

CERTIFICATE OF COMPLIANCE

Certificate Number 2018-11-30 (A0/C0) ; 2019-01-07 (A1/C0); 2019-07-31(A2/C0)-E321744

Report Reference E321744-D1020-1/A2/C0-ULCB

Issue Date 2018-11-30 (A0/C0) ; 2019-01-07 (A1/C0); 2019-07-31(A2/C0)

Issued to: XP Power LLC
Applicant Company: 15641 Red Hill Ave., Suite 100
Tustin, CA 92780 USA

Listed Company: Same as Applicant

This is to certify that representative samples of Component Power Supply intended for Building-in EPL150PSXX (where XX can be any number between 12 and 48 designating the output voltage), may also be provided with suffix "-SF" or "-T" or "-YYYYYY"

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.



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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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:	Component Power Supply intended for Building-in
Model:	EPL150PSXX (where XX can be any number between 12 and 48 designating the output voltage), may also be provided with suffix "-SF" or "-T" or "-YYYYYY"
Rating:	Input: 100-240 Vac, 50/60Hz, 2.5 A; Output: See Model Differences for details
Applicant Name and Address:	XP Power LLC 15641 Red Hill Ave., Suite 100 Tustin, CA 92780, 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.

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.

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Prepared by: Rahul Baria/Project
Handler

Reviewed by: Ahmad Daoudi / Project
Reviewer

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 an open frame AC/DC switching mode power supply and is intended for building-in Class I or Class II from factory installation to be used as part of Medical Electrical Equipment.
Refer to the Report Modifications page for any modifications made to this report.

Model Differences

All models in the Model EPL150PSXX 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:

EPL150PS12: 12Vdc (10.1 - 13.5 Vdc), 12.5 A max, 150W max (50C, forced-air with 10 cfm fan)
 EPL150PS15: 15Vdc (13.6 - 17 Vdc), 10.0 A max, 150W max (50C, forced-air with 10 cfm fan)
 EPL150PS18: 18Vdc (17.1 - 21 Vdc), 8.33 A max, 150W max (50C, forced-air with 10 cfm fan)
 EPL150PS24: 24Vdc (21.1 - 26 Vdc), 6.25 A max, 150W max (50C, forced-air with 10 cfm fan)
 EPL150PS28: 28Vdc (26.1 - 31 Vdc), 5.36 A max, 150W max (50C, forced-air with 10 cfm fan)
 EPL150PS33: 33Vdc (31.1 - 33 Vdc), 4.55 A max, 150W max (50C, forced-air with 10 cfm fan)
 EPL150PS36: 36Vdc (33.1 - 42 Vdc), 4.17 A max, 150W max (50C, forced-air with 10 cfm fan)
 EPL150PS48: 48Vdc (42.1 - 52 Vdc), 3.13 A max, 150W max (50C, forced-air with 10 cfm fan)

EPL150PS12: 12Vdc (10.1 - 13.5 Vdc), 6.25 A max, 75W max (70C, forced-air with 10 cfm fan)
 EPL150PS15: 15Vdc (13.6 - 17 Vdc), 5.0 A max, 75W max (70C, forced-air with 10 cfm fan)
 EPL150PS18: 18Vdc (17.1 - 21 Vdc), 4.17 A max, 75W max (70C, forced-air with 10 cfm fan)
 EPL150PS24: 24Vdc (21.1 - 26 Vdc), 3.13 A max, 75W max (70C, forced-air with 10 cfm fan)
 EPL150PS28: 28Vdc (26.1 - 31 Vdc), 2.68A max, 75W max (70C, forced-air with 10 cfm fan)
 EPL150PS33: 33Vdc (31.1 - 33 Vdc), 2.27 A max, 75W max (70C, forced-air with 10 cfm fan)
 EPL150PS36: 36Vdc (33.1 - 42 Vdc), 2.08 A max, 75W max (70C, forced-air with 10 cfm fan)
 EPL150PS48: 48Vdc (42.1 - 52 Vdc), 1.56 A max, 75W max (70C, forced-air with 10 cfm fan)

EPL150PS12: 12Vdc (10.1 - 13.5 Vdc), 8.33 A max, 100W max (50C, convection)
 EPL150PS15: 15Vdc (13.6 - 17 Vdc), 6.67 A max, 100W max (50C, convection)
 EPL150PS18: 18Vdc (17.1 - 21 Vdc), 5.56 A max, 100W max (50C, convection)
 EPL150PS24: 24Vdc (21.1 - 26 Vdc), 4.17 A max, 100W max (50C, convection)
 EPL150PS28: 28Vdc (26.1 - 31 Vdc), 3.57 A max, 100W max (50C, convection)
 EPL150PS33: 33Vdc (31.1 - 33 Vdc), 3.03 A max, 100W max (50C, convection)
 EPL150PS36: 36Vdc (33.1 - 42 Vdc), 2.78 A max, 100W max (50C, convection)
 EPL150PS48: 48Vdc (42.1 - 52 Vdc), 2.1 A max, 100W max (50C, convection)

EPL150PS12: 12Vdc (10.1 - 13.5 Vdc), 4.17 A max, 50W max (70C, convection)
 EPL150PS15: 15Vdc (13.6 - 17 Vdc), 3.33 A max, 50W max (70C, convection)

