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UL TEST REPORT AND PROCEDURE

Standard: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical

Equipment - Part 1: General Requirements for Basic Safety and

Essential Performance)

CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment -

Part 1: General Requirements for Basic Safety and Essential

Performance)

Certification Type: Component Recognition

CCN: QQHM2, QQHM8 (Power Supplies, Medical and Dental)

Product: Component switching power supply

Model: GSP500PSXXY (where XX = represents the output voltage between

12- 48 and Y = P or blank, maybe followed with additional suffix "-"

followed by "EF" or/and "SF")

Rating: Input: 100-240 Vac, 50/60 Hz, 6.5A

Output: See Model Differences for details

Applicant Name and Address: XP POWER L L C

SUITE 150 1241 E DYER RD SANTA ANA CA 92705

UNITED STATES

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.

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

Prepared by: Wojciech Poleszak Reviewed by: Richard Dolle

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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.

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Product Description

The models covered in this report are component power supplies intended for use in Medical Electrical Equipment. They are open frame power supplies intended for building-in.

Model Differences

The power supplies in the series are differentiated by the output voltage and current ratings, number of turns of primary/secondary windings in the Transformers (T1 (Power)), and minor differences in the secondary circuit components and PWB layout.

The basic model is provided with U-shaped chassis and top cover.

See below for Model Ratings Table Below:

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Convection Cooling Method: 180W output max
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Model GSP500PS12: Output Rated (V1): 10.1 - 13.5 Vdc, 17 A max (180 W) @ 50 C ambient;

10.1 - 13.5 Vdc, 8.5 A (90 W) @ 70 C ambient

Model GSP500PS15: Output Rated (V1): 13.6 - 17 Vdc, 12 A (180 W) @ 50 C ambient;

13.6 - 17 Vdc, 6 A (90 W) @ 70 C ambient

Model GSP500PS18: Output Rated (V1): 17.1 - 21 Vdc, 10 A max (180 W) @ 50 C ambient;

17.1 - 21 Vdc, 5 A (90 W) @ 70 C ambient

Model GSP500PS24: Output Rated (V1): 21.1 - 26 Vdc, 7.5 A (180 W) @ 50 C ambient;

21.1 - 26 Vdc, 3.75 A (90 W) @ 70 C ambient

Model GSP500PS28: Output Rated (V1): 26.1 - 31 Vdc, 6.43 A (180 W) @ 50 C ambient;

26.1 - 31 Vdc, 3.22 A (90 W) @ 70 C ambient

Model GSP500PS36: Output Rated (V1): 33.1 - 42 Vdc, 5 A (180 W) @ 50 C ambient;

33.1 - 42 Vdc, 2.5 A (90 W) @ 70 C ambient

Model GSP500PS48: Output Rated (V1): (42.1 - 52 Vdc, 3.75 A (180 W) @ 50 C ambient; 42.1 - 52 Vdc, 1.88 A (90 W) @ 70 C ambient

Forced air cooling method: 500W output max

Model GSP500PS12: Output Rated (V1): (V1) 10.1 - 13.5 Vdc, 42 A (500 W) @ 50 C ambient;

10.1 - 13.5 Vdc, 25 A (250 W) @ 70 C ambient

Model GSP500PS15: Output Rated (V1): (V1) 13.6 - 17 Vdc, 33.33 A (500 W) @ 50 C ambient;

13.6 - 17 Vdc, 16.67 A (250 W) @ 70 C ambient

Model GSP500PS18: Output Rated (V1): 17.1 - 21 Vdc, 10 A max (180 W) @ 50 C ambient;

17.1 - 21 Vdc, 5 A (90 W) @ 70 C ambient

Model GSP500PS24: Output Rated (V1): 21.1 - 26 Vdc, 21 A (500 W) @ 50 C ambient;

21.1 - 26 Vdc, 10.5 A (250 W) @ 70 C ambient

Model GSP500PS28: Output Rated (V1): 26.1 - 31 Vdc, 17.86 A (500 W) @ 50 C ambient;

26.1 - 31 Vdc, 8.93 A (250 W) @ 70 C ambient

Model GSP500PS36: Output Rated (V1): 33.1 - 42 Vdc, 13.89 A (500 W) @ 50 C ambient;

33.1 - 42 Vdc, 6.95 A (250 W) @ 70 C ambient

Model GSP500PS48: Output Rated (V1): 42.1 - 52 Vdc, 10.5 A (500 W) @ 50 C ambient;

42.1 - 52 Vdc, 5.25 A (250 W) @ 70 C ambient

Stand-by Output for all models: (V2) 5Vdc, 2A Fan Output for all models: (V3) 12 Vdc, 0.3 A

Units provided with suffix "-EF" provided with End Fan (15 CFM)

Units provided with suffix "-SF" indicates models provided with only one fuse in the line and no fuse in the

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neutral.

Units provided with P (e.g. GSP500PS12P) indicates construction variation to current sensing transformer T100.

See Enclosure for details.

