Ref. Certif. No.

US-24029-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	Power Supply
Name and address of the applicant Nom et adresse du demandeur	XP POWER LLC SUITE 150, 1241 E DYER RD SANTA ANA CA 92705, USA
Name and address of the manufacturer Nom et adresse du fabricant	XP POWER LLC SUITE 150, 1241 E DYER RD SANTA ANA CA 92705, USA
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 2ème page*	XP POWER LLC 990 BENECIA AVE SUNNYVALE CA 94085 USA ☒ Additional Information on page 2
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	Input Rated: 100-240 V~, 50/60 Hz, 9 A Output Rated: Refer to Model Differences in Test Report for details.
Trademark (if any) Marque de fabrique (si elle existe)	XP
Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur	SMT
Model / Type Ref. Ref. De type	MHP650PSXXYY See Page 2
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2ème page	Additionally evaluated to EN 60601-1:2006/A1:2013; 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	4786488107-20110630 issued on 2014-09-24

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

☒ 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: 2014-10-06

Signature:

Jolanta M. Wroblewska

Ref. Certif. No.

US-24029-UL

Model Details:

MHP650PSXXYY (XX = Output Voltage 12-48 and YY = EF, TF or blank)

Factories:

XP POWER (KUNSHAN) LTD
230 BIN JIANG NAN RD ZHANGPU TOWN KUNSHAN JIANGSU 215300
CHINA

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

- [x] 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: 2014-10-06

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.....:	**4786488107-20110630**
Date of issue .....:	**2014-09-24**
Total number of pages.....:	**178**
CB Testing Laboratory.....:	**UL Northbrook**
Address .....:	**333 Pfingsten Rd. Northbrook, IL 60062-2096, USA**
Applicant's name.....:	**XP POWER LLC**
Address .....:	**SUITE 150** **1241 E DYER RD** **SANTA ANA CA 92705** **UNITED STATES**
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……..:	N/A
Test Report Form No.....:	IEC60601_1J
Test Report Form Originator .....:	UL(US)
Master TRF .....:	2014-07

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.

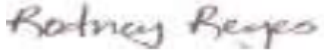
This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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 .....:	Power Supply
Trade Mark .....:	
Manufacturer.....:	XP POWER LLC SUITE 150 1241 E DYER RD SANTA ANA CA 92705 UNITED STATES
Model/Type reference.....:	Model MHP650PSXXYY (XX = Output Voltage 12-48 and YY = EF, TF or blank)
Ratings.....:	Input Rated: 100-240 V~, 50/60 Hz, 9 A Output Rated: Refer to Model Differences for details

Testing procedure and testing location:			
☐	**CB Testing Laboratory:**		
Testing location/ address .....:			
☐	**Associated CB Testing Laboratory:**		
Testing location/ address .....:			
Tested by (name + signature).....:			
Approved by (name + signature) .....:			
☐	**Testing procedure: TMP/CTF Stage 1:**		
Testing location/ address .....:			
Tested by (name + signature).....:			
Approved by (name + signature) .....:			
☐	**Testing procedure: WMT/CTF Stage 2:**		
Testing location/ address .....:			
Tested by (name + signature).....:			
Witnessed by (name + signature) .....:			
Approved by (name + signature) .....:			
☒	**Testing procedure: SMT/CTF Stage 3 or 4:**		
Testing location/ address		XP Power LLC, 1241 E. Dyer Rd #150, Santa Ana, CA 92705, USA	

:		
Tested by (name + signature)..... :	Rodney Reyes	
Witnessed by (name + signature) ..... :		
Approved by (name + signature) ..... :	Tac Pham	
Supervised by (name + signature)..... :	Bernadette Matsuoka	

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

National Differences (9 Pages as part of this Test Report)

Enclosure (106 Pages)

Summary of testing

All tests were conducted at XP Power/ 1241 E. Dyer Rd #150, Santa Ana, CA, 92705, USA
:

