

CERTIFICATE

No. B 12 07 57396 155

XP Power LLC. Holder of Certificate:

1241 East Dyer Road, Suite 150

Santa Ana CA 92705

USA

Production Facility(ies):

72220

Certification Mark:



Product:

Switching power supply unit (Switching Power Supply)

Model(s):

ECP60USXX, ECP60UDXX, ECP60UTXX (where XX can be number 01-05 indicating different output voltage configurations).

Parameters:

Rated Input Voltage:

100-240 V AC,

Rated Input Current:

1.2 A

Rated input frequency: Rated Output Ratings: 50/60 Hz See attachment for details

Protection Class:

Class I at end use

Temperature, Ambient:

50°C with maximum output power 70°C with half maximum output power.

Elevation for use

0-3048m above sea level

See attachment for additional information

Tested according to:

EN 60950-1/A12:2011

The product was tested on a voluntary basis and complies with the essential requirements. The certification mark shown above can be affixed on the product. It is not permitted to alter the certification mark in any way. In addition the certification holder must not transfer the certificate to third parties. See also notes overleaf.

Test report no.:

SI1207318-000

Date, 2012-07-13

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ATTACHMENT TO CERTIFICATE NO. B 12 07 57396 155 FOR XP POWER LLC

SWITCHING POWER SUPPLY

Power supply model ECP60USXX, ECP60UDXX and ECP60UTXX series are AC/DC component type switching power supplies intended for use in IT equipment. They are open frame power supplies intended for building-in Class I end product..

Output rating:

	OUTPUT RATING		
Model Number	Output 1	Output 2	Output 3
	(Vdc/A)	(Vdc/A)	(Vdc/A)
ECP60US05	5Vdc/11A		
ECP60UD01	5Vdc/7A	12Vdc/3A	60 50
ECP60UD02	5Vdc/7A	15Vdc/2A	wa to
ECP60UD03	5Vdc/7A	24Vdc/1.5A	en co
ECP60UT01	5Vdc/7A	12Vdc/3A	-12Vdc/0.3A
ECP60UT02	5Vdc/7A	15Vdc/2A	-15Vdc/0.3A
ECP60UT03	5Vdc/7A	24Vdc/1.5A	12Vdc/0.3A
ECP60UT04	5Vdc/7A	24Vdc/1.5A	-12Vdc/0.3A

Conditions of Acceptability:

When installing the equipment, all requirements of the standards and the manufacturer's specifications must be met.

The models require:

- A suitable electrical and fire enclosure must be provided in the end use equipment.
- Proper earthing at end product is requirement. Touch current and earthing test shall be conducted at end product.
- Units are provided with double pole fusing. Needs for the proper warning to service persons is determined at end product.

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CERTIFICATE

No. B 12 08 57396 162

Holder of Certificate: XP Power LLC.

1241 East Dyer Road, Suite 150

Santa Ana CA 92705

USA

Production Facility(ies):

72220

Certification Mark:



Switching power supply unit **Product:**

(Switching Power Supply)

ECP60USXX, ECP60UDXX, ECP60UTXX Model(s):

> (where XX can be number 01-05 indicating different output voltage configurations.)

Parameters: Rated Input Voltage: 100-240 VAC

50/60 Hz Rated Frequency: Rated Input Current: 1.2 A

See attachment Rated Output Ratings: Protection Class: Class I at end use

50°C with maximum output power, Temperature, Ambient:: 70°C with half maximum output power

0-3000 m above sea level Elevation for use:

See attachment for additional information.

Tested according to: EN 60601-1:2006

The product was tested on a voluntary basis and complies with the essential requirements. The certification mark shown above can be affixed on the product. It is not permitted to alter the certification mark in any way. In addition the certification holder must not transfer the certificate to third parties. See also notes overleaf.

Test report no.: SI1207887-000

Date. 2012-08-13

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ATTACHMENT TO CERTIFICATE NO. B 12 08 57396 162 FOR XP POWER LLC

SWITCHING POWER SUPPLY

Power supply model ECP60USXX, ECP60UDXX and ECP60UTXX series are AC/DC component type switching power supplies intended for use in Medical equipment. They are open frame power supplies intended for building-in Class I end product.

Output rating:

-	OUTPUT RATING		
Model Number	Output 1	Output 2	Output 3
	(Vdc/A)	(Vdc/A)	(Vdc/A)
ECP60US05	5Vdc/11A		
ECP60UD01	5Vdc/7A	12Vdc/3A	
ECP60UD02	5Vdc/7A	15Vdc/2A	
ECP60UD03	5Vdc/7A	24Vdc/1.5A	
ECP60UT01	5Vdc/7A	12Vdc/3A	-12Vdc/0.3A
ECP60UT02	5Vdc/7A	15Vdc/2A	-15Vdc/0.3A
ECP60UT03	5Vdc/7A	24Vdc/1.5A	12Vdc/0.3A
ECP60UT04	5Vdc/7A	24Vdc/1.5A	-12Vdc/0.3A

Model Differences:

All models are similar except number of outputs, output ratings, transformer secondary windings, and minor secondary components for different output voltages.

Technical Considerations:

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

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- 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; Flammable Anaesthetic Mixtures Protection: Annex G

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.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage to be

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considered as part of the end product.

- This power supply was evaluated with One MOPP/ Two MOOP between Primary and Secondary; One MOPP/ One MOOP between primary and Earth. Additional MOPP between Primary and Secondary 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 available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
- The Dielectric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal: 356 Vpk, 245 Vrms; Primary-SEC: 603 Vpk, 250 Vrms.
- Protective bonding testing shall be considered in the end product application.
- 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.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- Unit to be properly earthed as part of the end product.
- Q1 Heatsink considered live and should not be earthed.
- End product shall provide necessary creepage and clearance for 250Vrms from input connector pins to mounting means.

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Power supply fuse was provided with limited breaking capacity and was evaluated for installation
where the maximum fault current was limited. End product shall ensure the power supply is used in
applications where the limited breaking capacity does not result in unacceptable risk.

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