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.....:	**4786488108-6**
Date of issue .....:	**2014-08-15, Amendment 1 2016-06-28**
Total number of pages.....:	**157**
CB Testing Laboratory.....:	**UL Fremont**
Address .....:	**47173 Benecia St., Fremont, CA 94538-7366 USA**
Applicant's name.....:	**XP Power LLC**
Address .....:	**15641 Red Hill Ave, Suite 100, Tustin, CA 92780 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

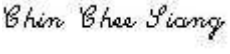
If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

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 Switching Power Supply	
Trade Mark .....:		
Manufacturer.....:	XP Power LLC 15641 Red Hill Ave, Suite 100, Tustin, CA 92780 USA	
Model/Type reference.....:	AHM150PSXXYY-ZZ (where XX is any number between 12-48 designating output voltage and YY can be blank or "C2", -ZZ can be "-A", "-6", "-6A", "8"," -8A", or blank)	
Ratings.....:	Input Rated: 100-240 Vac, 50/60 Hz, 1.8 A Output Rated: Refer to Model Differences for additional details.	
Testing procedure and testing location:		
☐ **CB Testing Laboratory:**		
Testing location/ address	UL Fremont, 47173 Benecia St., Fremont, CA 94538-7366 USA	
☐ **Associated CB Testing Laboratory:**		
Testing location/ address		
Tested by (name + signature).....	Haydee Gonzalez	
Approved by (name + signature)	Ahmad Daoudi	
☐ **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 Limited, 401 Commonwealth Drive, Haw Par Technocentre, Lobby B, #02- 02, Singapore 149598	
Tested by (name + signature).....	Chin Chee Siang	
Witnessed by (name + signature)	-	-
Approved by (name + signature)	Ahmad Daoudi/Reviewer	
Supervised by (name + signature).....	Haydee Gonzalez/Project Handler	

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

National Differences (9 pages)

Enclosures (48 pages)

Summary of testing: Tests were conducted at the following locations:

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

Tests performed (name of test and test clause):	**Testing location:**
Power Input Test (4.11)	
Humidity Preconditioning Treatment (5.7)	
Durability of Markings (7.1.3)	**XP Power Limited**
Voltage or Charge Limitation (8.4.3, 8.4.4)	
Working Voltage Measurement (8.5.4)	
Dielectric Voltage Withstand (8.8.3)	**XP Power Limited**
Ball Pressure (8.8.4.1)	
Temperature Test (11)	
Abnormal Operation and Single Fault Conditions (13)	
Push (Rigidity) (15.3.2)	**XP Power Limited**
Ball Impact (15.3.3)	
Drop Impact (15.3.4)	**XP Power Limited**
Mold Stress Relief (15.3.6)	
Transformer Overload and Short-Circuit Tests (15.5.1)	
Leakage Current Test (8.7)	**XP Power Limited**
RISK MANAGEMENT FILE Review (4.2)	

Summary of compliance with National Differences

List of countries addressed: Austria, Canada, Republic of Korea, Sweden, UK, USA

☒ The product fulfils the requirements of IEC 60601-1:2005, Third Ed with Am. 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.

Multiple files attached to Enclosure - Marking Plate ID 13-01
Labels provided are considered representative of the entire series.

GENERAL INFORMATION

Test item particulars (see also Clause 6):

Classification of installation and use ..... :	External Transportable
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location) :	Component switching power supply
Mode of operation .....:	Continuous
Supply connection	Appliance coupler
Accessories and detachable parts included.....:	None
Other options include .....:	None

Testing

Date of receipt of test item(s) .....:	2010-05-28, 2010-02-02, 2015-12-21
Dates tests performed .....:	2010-11-01 to 2010-12-28, 2011-02-09 to 2011-05-12, 2011-05-26, 2016-04-25 to 2016-04-27

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) LTD 230 BIN JIANG NAN RD ZHANGPU TOWN KUNSHAN JIANGSU 215300 CHINA XP POWER (S) PTE LTD LIPO BLDG, #05-01 621 ALJUNIED RD SINGAPORE 389834 SINGAPORE XP POWER HORSESHOE PARK PANGBOURNE RG8 7JW UNITED KINGDOM

General product information:

Products covered are external power supplies intended to be used with Medical Electrical Equipment. Units are Class I or Class II.