Tests performed (name of test and test clause):	**Testing location:**
Input Test (4.11)	
Humidity Preconditioning (5.7)	
Limitation of Voltage, Current or Energy (8.4.3 & 8.4.4)	
Impedance of PE Connection (8.6.4)	
Earth Leakage Current (8.7.4.5)	
Touch Current (8.7.4.6)	
Working Voltage Measurement (8.8.3 & 8.10.4.1)	
Dielectric Strength (8.8.3)	
Ball Pressure (8.8.4.1)	
Single Fault Conditions (13.2.2)	
Ball Impact (15.3.3)	
Mains transformers (short and overload) 15.5, 13.2.3	

Summary of compliance with National Differences

List of countries addressed:

Austria, Korea, USA, Canada, United Kingdom, Sweden

☒ The product fulfils the requirements of AAMI ES60601-1:2005 (R21012) Medical electrical equipment- Part 1: General requirements for basic safety and essential Performance; CSA CAN/CSA-C22.2 NO. 60601-1:14: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance - Third Edition; IEC 60601-1 AMD 1 :2014 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance - Edition 3.1

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.

Marking plate below is considered representative of the entire series with the exception that “BETA” is not provided.

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	Building-in, to be determined in the end product
Accessories and detachable parts included.....:	None
Other options include .....:	None
Testing	
Date of receipt of test item(s) .....:	2009-03-10
Dates tests performed.....:	2009-03-10 to 2010-01-14
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.	- single fault condition.....: S.F.C.
- means of Operator protection .....: MOOP	- means of Patient protection ....: MOPP
General remarks: **Throughout this report a ☐ comma / ☒ point is used as the decimal separator.**	
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012	
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..... :	☒ **Yes** ☐ **Not applicable**
When differences exist; they shall be identified in the General product information section.	

Name and address of factory (ies)..... :	XP POWER LLC 990 BENECIA AVE SUNNYVALE CA 94085 UNITED STATES XP POWER (KUNSHAN) LTD 230 BIN JIANG NAN RD ZHANGPU TOWN KUNSHAN JIANGSU 215300 CHINA

General product information:

Report Summary

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

Product Description

Component Medical Power Supply intended for use in Medical Electrical Equipment.

Model Differences

The power supplies in this series are differentiated by the output voltage and current ratings, number of turns of primary/secondary windings in the Power Transformers (T302), type of Chassis Fan Cover and minor differences in the secondary circuit components and PWB layout.

See below for Model Ratings Table Maximum output rating listed below are based upon 50C ambient:

Model No.	Output Voltage (Vdc)	Output Ratings			
		50°C Ambient		70°C Ambient	
		Max. Output Current (A)	Max. Output Power (W)	Max. Output Current (A)	Max. Output Power (W)
MHP650PS12YY	10.1 to 13.5	50	607	25	300
MHP650PS15YY	13.6 to 17	40	607	20	300
MHP650PS18YY	17.1 to 21	33.3	607	16.6	300
MHP650PS24YY	21.1 to 26	27	657	13.5	324
MHP650PS28YY	26.1 to 31	23	651	11.5	322
MHP650PS33YY	31.1 to 33	19.7	651	9.75	322
MHP650PS36YY	33.1 to 42	18	657	9	324
MHP650PS48YY	42.1 to 54	13.5	657	6.75	324

All models are provided with Fan Supply Connection (12Vdc, 0.5 A) and Standby Connection (5 Vdc, 0.2A). See also Enclosure-Miscellaneous for additional details.

Models provided with the following YY values differ as follows:

Model MHP650PSXXEF provided with top cover with fan located at the end of the power supply chassis.
Model MHP650PSXXTF provided with top cover with fan located at the top of the power supply chassis.
Model MHP650PSXX not provided with top cover and no fan, only provide with U-shaped chassis.

Additional Information

The clearance distances have additionally been assessed for suitability up to 3000 m elevation. The creepage and clearance measurement in Table: To insulation diagram are derived from 2nd edition evaluation.

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

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.

