



No. B 057396 0923 Rev. 00

Holder of Certificate: XP Power LLC.

340 Commerce, Suite 100

Irvine CA 92602

USA

Certification Mark:



Product: General Medical Devices

Medical Grade 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. This certificate is valid until the listed date, unless it is cancelled earlier. All applicable requirements of the testing and certification regulations of TÜV SÜD Group have to be complied. For details see: www.tuvsud.com/ps-cert

Test report no.: 095-72194305-000

Valid until: 2024-10-18

Date, 2023-12-07

(Antony Young-Taylor)



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Model(s): CCP550PSxx-y-zz-qqqqq

Where xx can be 12, 15, 18, 24, 36, or 48 which represents rated output voltage, y can be blank or A for optional 5V Standby, zz can be blank or SF for single line fuse, qqqqq can be blank or any

digits or letter for marketing purpose.

Brand Name: XP

Parameters:

Rated Input: 100-240 VAC, 7.5 A, 50/60 Hz
Rated Output: See next page for output ratings
Protection Class: Component only to be determined in

the end product

Max Ambient Temperature: Refer to Condition of Acceptability

Elevation for use: 0-4000 m above sea level

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



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Approved models and Rated Outputs:

CCP550PS12: 12Vdc (10.1 - 13.5 Vdc), 25 A max, 300W max (50°C, convection) CCP550PS15: 15Vdc (13.6 - 17 Vdc), 20 A max, 300W max (50°C, convection) CCP550PS18: 18Vdc (17.1 – 21 Vdc), 16.67 A max, 300W max (50°C, convection) CCP550PS24: 24Vdc (21.1 - 26 Vdc), 12.5 A max, 300W max (50°C, convection) CCP550PS36: 36Vdc (33.1 - 42 Vdc), 8.33 A max, 300W max (50°C, convection) CCP550PS48: 48Vdc (42.1 - 52 Vdc), 6.25 A max, 300W max (50°C, convection) CCP550PS12: 12Vdc (10.1 - 13.5 Vdc), 33.33 A max, 400W max (50°C, conduction) CCP550PS15: 15Vdc (13.6 - 17 Vdc), 26.67 A max, 400W max (50°C, conduction) CCP550PS18: 18Vdc (17.1 - 21 Vdc), 22.23 A max, 400W max (50°C, conduction) CCP550PS24: 24Vdc (21.1 - 26 Vdc), 16.67 A max, 400W max (50°C, conduction) CCP550PS36: 36Vdc (33.1 - 42 Vdc), 11.1 A max, 400W max (50°C, conduction) CCP550PS48: 48Vdc (42.1 - 52 Vdc), 8.33 A max, 400W max (50°C, conduction) CCP550PS12: 12Vdc (10.1 - 13.5 Vdc), 45.8 A max, 550W max (50°C, forced-air with 20 cfm fan) CCP550PS15: 15Vdc (13.6 - 17 Vdc), 36.67 A max, 550W max (50°C, forced-air with 20 cfm fan) CCP550PS18: 18Vdc (17.1 - 21 Vdc), 30.56 A max, 550W max (50°C, forced-air with 20 cfm fan) CCP550PS24: 24Vdc (21.1 - 26 Vdc), 22.9 A max, 550W max (50°C, forced-air with 20 cfm fan) CCP550PS36: 36Vdc (33.1 - 42 Vdc), 15.27 A max, 550W max (50°C, forced-air with 20 cfm fan) CCP550PS48: 48Vdc (42.1 - 52 Vdc), 11.45 A max, 550W max (50°C, forced-air with 20 cfm fan)

All models are provided with a Fan output (12 Vdc, 0.5A).

Additional Suffix "-A" denotes optional 5V Standby, rated at 1A convection or conduction cooled and 2A. forced-air cooled.

Additional Suffix "-SF" denotes units provided with only a single line side fuse.

Additional Suffix "-YYYYYY" can be any digits or letters or blank for marketing purpose.

All "-"considered optional.

