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.....:	4786488107-20111229
Date of issue.....:	2014-09-16
Total number of pages.....:	169
CB Testing Laboratory.....:	UL Camas
Address.....:	2600 NW Lake Rd., Camas, WA 98607, 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

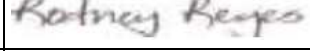
If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.

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, Suite 150, 1241 E Dyer Road, Santa Ana, CA 92705 USA
Model/Type reference.....:	HPU1K5PSXX-M (where XX can be any number 12-48, may also be followed by suffix SF).
Ratings.....:	Input Rated: ~ 100-240 Vac, 50/60 Hz, 16.5 A Output Rated: 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, 1241 E. Dyer Rd #150, Santa Ana, CA 92705, USA	
Tested by (name + signature)..... :		Rodney Reyes	
Approved by (name + signature) ..... :		Tac Pham	

Supervised by (name + signature)..... :	Timothy L. Gambrell	

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

National Differences (9 pages)

Enclosure (59 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 11CA52741 and CB Certificate US-18302-UL. The tests conducted per 3rd ed of IEC 60601-1 were considered representative of the corresponding tests required by IEC 60601-1: 2012, 3rd Edition with Am. 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) Leakage Current (8.7) Working Voltage Measurement (8.5.4) Dielectric Voltage Withstand (8.8.3) Temperature Test (11.1) Abnormal Operation and Single Fault Conditions (13.2) Mains Transformers (short and overload) (15.5, 13.2.3)	XP Power LLC, 1241 E. Dyer Rd #150, Santa Ana, CA 92705, USA

Summary of compliance with National Differences

List of countries addressed:

US, CAN, AUSTRIA, REPUBLIC OF KOREA, SWEDEN and UNITED KINGDOM

☒ The product fulfils the requirements of IEC 60601-1:2012, Edition 3 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.

Labels provided are 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	To be determined in the end product
Accessories and detachable parts included.....:	N/A
Other options include .....:	N/A

Testing

Date of receipt of test item(s) .....:	2008-12-01, 2009-07-28, 2011-08-10
Dates tests performed .....:	2008-12-02 to 2009-05-20, 2009-09-14 to 2010-02-04, 2011-08-09 to 2011-11-23

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, USA XP Power (Kunshan) Limited., 230, Bin Jiang Nan Road, Zhang Pu Town, Kunshan, Jiangsu 215300 China

General product information:

Product Description
Model covered in this report is a component power supply intended for use in Medical Electrical Equipment. The need for the additional testing and evaluation shall be determined in the end product evaluation. This is a Class I, open frame power supply intended for building-in.

Model Differences
The power supplies in the series are differentiated by the output voltage and current ratings, number of turns of primary/secondary windings in the Transformers (T2 (Power)) and minor differences in the secondary circuit components and PWB layout.

See below for Model Ratings Table for 50°C below:

Model No.	V1 Output			
	Voltage (Vdc)	Input Rated (Vac)	Max. Current (A)	Max. Power (W)
HPU1K5PS12-M	10.1 to 13.5	100-240	100	1200
HPU1K5PS15-M	13.6 to 17	100-240	80.0	1200
HPU1K5PS18-M	17.1 to 21	100-240	66.6	1200
HPU1K5PS24-M	21.1 to 26	100-180	50.0	1200
HPU1K5PS24-M	21.1 to 26	180-240	62.5	1500
HPU1K5PS28-M	26.1 to 31	100-180	42.80	1200
HPU1K5PS28-M	26.1 to 31	180-240	53.57	1500
HPU1K5PS33-M	31.1 to 33	100-180	36.36	1200
HPU1K5PS33-M	31.1 to 33	180-240	45.45	1500
HPU1K5PS36-M	33.1 to 42	100-180	33.3	1200
HPU1K5PS36-M	33.1 to 42	180-240	41.6	1500
HPU1K5PS48-M	42.1 to 54	100-180	25.0	1200
HPU1K5PS48-M	42.1 to 54	180-240	31.25	1500

See Enclosure-Miscellaneous for details for output de-rating table for higher ambient.

Units provided with SF suffix only provided with one fuse in the line side.

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. 11CA52741 and CBTC No. US-18302-UL.

Nameplate marking provided is considered representative of the series.

For licenses older than 3 years, manufacturer to provide updated licenses upon NCB's request.

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/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. 1

- The product was not investigated to the following standards or clauses:: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)

- 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

- 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

- 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.

Risk Controls/ Engineering Condition of Acceptability

- 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.
- 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. (See De-rating Curve, Enclosure 7-01 for details)
- Consideration shall 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.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage test shall be considered in the end product application.
- 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 42.4 Vac peak or 60 Vdc, under normal and single fault conditions.
- The secondary output circuits exceed 240 VA.
- The output connectors are suitable for factory wiring only.
- The maximum investigated branch circuit rating is: 20 A
- The Electric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal: 231 Vrms, 494 Vpk; Primary-SEC: 261 Vrms, 444 Vpk.
- Proper bonding to the end-product main protective earthing termination is required. Protective earthing testing shall be conducted 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, T2, T3, T4, L1-L4, L6, L7 and L8 (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.
- Models provided with suffix SF only provided with one line side fuse. Consideration should be made in the end-use product to determine the need of double pole fusing.

.