No additional testing was deemed necessary to evaluate the models covered under this Report to IEC 60601-1:2012, 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. 11CA22170 and CBTC No. US-17354-UL

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), IEC 60601-1: 2012, 3rd Edition with AM. 1Scope of Power Supply 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 Power Supply 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

- The product is Classified only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- The mode of operation is: Continuous
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product is suitable for use in the presence of a flammable anaesthetics mixture with air or oxygen or with nitrous oxide: No
- Manufacturer’s Recommended Ambient: 50°C at Full Load and 70°C at Half Load
- . Classification of installation and use: Building-in
- Supply connection: Building-in

- Accessories and detachable parts included in the evaluation: None
- Options included: None

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. When installed in an end-product, consideration must be given to the following:

- Considerations to the applied parts requirements shall be considered as part of the end-product evaluation.
- Units not provided with a fan were evaluated with 5m/s airflow across the unit. The need for airflow across units not provided with a fan shall be determined as part of the end-product evaluation.
- The end product should ensure that the requirements related to accompanying documents clause 7.9 are met.
- Attention to the output temperature limit of 120°C shall be considered in the end-use application when determining the appropriate level of airflow across the unit.
- 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 output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The input/output connectors are not acceptable for field connections; they are only intended for factory wiring inside the end-use product.
- The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
- Power supply provides the following MOPP (means of patient protection): two MOPP based upon a working voltage 246 Vrms, 348 Vpk between Primary to Secondary, one MOPP based upon a working voltage 250Vrms, 354 Vpk between Primary and Earth/Enclosure
- 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.
- Proper bonding to the end-product main protective earthing termination is required.
- Protective Earthing test should be conducted in the end-use product.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C at Full Load and 70°C at Half Load.
- Magnetic devices T301 and T303 employ a Class B (130°C) or higher insulation system. Magnetic devices L1, L2, L50, L301, T201, T302 employ a Class F (155°C) or higher insulation system.
- The PWB is rated 130°C.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
- The need for marking durability testing and legibility of marking testing to be considered as part of the end product application.
- The power supplies have been evaluated as continuous operation and have not been evaluated for use in the presence of flammable anaesthetic mixture with air, oxygen or nitrous oxide.
- A single maximum current rating of 9 A was provided for the entire100-240Vac voltage range. The end product evaluation shall consider the acceptability of this component power supply rating as it relates to the requirements of Clause 7.2.7.

Ref. Certif. No.

US-24027-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	Power Supply
Name and address of the applicant Nom et adresse du demandeur	XP POWER LLC SUITE 150 1241 E DYER RD SANTA ANA CA 92705 USA
Name and address of the manufacturer Nom et adresse du fabricant	XP POWER LLC SUITE 150 1241 E DYER RD SANTA ANA CA 92705 USA
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 2ème page*	XP POWER LLC 990 BENECIA AVE SUNNYVALE CA 94085 USA ☒ Additional Information on page 2
Ratings and principal characteristics Valeurs nominales et caractéristiques principales	Input Rated: 100-240 V~, 50/60 Hz, 13 A Output Rated: See Test Report - Model Differences for details
Trademark (if any) Marque de fabrique (si elle existe)	XP
Type of Manufacturer's Testing Laboratories used Type de programme du laboratoire d'essais constructeur	SMT
Model / Type Ref. Ref. De type	MHP1000PSXX See Page 2
Additional information (if necessary may also be reported on page 2) Les informations complémentaires (si nécessaire,, peuvent être indiqués sur la 2ème page	Additionally evaluated to EN 60601-1:2006 / A1:2013; 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	4786488107-20111216 issued on 2014-09-25

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/ncbnames

Date: 2014-10-06

Signature:

Jolanta M. Wroblewska

Ref. Certif. No.

