# **CERTIFICATE OF COMPLIANCE**

**Certificate Number** 2019-04-19-E321744

Report Reference E321744-D1022-1/A0/C0-ULCB

**Issue Date** 2019-04-19

Issued to: XP POWER L L C

Applicant Company: 15641 Red Hill Avenue, Suite 100

Tustin, CA 92780 USA

Listed Company: Same as Applicant

This is to certify that Power supply for Building-In

representative samples of ECP180PSXX, where XX can be any number between 12 and

48 designating the output voltage, may also be provided with

suffix "SF" for removal of F2

Have been investigated by UL in accordance with the

Standard(s) indicated on this Certificate.

**Standard(s) for Safety:** ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and

A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC

60601-1 Edition 3.1 (2012)

**Additional Standards:** EN 60601-1:2006 +A1:2013+A12:2014

Additional Information: See the UL Online Certifications Directory at

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.

Barney Jakon

Gelena D. Wolf

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.

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# Description

# **UL TEST REPORT AND PROCEDURE**

Standard: ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012) Certification Type: Component Recognition CCN: QQHM2 / QQHM8 **Complementary CCNs: Product:** Power supply for Building-In ECP180PSXX, where XX can be any number between 12 and 48 Model: designating the output voltage, may also be provided with suffix "SF" for removal of F2 Rating: Input: 100-240 Vac, 2.5 A, 50/60 Hz Output: See Enclosure Miscellaneous - (001), Ratings Table for details. **Applicant Name and** XP POWER L L C Address: 15641 Red Hill Avenue, Suite 100

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.

Tustin, CA 92780, USA

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability as applicable.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Prepared by: Rahul Baria, Project Reviewed by: Ahmad Daoudi, Project

Handler Reviewed by. Reviewer

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## 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 model covered in this report is a component power supply intended for use in Medical 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. Refer to the Report Modifications page for any modifications made to this report.

#### **Model Differences**

All models in the Model ECP180PSXX series are identical with exception to the Mains Transformer, TR1, and minor secondary components that allow for different output voltage ratings.

See below for Model Ratings Table for 50°C ambient with 10 cfm fan applied 5 cm from input connector CN1 blowing inward:

Model ECP180PS12: Output Rated: 12 Vdc, 15A Model ECP180PS15: Output Rated: 15 Vdc, 12A Model ECP180PS18: Output Rated: 18 Vdc, 10A Model ECP180PS24: Output Rated: 24 Vdc, 7.5 A Model ECP180PS28: Output Rated: 28 Vdc, 6.43 A Model ECP180PS36: Output Rated: 36 Vdc, 5A Model ECP180PS48: Output Rated: 48 Vdc, 3.75A

See Enclosure "Miscellaneous - (001) 7-01 Ratings Table" for additional ratings information.

#### Additional Information

This report is a re-issue of CBTR Ref. No. 4786640925-20141121A, CB Test Certificate Ref. No.US-24350-UL and E321744-A18 merged into a combined report. Based on previously conducted testing and a review of the product construction, it was determined that partial testing was necessary in order to comply with the standard(s) referenced in this report.

The following test(s) were conducted as a result of the noted changes to the report:

Cl 8.8.3 – Dielectric Voltage Withstand Test

Cl 13 – Component Abnormal test w/ Earth leakage (Cl 8.7.4.5) after the test.

The following changes were made to the report:

- 1) Addition of 2b., Alternate Secondary Connector (CN2, CN3), to the critical component list.
- 2) Updated Critical Component 13-1, Transformer (TR1), model 225-15, to include "for model ECP180PS18."
- 3) Added new Model ECP180PS18, Rated Output: 18 Vdc, 10A to report.
- 4) Model differences are added in the GPI; the addition being "Model ECP180PS18: Output Rated: 18Vdc, 10 A."

