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. .....:	**4786488107-20120201**
Date of issue .....:	**2014-09-24**
Total number of pages .....:	**167**
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, USA**
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.

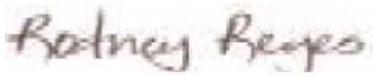
This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

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.....:	Component Power Supply
Trade Mark .....:	
Manufacturer.....:	XP POWER LLC, SUITE 150, 1241 E DYER RD., SANTA ANA CA 92705, UNITED STATES
Model/Type reference.....:	CCM250PSXXYY, where XX can be any number between 12 to 48 designating the output voltage and where YY is SF or blank to indicate single pole fusing and CCM250PS12-XB0352
Ratings .....:	Models CCM250PSXXYY: Input Rated: 100-240 V~, 50/60 Hz, 3.2A max Model CCM250PS12-XB0352: Input Rated: 100-240 V~, 50/60 Hz, 3.2A max, or 133-337Vdc, 3.2A max Output: See 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, SUITE 150, 1241 E DYER RD, 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)

Enclosures (50 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 E146893-A38-CB-1 and CB Certificates US-18422-A1-UL & US-21411-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:**
Test Testing Location/Comments	
Power Input Test (4.11)	
Humidity Preconditioning Treatment (5.7)	
Working Voltage Measurement (8.5.4)	
Earthing and Potential Equalization Test (8.6.4a)	
Dielectric Voltage Withstand (8.8.3) Ball Pressure (8.8.4.1)	**Testing on triple insulated wire type TRW by Great Leoflon, covered under Report E146893-A25-CB-1**
Temperature Test (11)	
Abnormal Operation and Single Fault Conditions (13)	
Transformer Overload and Short-Circuit Tests (15.5.1)	
Transformer Dielectric Voltage Withstand (15.5.2)	
Leakage Current Test (8.7)	

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.

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) ..... :	2011-06-17, 2013-02-20
Dates tests performed ..... :	2011-06-21 to 2011-10-22, 2013-02-20
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 (KUNSHAN) LTD** **230 BIN JIANG NAN RD** **ZHANGPU TOWN** **KUNSHAN** **JIANGSU 2153200 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

All models in the Model CCM250PSXXYYseries are identical with exception to the Mains Transformer (TR1), primary fusing, and minor secondary components that allow for different output voltage ratings. See below for maximum output ratings for up to 50°C:

Model No.	Output Voltage (Vdc)	Max. Output Current (A)	Max. Output Power (W)
CCM250PS12	10.1 to 13.5	20.8	250
CCM250PS15	13.6 to 17	16.7	250
CCM250PS18	17.1 to 21	13.9	250
CCM250PS24	21.1 to 26	10.4	250
CCM250PS28	26.1 to 31	8.9	250
CCM250PS33	31.1 to 33	7.6	250
CCM250PS36	33.1 to 42	6.9	250
CCM250PS48	42.1 to 54	5.2	250

Model CCM250PS12-XB0352 is the same as Model CCM250PS12 except for the rating: Input Rated: 100-240 V~, 50/60 Hz, 3.2A, or 133-337Vdc, 3.2A max and output rated 12Vdc, 20.8A; V Standby: 5Vdc, 0.5A

The outputs are linearly derated to 50% of the maximum output ratings in a 70°C ambient

Additional Suffix "SF" denotes units provided with only a single line side fuse.

Additional Information

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. E146893-A38-CB-1 issued on 2013-04-19 and CBTC No.s US-18422-A1-UL & US-21411-UL.

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 need for the additional testing and evaluation shall be determined in the end product investigation.

Nameplate markings provided as part of Enclosure were considered representative of the entire series.

Technical Considerations

- The product was investigated to the following additional standards: 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, EN 60601-1:2006 + CORR:2010 + AM1 (2013)
- The product was not investigated to the following standards or clauses:: Biocompatibility (ISO 10993-1), Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 60601-1-2)
- The degree of protection against harmful ingress of water is:: Ordinary
- 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
- The power supply was evaluated for use in 50°C ambient at Full Rated Output and 50% of the Rated Output in 70°C ambient.

Engineering Conditions of Acceptability

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

- The component shall be considered for compliance with the Marking (clause 7) and Separation (clause 8) requirements as part of the end use application evaluation.
- Repeat of 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 anaesthetic 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 shall 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 input/output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.
- The Dielectric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal: 356 Vpk, 244 Vrms; Primary-SEC: 680 Vpk, 323 Vrms.
- 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): T1-T5, L1, and L3 (Class F, 155°C)

- Printed Wiring Board rated 130°C.
- 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.
- Units provided with additional suffix “SF”, provided with only one fuse. The need for additional fusing shall be determined as part of the end product.
- The maximum investigated branch circuit rating is: 20 A
- Model CCM250PS12-XB0352: Suitable dc rated input fuse shall be provided in the end product and consideration shall be given to repeating the component fault testing in the end product with the dc input fuse.