US-24027-UL

Model Details:
MHP1000PSXX (where xx can be any number between 12 and 48 designating the output voltage)

Factories:
XP POWER (KUNSHAN) LIMITED
230, BIN JIANG NAN ROAD, ZHANG PU TOWN KUNSHAN, JIANGSU 215300
CHINA

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

- [x] 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: 2014-10-06

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. .....:	**4786488107-20111216**
Date of issue .....:	**2014-09-25**
Total number of pages .....:	**157**
CB Testing Laboratory .....:	**UL Northbrook**
Address .....:	**333 Pfingsten Rd. Northbrook, IL 60062-2096, USA**
Applicant's name .....:	**XP POWER LLC**
Address .....:	**SUITE 150** **1241 E DYER RD** **SANTA ANA CA 92705** **UNITED STATES**
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 .....:	N/A
Test Report Form No. .....:	IEC60601_1J
Test Report Form Originator .....:	UL(US)
Master TRF .....:	2014-07

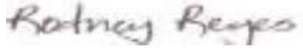
If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

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.....:	Power Supply	
Trade Mark .....:		
Manufacturer.....:	XP POWER LLC SUITE 150 1241 E DYER RD SANTA ANA CA 92705 UNITED STATES	
Model/Type reference.....:	Model MHP1000PSXX (where xx can be any number between 12 and 48 designating the output voltage)	
Ratings .....:	Input Rated: 100-240 V~, 50/60 Hz, 13 A Output Rated: Refer to Model Differences for details	
Testing procedure and testing location:		
☐ **CB Testing Laboratory:**		
Testing location/ address.....		
☐ **Associated CB Testing Laboratory:**		
Testing location/ address.....		
Tested by (name + signature)		
Approved by (name + signature)		
☐ **Testing procedure: TMP/CTF Stage 1:**		
Testing location/ address.....		
Tested by (name + signature)		
Approved by (name + signature)		
☐ **Testing procedure: WMT/CTF Stage 2:**		
Testing location/ address.....		
Tested by (name + signature)		
Witnessed by (name + signature).....		
Approved by (name + signature)		
☒ **Testing procedure: SMT/CTF Stage 3 or 4:**		
Testing location/ address.....	XP Power LLC, 1241 E. Dyer Rd #150, Santa Ana, CA 92705, USA	

Tested by (name + signature)	Rodney Reyes	
Witnessed by (name + signature)		
Approved by (name + signature)	Tac Pham	
Supervised by (name + signature).....	Bernadette Matsuoka	

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

National Differences (9)

Enclosures (189 pages)

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 11CA41873 and CB Certificate US-18260-UL. The tests conducted per 3rd ed of IEC 60601-1 were considered representative of the corresponding tests required by IEC 60601-1: 2012, Edition 3.1

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 (8.7.4.5)	
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)	

Summary of compliance with National Differences

List of countries addressed:

Austria, Korea, USA, Canada, United Kingdom, Sweden

☒ The product fulfils the requirements of AAMI ES60601-1:2005 (R21012) Medical electrical equipment-Part 1: General requirements for basic safety and essential Performance; CSA CAN/CSA-C22.2 NO. 60601-1:14: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance - Third Edition; IEC 60601-1 AMD 1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance - Edition 3.1

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.

Refer to Enclosure titled Marking Plate for copy.

Label provided is 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	Building-in, to be determined in the end product
Accessories and detachable parts included ..... :	None
Other options include ..... :	None
Testing	
Date of receipt of test item(s) ..... :	2010-06-23
Dates tests performed ..... :	2010-07-01 to 2010-10-13, 2011-07-18
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.	- single fault condition .....: S.F.C.
- means of Operator protection ..... : MOOP	- means of Patient protection ....: MOPP

General remarks:

Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version "J" of TRF for IEC for 60601-1 3rd edition with Amendment 1.

"(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 ☐ comma / ☒ point is used as the decimal separator.

Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012

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 ..... :	☒ **Yes** ☐ **Not applicable**

When differences exist; they shall be identified in the General product information section.	
Name and address of factory (ies) ..... :	**: XP POWER LLC** **990 BENECIA AVE** **SUNNYVALE CA 94085** **UNITED STATES** **XP POWER (KUNSHAN) LIMITED** **230, BIN JIANG NAN ROAD,** **ZHANG PU TOWN** **KUNSHAN,** **JIANGSU 215300 CHINA**

General product information:

Report Summary

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

Product Description

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

Model Differences

The power supplies in this series are differentiated by the output voltage and current ratings, number of turns of primary/secondary windings in the Power Transformers (T302), type of Chassis Fan Cover and minor differences in the secondary circuit components and PWB layout. See below for Model Ratings for up to 50°C ambient:

Model No.	Input Voltage (Vac)	Output Voltage (Vdc)	Output Ratings			
			50°C Ambient		70°C Ambient	
			Max. Output Current (A)	Max. Output Power (W)	Max. Output Current (A)	Max. Output Power (W)
MHP1000PS12	100-240	10.1 to 13.5	83	1001	41.5	500
MHP1000PS15	100-240	13.6 to 17	67	1010	33.5	500
MHP1000PS18	100-240	17.1 to 21	56	1010	27.7	500
MHP1000PS24	100-180	21.1 to 26	42	1013	21	500
MHP1000PS24	180-240	21.1 to 26	50	1200	21	500
MHP1000PS28	100-180	26.1 to 31	36	1013	18	500
MHP1000PS28	180-240	26.1 to 31	43	1204	20	600
MHP1000PS33	100-180	31.1 to 33	31	1013	15.2	500
MHP1000PS33	180-240	31.1 to 33	36	1204	18.2	600
MHP1000PS36	100-180	33.1 to 42	28	1013	14	500
MHP1000PS36	180-240	33.1 to 42	33	1188	16.5	600
MHP1000PS48	100-180	42.1 to 54	21	1013	10.5	500
MHP1000PS48	180-240	42.1 to 54	25	1200	12.5	600

All models are provided with Fan Supply Connection (12Vdc, 0.5 A) and Standby Connection (5 Vdc, 0.2A).

See also Enclosure-Miscellaneous for additional details.

Additional Information

This report is a reissue of CBTR Ref. No.: 11CA41873, CB Test Certificate Ref. No. US-18260-UL. Based on

the previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams and similar, has been determined that the product continues to comply with the standard

Based on previously conducted testing and the review of product construction, no tests were deemed necessary.

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 power supply series covered by this report employ Double/Reinforced Insulation between Primary and Secondary circuits.

Abnormal condition testing conducted was considered representative of all fuse (Cooper Bussmann, Type MDA-20-R) based upon comparison of the time to blow characteristics curves.

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.

Technical Considerations

- Classification of installation and use : For building-in
- Supply connection : For building-in
- Accessories and detachable parts included in the evaluation: None
- Options included: None
- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1:2005/C1:2009 (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:08 (includes National Differences for Canada), EN 60601-1:2006 / A1:2013
- Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product evaluation: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)
- Supply connection: Overvoltage Category II
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- The mode of operation is: Continuous
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- The product is suitable for use in the presence of a flammable anesthetics mixture with air or oxygen or with nitrous oxide: No
- The product was submitted and evaluated for use at the maximum ambient temperature (Tmra) permitted by the manufacturer's specification of: 50°C with output loaded to 100% rated and 70°C with output loaded to 50% rated (See De-rating Curve, Enclosure 7-01 (Ill. 14) for details).

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. When installed in an end-product, consideration must be given to the following:

- The component shall be installed in compliance with the Marking (clause 7) and Separation (clause 8) requirements of the end use application.
- Repeating leakage current testing and consideration of non-frequency weighted leakage to be considered as part of the end product.
- This power supply was evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth.
- 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 should 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 hazardous energy levels: Main Power Output
- 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 Dielectric Withstand Voltage 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: 578 Vpk, 240 Vrms.
- Protective bonding testing shall be considered in the end product application.
- For Class I application: Protective bonding testing shall be considered in the end product application.
- 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-L3, T201, T301-T303, and L301 (min. Class B, min. 130°C) and L50 (min. Class F, min. 155°C)
- Printed Wiring Board rated 130°C.
- Cleaning test to 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.