Model Differences:

All models in the Model AHM150PSXXYY-ZZ Series are identical with exception to the Mains Transformer, T2, and minor secondary components that allow for different output voltage ratings per the output voltage range noted below. See below for Model Ratings Table Below for 40°C:

Model AHM150PS12: 10.1-13.5 Vdc, 12.5 A max. (150W max.)
Model AHM150PS15: 13.6-17.0 Vdc, 10.0 A max. (150W max.)
Model AHM150PS19: 17.1-21.0 Vdc, 7.89 A max. (150W max.)
Model AHM150PS24: 21.1-26.0 Vdc, 6.25 A max. (150W max.)
Model AHM150PS28: 26.1-31 Vdc, 5.36 A max. (150W max.)
Model AHM150PS33: 31.1-33 Vdc, 4.55 A max. (150W max.)
Model AHM150PS36: 33.1-42 Vdc, 4.17 A max. (150W max.)
Model AHM150PS48: 42.1-54.0 Vdc, 3.13 A max. (150W max.)

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

Models may have an additional -ZZ identifier which can be "-A", "-6", "-6A", "-8", "-8A", or blank to designate the type of input connector:

blank = C14 style input connector (Class I construction) ;
"-A" = C14 style input connector with optional IEC cable retention;
"-6" = C6 style input connector (Class I);
"-6A" = C6 style input connector with optional IEC cable retention;
"-8" = C8 style input connector (Class I)
"-8A" = C8 style input connector with optional IEC cable retention.

Models may have an additional YY identifier which can be blank or "C2". Units designated “C2” have a Class II configuration.

Additional Information:

The original report 4786488108-6, dated 2014-08-15 was amended to include an alternate construction with testing, to update the applicant address and add two manufacturing locations. Note that the original testing was conducted under the CTF program, however; presently that client’s laboratory location (XP Power LLC, suite 150, 1241 E. Dyer Rd, Santa Ana CA 92705, USA) does not participate in the program. No testing was conducted at the client’s facilities after the program was discontinued.

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.

The nameplate markings provided are considered representative of the entire series.

No additional testing was deemed necessary to evaluate the models covered under this Report to IEC 60601-1, 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. 10ME03010, CBTC No. US-17207-UL.

Technical Considerations:

- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)+AM1 (2012) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States), CAN/CSA-C22.2 No. 60601-1 (2008) +AM1 (2014) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), EN 60601-1+ AM1 (2013) (Medical electrical equipment Part 1: General requirements for basic safety and essential performance), IEC 60601-1:2005, Third Ed. With Am.1
- 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
- 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 evaluated only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No
- Unit also complied with spacing requirements of UL60601-1 (1st), CSA C22.2 No. 60601-1 (2nd), and IEC 60601-1 (2nd) for Basic for 250 Vac from Primary to Ground, Double/Reinforced for 250Vac from Primary to Secondary, and Supplementary for 250 Vac from Secondary to Earth.

Risk Controls/ Engineering Condition of Acceptability

- The component shall be provided in compliance with the Marking (clause 7) and Separation (clause 8) requirements of the end use application.
- The power supply was evaluated for use in 40°C ambient at Full Rated Output and 60% of the Rated Output in 60°C ambient. (See De-rating Curve, Enclosure 7-01 for details).
- Repeating leakage current testing should be considered in the end product application.
- This power supply was evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth/Secondary Reference Conductor; and One MOPP between Secondary and Earth/ Secondary Reference Conductor.
- 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 output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use machine.
- The Electric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 432 Vpk, 244 Vrms; Primary-SEC: 432 Vpk, 244 Vrms.
- 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-L4 and T2 are Class B (130°C).
- Cleaning test to be considered as part of end product evaluation.
- The need for Marking Durability and Marking Legibility Testing to be considered as part of the end product installation.
- Power cord suitable for the application to be provided as part of the end product evaluation.