Conditions of Acceptability:

When installed in an end-product, consideration must be given to the following:

- 1. End product Risk Management Process to include consideration of requirements specific to the Power Supply.
- 2. End product Risk Management Process to consider the need for simultaneous fault condition testing.
- 3. End product Risk Management Process to consider the need for different orientations of installation during testing.
- Power Supply tested in 40°C, 93%RH. End product Risk Management Process to determine risk acceptability criteria.
- End product to determine the acceptability of risk in conjunction to insulation to resistance to heat, moisture, and dielectric strength.
- 6. End product to determine the acceptability of risk in conjunction to the movement of components as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the movement of conductors as part of the power supply.
- 8. End product to determine the acceptability of risk in conjunction to the routing of wires away from moving parts and sharp edges as part of the power supply.
- 9. Temperature Test was conducted without Test Corner. End product to determine the acceptability of risk in conjunction to temperature testing without test corner as part of the power supply.
- End product to determine the acceptability of risk in conjunction to the Cleaning and Disinfection Methods as it pertains to the power supply.
- End product to determine the acceptability of risk in conjunction to the Leakage of Liquids as it pertains to the power supply.
- 12. End product to determine the acceptability of risk in conjunction to the Arrangement of Indicators that are part of the power supply.
- 13. End product to determine the acceptability of risk in conjunction to the selection of components as it pertains to the intended use, essential performance, transport, storage conditions.





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- 14. The power supply has not been determined suitable for use in the presence of a flammable anaesthetics mixture with air or oxygen or with nitrous oxide. Note: Delete if not applicable
- 15. The output(s) circuits have been evaluated for BF applied part spacings and dielectrics only. Acceptability to be determined in end-product application.
- 16. The input/output connectors are not acceptable for field connections.
- 17. The power supply has been evaluated for use up to a max altitude 4000 meters.
- 18. The power supply provides the following Means of Protection:
 - 1 MOPP based upon a working voltage of 240 Vrms and 339 Vpk between Mains and Earth
 - 2 MOPP based upon a working voltage of 271 Vrms and 576 Vpk between Mains and Secondary
 - 2 MOPP based upon a working voltage of 48 Vdc between Secondary and Earth
 - 1 MOPP based upon a working voltage of 240 Vrms and 339 Vpk between Secondary and Earth
- 19. The dielectric strength test was conducted based on the peak working voltages and means of protection above.
- Marking legibility (CI 7.1.2) and durability (CI 7.1.3) have not been evaluated.
- Printed Wiring Board(s) in the power supply are rated a minimum of 130 Degrees C and a minimum flame rating of
- 22. Transformer T1 employs a Class F (155 degrees C) Insulation System.
- 23. The power supply was evaluated as a Class I device.
- When installed in a Class I end product, the power supply shall be reliably earthed (bonded) to the end-product's 24. main protective earth.
- 25. Product provided with one fuse in each supply lead.
- 26. The power supplies covered in this report were tested on a 20 A branch circuit.
- 27. Testing was conducted with fuses rated 250 Vac, 8 A with a interrupt rating of 100A
- 28. Additional Overcurrent releases of adequate breaking capacity must be employed in the end product.
- The power supply was subjected to an elevated humidity test at 40°C, 93%RH for 48h.
- When convection cooling is being used, the power supply is rated for a maximum operating temperature of 50 degrees C at 300 W output load and a maximum operating temperature of 70 Degrees C and 150 W load.
- When conduction cooling is being used, the power supply is rated for a maximum operating temperature of 50 degrees C at 400 W output load and a maximum operating temperature of 70 Degrees C and 200 W load.
- When forced cooling is being used, the power supply is rated for a maximum operating temperature of 50 degrees C at 550 W output load and a maximum operating temperature of 70 Degrees C and 278 W load.
- The unit was evaluated for forced cooling with a 60x60mm external fan (20 CFM) spaced 50 mm from input side and the airflow directed from input to output.
- 34. Thermistor TH1 has ratings of 240 Vac, max operating temp of 200 degrees C, max current of 8A and resistance of 75 mΩ at max current at 25 degrees C.
- 35. Protective devices (fuses) have an interrupt rating of 100A. The need for additional fusing with higher interrupt rating shall be considered in the installation.
- 36. Scope of this 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 this 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.