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.....:	E146893-D1001-2-ULCB
Date of issue.....:	2015-04-10
Total number of pages.....:	228
CB Testing Laboratory.....:	UL Camas
Address.....:	2600 N.W. Lake Road, Camas, WA, 98607, USA
Applicant's name .....:	XP POWER LLC
Address.....:	15641 Red Hill Ave., Ste. 100 Tustin, CA 97280 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

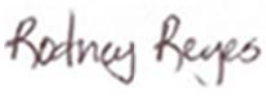
This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.

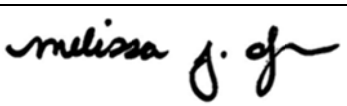
General disclaimer:

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 for use in Medical Electrical Equipment
Trade Mark:	"XP"
Manufacturer:	Same as Applicant
Model/Type reference:	CCL400PSXXYY (where XX = can be any number between 12 to 48 indicating main output voltage, "YY" can be SF or blank indicating Single Fuse), may also be provided with additional suffixes "-C", "-L".
Ratings:	Input: 100-240Vac, 50/60Hz, 5A 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):		
[X] Testing procedure: SMT/CTF Stage 3 or 4:		
Testing location/ address:	XP Power LLC 15641 Red Hill., Ste 100, Santa Ana, CA 92780 USA	
Tested by (name + signature):	Rodney Reyes	
Witnessed by (name + signature):	None	
Approved by (name + signature):	Tac Pham	

Supervised by (name + signature):	Melissa DeGuia	

List of Attachments (including a total number of pages in each attachment): Refer to Appendix A of this report. All attachments are included within this report.
Summary of testing
Tests performed (name of test and test clause): Testing location: *Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.*
Summary of compliance with National Differences List of countries addressed: Austria, Korea, Republic of, USA, Canada, United Kingdom, Sweden

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 the enclosure(s) titled Marking Plate in the Enclosures section in Appendix A of this report for a copy.

GENERAL INFORMATION	
Test item particulars:	
Classification of Installation and Use:	For Building-in
Device Type:	Component
Intended Use Statement:	Component power supply intended to provided regulated power to medical equipment
Mode of Operation:	Continuous
Supply Connection:	For Building-in
Accessories and detachable parts included:	None
Other Options Include:	
Testing	
Date of receipt of test item(s) .....:	2014-07-01, 2014-11-06, 2015-01-20
Dates tests performed .....:	2014-08-18 to 2014-12-06, 2015-03-30
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
- 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 point is used as the decimal separator. The Critical Component Table is located at the end of the Test Tables.	
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
When differences exist; they shall be identified in the General product information section.	

Name and address of factory (ies) .....:	XP Power Inc. 990 Benecia Ave. Sunnyvale, CA 94085 USA XP Power (Kunshan) Ltd 230 Bin Jiang Nan Rd, Zhangpu Town Kunshan, Jiangsu 215321 China XP Power (Vietnam) Co., Ltd. Lot D - 4Q- CN, My Phuoc 3 Industrial Park Ben Cat District, Binh Duong

GENERAL PRODUCT INFORMATION:

Report Summary

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

Refer to the Report Modifications page for any modifications made to this report.

Product Description

The product is a component AC-DC power supply for building-in, open frame type provided with a metal chassis, incorporating primary and SELV components.

Model Differences

All models in the Model CCL400PSXX-YY 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:

Output Ratings:

CCL400PS12: 10.1Vdc to 13.5Vdc, 33.3A Max., (400 W Max); Stand-by 5V, 0.5A, (2.5W Max)

CCL400PS15: 13.6Vdc to 17Vdc, 26.7A Max. (400 W Max); Stand-by 5V, 0.5A, (2.5W Max)

CCL400PS18: 17.1Vdc to 21Vdc, 22.2A Max. (400 W Max); Stand-by 5V, 0.5A, (2.5W Max)

CCL400PS24: 21.1Vdc to 26Vdc, 16.7A Max. (400 W Max); Stand-by 5V, 0.5A, (2.5W Max)

CCL400PS28: 26.1Vdc to 31Vdc, 14.3A Max. (400 W Max); Stand-by 5V, 0.5A, (2.5W Max)

CCL400PS33: 31.1Vdc to 33Vdc, 12.1A Max. (400 W Max); Stand-by 5V, 0.5A, (2.5W Max)

CCL400PS36: 33.1Vdc to 42Vdc, 11.1A Max. (400 W Max); Stand-by 5V, 0.5A, (2.5W Max)

CCL400PS48: 42.1Vdc to 54Vdc, 8.3A Max. (400 W Max); Stand-by 5V, 0.5A, (2.5W Max)

See Miscellaneous enclosure Power Output Table for additional information regarding power output and the various configurations.

Units provided with suffix "-SF" provide with single fuse.

Units provided with suffix "-C" provided with cover.

Units provided with suffix "-L" provided with input leads.

Additional Information

Marking label is representative of all models.

Licenses older than 3 years to be provided by the manufacturer upon request.

The required clearance values have been assessed for suitability up to 5000 m elevation for Patient

Protection (MOPP) (1.29 correction factor as per Table 8).

The models covered under this Report have been additionally evaluated to EN 60601-1:2006+A1 (2013)/A11:2011/A12:2014. Additional evaluation into EN 60601-1/A11:2011/A12:2014 was considered and deemed not applicable for the devices covered under this Report as they are component power supplies.

This report is a reissue of CBTR Ref. No.: E146893-D1001-1-ULCB, CB Test Certificate Ref. No. US-24818-UL, Issued 2015-03-17. 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.

Technical Considerations

- The product was investigated to the following additional standards:
  EN 60601-1:2006/A1:2013, KS C IEC 60601-1, ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, BS EN 60601:2006 A1, SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014
  Additional: 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)/A11:2011/A12:2014, IEC 60601-1: 2012, 3rd Edition with Am. 1
- The following additional investigations were conducted: N/A
- 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)
- The following accessories were investigated for use with the product: N/A
- 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.

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.

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.

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 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 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 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: 240 Vrms, 392 Vpk; Primary-SEC: 240 Vrms, 392 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 (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.

The suitability of the breaking capacity of the fuse per Clause 8.11.5 shall be verified in the end product.