0.75A, 50/60Hz Output – 12VDC to 48VDC, 60Watts				





Copy of marking plate		
	XP POWER MODEL NO.: PDM60US15 MAX POWER OUTPUT: 60W	
	INPUT: 100-240V-50/60H: 1.5-0.75A OUTPUT: 16V===4.6A max.	
	SA	
	- The second control of the second control o	
	Indoor use only	
	ACAUTION A FISK OF ELECTRIC SHOCK ATTENTION REPRESENTATION FATERITED SHOCK SHOCK FATERITED SHOCK SHOCK SHOCK SHOCK SHOCK FATERITED SHOCK S	
Summary of testing:		
XP Power, power supplies, mo 30, PDM60US36 and PDM600 60950-1:2001	odels: PDM60US12, PDM60US15, PDM60US18, PDUS48 fulfill the requirements of IEC 60950-1:2001 (1	M60US24, PDM60US st Edition) and/or EN





Particulars: test item vs. test requirements

Test case verdicts

Test case does not apply to the test object: N/A

Test item does meet the requirement: P(ass)

Test item does not meet the requirement ..: F(ail)

Testing

Date of receipt of test item: 2006-04-03

General remarks

"This report is not valid as a CB Test Report unless appended by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02".

The test result presented in this report relate only to the object(s) tested.

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"(see appended table)" refers to a table appended to the report.

Throughout this report a comma (point) is used as the decimal separator.

General product information:

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