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.....:	**4786488107-20111006**
Date of issue .....:	**2014-08-25**
Total number of pages.....:	**162**
CB Testing Laboratory.....:	**UL San Jose**
Address .....:	**455 E Trimble Rd, San Jose, CA 95131-1230, USA**
Applicant's name.....:	**XP Power LLC**
Address .....:	**Suite 150, 1241 E Dyer Road, 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……..:	
Test Report Form No.....:	**IEC60601_1J**
Test Report Form Originator .....:	**UL(US)**
Master TRF.....:	**2014-07**

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 Switching Power Supply
Trade Mark .....:	
Manufacturer.....:	XP Power LLC, Suite 150, 1241 E Dyer Road, Santa Ana, CA 92705 USA
Model/Type reference.....:	ECS45US05, ECS45USXX and ECS25USXX (where XX can be any number between 12 and 48 designating the output voltage, may also be follow by suffix SF or -C or both)
Ratings.....:	Input Rating: Model ECS45US05 and Model ECS45USXX Series: 100-240 Vac, 0.9 A, 50/60 Hz Model ECS25USXX Series: 100-240 Vac, 0.6 A, 50/60 Hz Output Rating: All Series: 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:**	XP POWER LLC, SUITE 150, 1241 E DYER RD, SANTA ANA CA 92705, USA	

Testing location/ address		
Tested by (name + signature).....	Rodney Reyes	
Witnessed by (name + signature)		
Approved by (name + signature)	Tac Pham	
Supervised by (name + signature).....	Melissa DeGuia	

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

National Differences (9 pages)

Enclosures (58 pages)

Summary of testing

All testing conducted under the Applicant's IEC 60601-1, 3rd Ed under CB Test Report 11CA34403 dated 2011-10-07 and corrected on 2011-11-03 and CB Certificate US-17816-UL, dated 2011-10-07. All tests conducted per 3rd ed of IEC 60601-1 were considered representative of the corresponding tests required by 3rd ed of IEC 60601-1+AM1

Tests performed (name of test and test clause):

Power Input Test (4.11)
Humidity Preconditioning (5.7)
Working Voltage Measurement (8.4.2)
Voltage or Charge Limitation, Voltage Limitation (8.4.3)
Impedance of PE Connection (8.6.4)
Leakage Current Test (8.7)
Dielectric Voltage Withstand (8.8.3)
Ball Pressure (8.8.4.1)
Temperature Test (11.1.1)
Abnormal Operation and Single Fault Conditions (13.2.2, 13.2.7)
Mains transformers (short and overload) (13.2.3, 15.5.1.2, 15.5.1.3)

Testing location:

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

Summary of compliance with National Differences

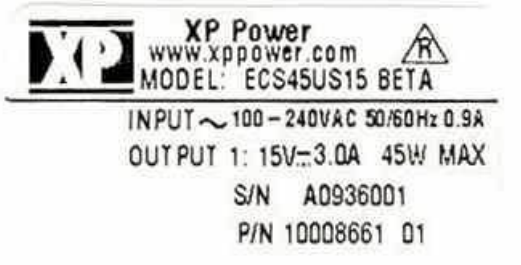
List of countries addressed: Austria, Canada, Republic of Korea, Sweden, United Kingdom and USA

☒ The product fulfils the requirements of IEC 60601-1, Edition 3.1 (2012)

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 ..... :	For 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	For building-in
Accessories and detachable parts included.....:	N/A
Other options include .....:	N/A

Testing

Date of receipt of test item(s) .....:	2009-08-21
Dates tests performed.....:	2011-07-12 to 2011-07-13

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:

"(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) LTD., 230 BIN JIANG NAN RD., ZHANGPU TOWN, KUNSHAN, JIANGSU 215300 CHINA

General product information:

Products are component power supplies intended to be used as part of Medical Electrical Equipment. It is an open frame power supply intended for building-in Class I or Class II end-products. Double insulated symbol is optionally provided. Earthing symbol may only be provided for Class I power supplies.

Model Differences

All models in the Model ECS45USXX series are identical with exception to the Mains Transformer, T1, and minor secondary components that allow for different output voltage ratings. See below for Model Ratings Table Below for 50°C:

Model ECS45US05: Output Rated: 4.1 Vdc to 6 Vdc, 6.0 A Max (30 W Max)
Model ECS45US12: Output Rated: 10.1 Vdc to 13.5 Vdc, 3.75 A Max (45 W Max)
Model ECS45US15: Output Rated: 13.6 Vdc to 17 Vdc, 3.00 A Max (45 W Max)
Model ECS45US18: Output Rated: 17.1 Vdc to 21 Vdc, 2.5 A Max (45 W Max)
Model ECS45US24: Output Rated: 21.1 Vdc to 26 Vdc Vdc, 1.90 A Max (45 W Max)
Model ECS45US28: Output Rated: 26.1 Vdc to 31 Vdc, 1.61 A Max (45 W Max)
Model ECS45US33: Output Rated: 31.1 Vdc to 33 Vdc, 1.36 A Max (45 W Max)
Model ECS45US36: Output Rated: 33.1 Vdc to 42 Vdc, 1.25 A Max (45 W Max)
Model ECS45US48: Output Rated: 42.1 Vdc to 54 Vdc, 0.95 A (45 W Max)

