

# CERTIFICATE OF COMPLIANCE

**Certificate Number** 2015-04-10-E146893  
**Report Reference** E146893-D1001-2-ULCB  
**Issue Date** 2015-04-10  
**Issued to:** XP POWER LLC  
15641 Red Hill Ave., Ste. 100  
Tustin, CA 97280 USA

**This is to certify that  
representative samples of**

Component power supply for use in Medical Electrical  
Equipment

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".

Have been investigated by UL in accordance with the  
Standard(s) indicated on this Certificate.

**Standard(s) for Safety:**

ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2  
NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)

**Additional Information:**

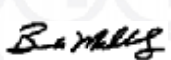
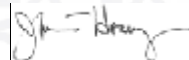
See the UL Online Certifications Directory at  
[www.ul.com/database](http://www.ul.com/database) for additional information.

Only those products bearing the UL Certification Mark should be considered as being covered by UL's  
Certification and Follow-Up Service.

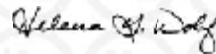
Recognized components are incomplete in certain constructional features or restricted in  
performance capabilities and are intended for use as components of complete equipment  
submitted for investigation rather than for direct separate installation in the field. The final  
acceptance of the component is dependent upon its installation and use in complete equipment  
submitted to UL LLC.

Look for the UL Certification Mark on the product.

This is to certify that representative samples of the product as specified on this certificate were tested  
according to the current UL requirements.

Bruce Mahrenholz, Assistant Chief Engineer, Global Inspection and Field Services, UL LLC  
Joseph Hosey, General Manager, Director of Sales – Canada, UNDERWRITERS LABORATORIES OF CANADA INC.



Helena Y. Wolf, Director, Global Market Access Operations, UL LLC

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Customer Service Representative [www.ul.com/contactus](http://www.ul.com/contactus)



Description

## UL TEST REPORT AND PROCEDURE

<b>Standard:</b>	ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)
<b>Certification Type:</b>	Component Recognition
<b>CCN:</b>	QQHM2, QQHM8
<b>Product:</b>	Component power supply for use in Medical Electrical Equipment
<b>Model:</b>	E146893-D1001-2-ULCB
<b>Rating:</b>	Input: 100-240Vac, 50/60Hz, 5A max. Output: See Model Differences for details
<b>Applicant Name and Address:</b>	XP POWER LLC 15641 Red Hill Ave., Ste. 100 Tustin, CA 97280, USA

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service Agreement. Only those products which properly bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

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Prepared by: Wojciech Poleszak

Reviewed by: Melissa J. DeGuia

### Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

- A. Authorization - The Authorization page may include additional Factory Identification Code markings.
- B. Generic Inspection Instructions -
  - i. **Part AC** details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.
  - ii. **Part AE** details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.
  - iii. **Part AF** details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test 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.

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

### 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: 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 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

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. 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.
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- 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.
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- 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).

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- The end product shall ensure that the requirements related to accompanying documents, clause 7.9, are met.
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- The available voltage for the secondary outputs does not exceed 42.4 Vac peak or 60 Vdc, under normal and single fault conditions.
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- The output connectors are suitable for factory wiring only.
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- The maximum investigated branch circuit rating is: 20 A
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- 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)
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- 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.
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- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
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- 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.
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- The suitability of the breaking capacity of the fuse per Clause 8.11.5 shall be verified in the end product.

<b>Markings and instructions</b>	
Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Serial number or lot or batch identifier	Serial number or lot or batch identifier
Date of manufacture or use by date	Date of manufacture or use by date
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Direct current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
Protective earth ground	
<b>Special Instructions to UL Representative</b>	
None	

<b>Production-Line Testing Requirements</b>			
<b>Test Exemptions</b> - The following models are exempt from the indicated test			
Test	Exemption Specifics	Details	
Grounding Continuity	The following models are exempt from the indicated test:	Not exempt	
Dielectric Voltage Withstand	The following models are exempt from the indicated test:	Not exempt	
Patient Circuit Dielectric Voltage Withstand	The following models are exempt from the indicated test:	All models	
Solid-State Components	The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	All models	
<b>Sample and Test Specifics for Follow-Up Tests at UL</b>			
The following tests shall be conducted in accordance with the Generic Inspection Instructions			
Plastic Enclosure or	Test	Sample(s)	Test Specifics

