



Product Service



CERTIFICATE

No. B 057396 0513 Rev. 00

Holder of Certificate: **XP Power LLC.**
15641 Red Hill Avenue, Suite 100
Tustin CA 92780
USA

Certification Mark:



Product:

Power supply

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.:

095-72139428-000

Valid until:

2023-07-30

Date,

2018-08-03


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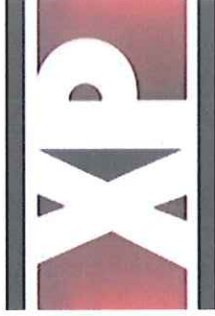
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Model(s):

GCU500PSxx
(where xx can be 12-48 for main output voltage, model number may be optionally followed by "-EF" for model with end fan, can have additional suffix "-SF" for single pole fusing, all "-" is optional)

Brand Name:

XP



Parameters:

Rated Input Voltage: 100-240 VAC
Rated Input Current: 6.0 A
Rated Input Frequency: 50/60 Hz
Protection Class: Class I or Class II at end use
Temperature, Ambient: 40°C at 50% Rated output (convection cooled)
50°C at 45% Rated output (with convection cooled)
50°C at 100% Rated output (with -EF and 13 cfm forced-air)
70°C at 23% Rated output (with convection cooling)
70°C at 50% Rated output (with -EF and 13 cfm forced-air)
Elevation for Use: 0-3000 m above sea level

General Product information:

Build-in Power Supply for Medical devices. The models covered are a component power supplies intended for use in medical devices. They are open frame power supplies 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.

Approved models and Rated Outputs:

Model Number	Voltage (VDC)	OUTPUT RATING											
		Forced air cooling(13 cfm) with end fan				Convectional Cooling							
		50°C		70°C		40°C		50°C		70°C			
		Max Current (A)	Max Power (W)	Max Current (A)	Max Power (W)	Max Current (A)	Max Power (W)	Max Current (A)	Max Power (W)	Max Current (A)	Max Power (W)	Max Current (A)	Max Power (W)
GCU500PS12	10.1-13.5	41.7	500	20.8	250	20.8	250	18.8	225	9.4	113		
GCU500PS15	13.6-17	33.3	500	16.7	250	16.7	250	15.0	225	7.5	113		
GCU500PS18	17.1-21	27.8	500	13.9	250	13.9	250	12.5	225	6.3	113		
GCU500PS24	21.1-26	20.8	500	10.4	250	10.4	250	9.4	225	4.7	113		
GCU500PS28	26.1-31	17.9	500	8.9	250	8.9	250	8.0	225	4.0	113		
GCU500PS33	31.1-33	15.2	500	7.6	250	7.6	250	6.8	225	3.4	113		
GCU500PS36	33.1-42	13.9	500	6.9	250	6.9	250	6.3	225	3.1	113		
GCU500PS48	42.1-54	10.4	500	5.2	250	5.2	250	4.7	225	2.4	113		

All models are provided with 5Vdc, 0.2 A standby output



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Conditions of Acceptability:

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

The models require:

- Suitable Mechanical, Fire and Electrical enclosure shall be provided in the end use equipment.
- Proper bonding to the end-product main protective earthing termination is required when the power supply is installed in Class I end product. Protective earthing testing shall be conducted in Class I end product application.
- Power supply provides 2 MOPP between Primary to Secondary, 1 MOPP between Primary and Earth/Enclosure.
- 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).
- Repeat of leakage current testing and consideration of non-frequency weighted leakage test shall be considered in the end product application. and 1 MOPP between Secondary and Earth/Enclosure.
- Consideration should 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
- 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 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).

Tested according to: EN 60601-1:2006/A12:2014

Production Facility(ies):

059061, 059319, 071712, 089850