All respective models in the Model ECS25USXX Series are identical Model ECS45USXX Series, except for the lower output power rating and the heatsink is not provided. See below for Model Ratings Table Below for 50°C:

Model ECS25US12: Output Rated: 10.1 Vdc to 13.5 Vdc, 2.08 A Max (25 W Max)
Model ECS25US15: Output Rated: 13.6 Vdc to 17 Vdc, 1.67 A Max (25 W Max)
Model ECS25US18: Output Rated: 17.1 Vdc to 21 Vdc, 1.39 A Max (25W Max)
Model ECS25US24: Output Rated: 21.1 Vdc to 26 Vdc, 1.04 A Max (25 W Max)
Model ECS25US28: Output Rated: 26.1 Vdc to 31 Vdc, 0.89 A Max (25 W Max)
Model ECS25US33: Output Rated: 31.1 Vdc to 33 Vdc, 0.76 A Max (25 W Max)
Model ECS25US36: Output Rated: 33.1 Vdc to 42 Vdc, 0.69 A Max (25 W Max)
Model ECS25US48: Output Rated: 42.1 Vdc to 54 Vdc, 0.52 A Max (25W Max)

See Enclosure - Miscellaneous for de-rated output values for higher ambients.

Suffix "SF" indicates units provided with a single fuse provided in the line side of the primary.

Suffix "-C" indicates unit provided with cover and chassis. Only Class I units are provided with cover and chassis.

Additional Information

The clearance distances have additionally been assessed for suitability up to 3000 m elevation. The creepage and clearance measurement in Table:

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

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

These power supplies have been previously evaluated by UL to IEC 60601-1, 3rd Ed under CB Test Report 11CA34403 dated 2011-10-07 and corrected on 2011-11-03 and CB Certificate US-17816-UL, dated 2011-10-07. All tests conducted per 3rd ed of IEC 60601-1 were considered representative of the corresponding tests required by 3rd ed of IEC 60601-1+AM1.

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: ANSI/AAMI ES60601-1:2005 (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, Edition 3.1 (2012)
- Scope 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 (See De-rating Curve, Enclosure 7-01 and Enclosure 7-02 for details).

Risk Controls/ Engineering Condition 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.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- 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 available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
- The input/output connectors are not acceptable for field connections, they are only intended for connection to mating connectors of internal wiring inside the end-use equipment.
- Heatsink 1 was considered floating live and should not be connected to earth in the end-product.
- The power supply shall be mounted on insulating post when installed in a Class II end-product.
- The "floating" mounting hole shall be mounted on insulating post or properly earthed for Class I end-product.
- Units may be provided with one fuse in the Line side for models with SF suffix or one fuse in both the Line and Neutral sides. The need for additional fusing shall be determined as part of the end-product

evaluation.

- Units provided with either a Cover or Chassis should be used only in a Class I application with earthing symbol applied. The cover and chassis shall be reliably earthed in the end-use application.
- When installed in a Class I end product, and if the Chassis and Cover are not provided, the power supply shall be mounted in a manner that provides, at a min. 2.5 mm Clearance between the primary side of the power supply and protectively earthed accessible conductive parts. In addition, when installed in a Class I end product, the protective bonding terminal of the power supply shall be reliably connected to the main protective earthing terminal of the end product.
- When installed in a Class II end product, the power supply shall be mounted, on insulating posts, in a manner that provides, at a min. 5 mm Clearance between the primary side of the power supply and any accessible conductive parts.
- Power supply provides the following MOPP (means of patient protection): two MOPP based upon a working voltage 250 Vrms, 531 Vpk between Primary to Secondary, one MOPP based upon a working voltage 250 Vrms, 354 Vpk between Primary and Earth/Enclosure.
- Temperature, Leakage Current including when measured with a non-frequency-weighted device (Clause 8.7.3e), Protective Bonding, 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 evaluated for use at the maximum ambient temperature (Tmra) permitted by the manufacturer's specification of: 50°C (See De-rating Curve, Enclosure 7-01 and Enclosure 7-02 for details)
- Magnetic devices T1 employs a Class F (155°C) insulation system. Magnetic devices L1, L2, L3 employ a Class F (155°C 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 need for Marking Durability and Legibility of Marking testing to be considered as part of the end product application.
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- A single maximum current rating of 0.9A or 0.6A were provided for the entire 100-240Vac 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.