EPL150PS18: 18Vdc (17.1 - 21 Vdc), 2.78 A max, 50W max (70C, convection)
 EPL150PS24: 24Vdc (21.1 - 26 Vdc), 2.08 A max, 50W max (70C, convection)
 EPL150PS28: 28Vdc (26.1 - 31 Vdc), 1.79 A max, 50W max (70C, convection)
 EPL150PS33: 33Vdc (31.1 - 33 Vdc), 1.52 A max, 50W max (70C, convection)
 EPL150PS36: 36Vdc (33.1 - 42 Vdc), 1.39 A max, 50W max (70C, convection)
 EPL150PS48: 48Vdc (42.1 - 52 Vdc), 1.04 A max, 50W max (70C, convection)

All models are provided with a Fan output @ CN3 (12 Vdc, 0.5A).
 Additional Suffix "-SF" denotes units provided with only a single line side fuse.
 Additional Suffix "-T" denotes units provided with screw type terminal.
 Additional Suffix "-YYYYYY" can be any digits or letters or blank for marketing purpose.
 All "-" considered optional.

See Enclosure - Miscellaneous for Output Ratings Table for additional details

Additional Information

The required clearance values have been assessed for suitability up to 5000 m elevation (1.29 correction factor as per IEC 60606-1, Table 8).

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

The nameplate markings provided as an Enclosure - Marking Plate are considered representative of the entire series.

The power supply series covered by this report employ Double/Reinforced Insulation between Primary and Secondary circuits.

Equipment mobility : for building-in

Connection to the mains : To be determined in the end-use product.

Over voltage category (OVC) : OVC II

Mains supply tolerance (%) or absolute mains supply values : +10%, -10%

Considered current rating of protective device as part of the building installation (A) : 20 A

Pollution degree (PD) : PD 2

IP protection class : IPX0

Altitude of operation (m) : 5000

Altitude of test laboratory (m) : less than 2000 meters

The product was submitted and evaluated for use at the maximum ambient temperature (T_{ma}) permitted by the manufacturer's specification of: 50°C for full load; 70°C for half load.

The maximum continuous power supply output (Watts) relied on forced air cooling from: 10cfm fan applied 1 inch from input side, blowing inward.

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: N/A
 - The product was not investigated to the following standards or clauses: Biocompatibility, EMC, Annex Z of EN standards for compliance with the MDD
 - The following accessories were investigated for use with the product: None
 - 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 product was submitted and evaluated for use at the maximum ambient temperature (T_{ma}) permitted by the manufacturer's specification of: 50°C at full rated load and 70°C at 50% rated load. See the Output Ratings Table in the Model Differences section for details.

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 end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-Secondary: 259 Vrms, 504 Vpk, Primary-Earthed Dead Metal: 237 Vrms, 384 Vpk

This power supply was evaluated with Two MOPP between Primary and Secondary for 504Vpk/259Vrms; One MOPP primary and Earth for 354Vpk/250Vrms; Two MOPP between Secondary to Ground for working voltage of 48Vdc and 1 MOPP for working voltage of 240Vrms between Secondary and Earth for BF output considerations.

The following secondary output circuits are at hazardous energy levels: All

The power supply terminals and/or connectors are: Not investigated for field wiring

The maximum investigated branch circuit rating is: 20A

Proper bonding to the end-product main protective earthing termination is: Required (Class I configuration only)

An investigation of the protective bonding terminals has: Not been conducted

The following input terminals/connectors must be connected to the end-product supply neutral: Input Connector (CN1) N terminal.

The following magnetic devices (e.g. transformers or inductor) are provided with an OBJY2 insulation system with the indicated rating greater than Class B (130C): TR1 (Class B)

The following end-product enclosures are required: Fire, Mechanical, Electrical

Suitable disconnect device is to be provided in the end system.

Temperature, Leakage Current with a non-frequency weighted device and Dielectric Strength testing shall be considered in the end system.

Printed Wiring Board rated 130C.

Heatsinks are floating and considered live. They should not be accessible in the end-product.

Heating test was not conducted on unit with input/output leads. If unit is provided with input and/or output leads, then temperature on leads must be measured and cannot exceed 105C.

The equipment is provided with a fuse in both the Line and Neutral of the primary circuit. The need

for a marking warning service person of the hazards associated with neutral fusing shall be considered in the end-product.

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 need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation.




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.

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 accessible conductive parts.

Proper bonding to the Class I end-product main protective earthing termination is required (via mounting holes on the PCB), unless for Class II applications. For Class II applications the primary side mounting pads are isolated from accessible conductive chassis by Reinforced Insulation.

Energy not exceeding 240 VA or 20 J to be considered in the end-product evaluation.

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
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
Alternating current	
Direct current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
Fuses	Ratings (current and voltage) and type. (located adjacent to fuse OR as a diagram inside enclosure)
Protective earth ground	

Special Instructions to UL Representative

None

Production-Line Testing Requirements**Test Exemptions** - The following models are exempt from the indicated test

Test	Exemption Specifics	Details
Grounding Continuity	The following models are exempt from the indicated test:	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:	Exempt
Solid-State Components	The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	Exempt