Technical Considerations

Classification of installation and use : for building-in

- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location): Component switching power supply
- Mode of operation : Continuous
- Supply connection : for building-in
- Accessories and detachable parts included : None
- Other options include : None
- The product was investigated to the following additional standards:: EN 60601-1: 2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance), ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance) (includes Deviations for United States), CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada),
- The product was not investigated to the following standards or clauses:: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)
- 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
- The means of connection to the mains supply is: for building-in, to be determined in end-product

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:

- These components have been judged on the basis of the required spacings in the ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance)CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance), which covers the end-use product for which the component was designed
- The product was submitted and evaluated for use at the maximum ambient temperature (Tma) permitted by the manufacturer's specification of: 50°C at full rated load and 70°C at 50% of rated load.
- Power supply provides the following MOPP (means of patient protection): two MOPP based upon a working voltage 284 Vrms, 475 Vpk between Primary to Secondary, one MOPP based upon a working voltage 241 Vrms, 343 Vpk between Primary and Earth/Enclosure, two MOPP based upon a working voltage 60Vdc between secondary to floated earth trace on PWB for BF output consideration, one MOPP based upon a working voltage 250 Vrms between secondary and earthing

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trace or chassis for BF output consideration.

- The power supply terminals and/or connectors are: Not investigated for field wiring
- The maximum investigated branch circuit rating is: 20 A
- The investigated Pollution Degree is: 2
- Proper bonding to the end-product main protective earthing termination is: Required
- 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 (CON1) 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 A (105°C): T1, and (Class F, 155°C), T2 and T100 (Class B, 130°C or Class F, 155°C)
- The following end-product enclosures are required: Electrical, Mechanical, Fire
- Suitable disconnect device is to be provided in the end system
- Temperature, Leakage and Dielectric Strength testing shall be considered in the end system and consideration of non-frequency weighted leakage current (clause 8.7.3e) to also be considered as part of the end product.
- Clearance spacing evaluated for 5000 m altitude. Additional consideration maybe necessary in the end-use product.
- Printed Wiring Board rated 130°C
- Units provided with additional suffix "SF", provided with only one fuse. The need for additional fusing shall be determined as part of the end product.
- Heatsinks are floating and considered live. They should not be accessible in the end-product
- The device shall be installed in compliance with the enclosure, mounting, spacing, casualty, markings, and segregation requirements of the end-use application
- ME Equipment is component for building-in. Applicability of the following is to be determined in End Product Evaluation: 5.9 Accessibility, 7 Identification marking and Documents, 8.4.2 Accessible Parts Including Applied Parts, 8.4.4 Voltage or Chrge Limitation, 8.6 Protective Earthing, 8.11.1 Isolation from Supply Mains, 8.11.3 Power Supply Cords, 9 Protection against mechanical hazards, 11.3 Fire Enclosure, 11.8 Interruption of power supply, 15.3 Mechanical Strength, 15.4.1 Construction of Connectors, 15.4.4 Indicators
- Overcurrent releases of adequate breaking capacity must be employed in the end product.
- 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.
- The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions
- Cleaning test shall be considered as part of end product evaluation.
- The need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation
- Models covered under this Report have been evaluated for 50°C and 70°C ambient with either an
 end fan option or 15 cfm external air-flow for open frame and U-channel options applied at chassis
 edge (near C20 and D60)
- The Limited Short-Circuit Test (Clause 2.6.3.4 in IEC 609501-1) in addition to the Protective Bonding Test II (Clause 2.6.3.4, 2.6.1 in IEC 60950-1) was not performed.

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Additional Information

The required clearance values have been assessed for suitability up to 5000 m elevation (1.29 correction factor as per Table 8 of IEC 60601-1).

IEC 60601-1 Edition 3.1, 2012-08, ES 60601-1, AMD1, CSA C22.2 No. 60601-1:14, EN 60601-1:2006 +A1:2013 (for reference only)

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 MOPP between Primary and Secondary circuits.

Testing to IEC 60601-1-2 was not conducted by UL and no supporting evidence of compliance has been presented. When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with IEC 60601-1-2.

The models covered under this Report were additionally evaluated to to include IEC 60601-1 Edition 3.1, 2012-08 (for UL report only). Separate CBTR/CBTC issued.

Licenses older than 3 years to be provided by the manufacturer upon request.

The schematics are kept on file at the CBTL and can be provided by the manufacturer upon request by NCB's/CBTL's.

Additional Standards

The product fulfills the requirements of: N/A

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		
Alternating current			
Direct current			
Supply Frequency	Rated frequency range in hertz		
Power Input	Amps, VA, or Watts		
Output	Rated output voltage, power, frequency.		

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Protective earth ground

Amendment 1, Cl. 7.2.2 Serial number and date of manufacturer. See Enclosures - Miscellaneous 7-04 for details.

Special Instructions to UL Representative

N/A

Production-Line Testing Requirements				
<u>Test Exemptions</u> - The following models are exempt from the indicated test				
Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand	
All models	Exempt	Not exempt	Exempt	
Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test: Component				
Component				
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	-	-	_	