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- 5) Updated Ratings Table enclosure Miscellaneous (001) "01 Ratings Table" to include Model ECP180PS18.
- 6) Corrected Test Table 8.2.4 (Working Voltage /Power Measurement) to "8.5.4."
- 7) Removed label RT-05 from CC table, not tested per clause 7.3 or 7.4
- 8) Removed Essential Performance at the request of report applicant.
- 9) Updated critical components list to include applicable standards and applicable IEC licenses.
- 10) Added alternate Fuse (F1,F2), Littelfuse 215 Series, Rated 3.15 A, 250 V, 1500A Interrupting rating. IEC license (VDE, 40013521).
- 11) Corrected required creepages & clearance distances and Working voltages in the Insulation Table.
- 12) Corrected Insulation Area B from 2 MOPP to 1 MOPP in insulation table. Additionally revised Clause 8.5.1.2.
- 13) Revised Clause 8.5.1.3 to "Pass"
- 14) Added load conditions to Test Table 11.1.1 and corrected typo for ECP180PS12 (Convection Cooling): 60 Hz, Ambient = 50C, Duration= 2 hours, Test Voltage from "164V" to "264V".

### Additional Information:

The clearance distances have additionally been assessed for suitability up to 5000 m elevation (1.29 correction factor from Table 8 of IEC 60601-1, 3.1 Ed.).

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

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

The power supply series covered by this report employ 2 Means of Patient Protection (MOPP) between Primary and Secondary circuits.

#### **Technical Considerations**

- The product was investigated to the following additional standards: EN 60601-1:2006
   +A1:2013+A12:2014
- The following additional investigations were conducted:
- The product was not investigated to the following standards or clauses: Biocompatibility (ISO 10993 1)

Clause 14, Programmable Electronic Systems

- The following accessories were investigated for use with the product: None
- 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

### **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:

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

Considerations to the applied parts requirement, to be conducted as end-product.

The input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.

The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.

Power supply provides the following MOPP (means of patient protection): 2 MOPP based upon a working voltage 250 Vrms, 388 Vpk between Primary to Secondary, 1 MOPP based upon a working voltage 241 Vrms, 343 Vpk between Primary and Earth, two MOPP based upon a working voltage 48Vdc between secondary to floated earth trace on PWB for BF output consideration, one MOPP

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based upon a working voltage 250 Vrms between secondary and earthing trace or chassis for BF output consideration.

Temperature, Leakage Current (including the use of non-frequency weighted device of 8.7.3e), Protective Earthing, 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 tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C at Full Load and 70°C at Half Load.

Magnetic devices TR1 employ a Class B (130°C) or higher insulation system.

The PWB is rated 130°C.

The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.

The following input terminals/connectors must be connected to the end-product supply neutral: AC-N CN1

The maximum continuous power supply output (Watts) relied on forced air cooling from: 10 cfm fan applied 5 cm from input connector CN1 blowing inward

For models marked "SF", additional fusing may be required in the end product to meet the requirement of Cl. 8.11.5, Mains fuses and Over Current Release. These products are only provided with a single fuse.

Unit is rated 100-240 Vac with an output of 120W, however when conducting heating test at -10% tolerance (90 Vac) using convection cooling, the unit was loaded to 110W. Consideration for additional testing to be considered in the end product.

When installed in a Class I end product, the power supply shall be mounted in a manner that provides sufficient clearance and creepage distance 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 in a manner that provides sufficient clearance and creepage distance between the hazardous parts and any accessible conductive parts.

Overcurrent releases of adequate breaking capacity must be employed in the end product.

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Markings and instructions			
Clause Title	Marking or Instruction Details		
Company identification	Classified or Recognized company's name, Trade name, Trademark or File		
Model	Model number		
Supply Connection	Voltage range, ac/dc, phases if more than single phase		
Supply Frequency	Rated frequency range in hertz		
Power Input	Amps, VA, or Watts		
Output	Rated output voltage, power, frequency.		
Refer to instruction manual/booklet			

# Special Instructions to UL Representative

N/A

Production-Line Testing Requirements  Test Exemptions - The following models are exempt from the indicated test				
Grounding Continuity	The following models are exempt from the indicated test:	All models		
Dielectric Voltage Withstand	The following models are exempt from the indicated test:	None		
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:	N/A		

Sample and Test Specifics for Follow-Up Tests at UL					
The following tests shall be conducted in accordance with the Generic Inspection Instructions					
Plastic Enclosure or Part	Test	Sample(s)	Test Specifics		
N/A	N/A	N/A	N/A		