CERTIFICATE OF COMPLIANCE

Certificate Number	2016-10-28-E146893
Report Reference	E146893-D1003-3/A0/C0-ULCB
Issue Date	2016-10-28
Issued to:	XP POWER LLC
Applicant Company:	15641 RED HILL AVE., STE 100 TUSTIN, CA 92780 USA
Listed Company:	Same as Applicant
This is to certify that representative samples of	Component power supply for building-in and supplying regulated power to medical equipment. GCS350PSxxyy where xx can be any number between 12 and 56 and yy is -C, -TF , -EF or blank; all - considered optional; may also be provided with additional suffix SF, S, J and AVPQ150M165170Z Have been investigated by UL in accordance with the Standard(s) indicated on this Certificate.
Standard(s) for Safety:	ANSI/AAMI ES60601-1:2005/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)
Additional Standards:	ANSI/AAMI ES60601-1:2005/C1:2009 +AM1(R2012) (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:14 (includes National Differences for Canada), EN 60601-1:2006+A1 (2013)/A11:2011/A12:2014, IEC 60601-1: 2012, 3rd Edition with Am. 1
Additional Information:	See the UL Online Certifications Directory at www.ul.com/database for additional information.

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

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 **Helena Y. Wolf, Director, Global Market Access Operations, UL LLC**
Joseph Hosey, General Manager, Director of Sales – Canada, UNDERWRITERS LABORATORIES OF CANADA INC.

Description

UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005/(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 for building-in and supplying regulated power to medical equipment.
Model:	GCS350PSxxyy where xx can be any number between 12 and 56 and yy is -C, -TF , -EF or blank; all - considered optional; may also be provided with additional suffix SF, S, J and AVPQ150M165170Z
Rating:	Input: GCS350PS: 100-240Vac, 50/60, 4.9A, AVPQ150M165170Z: 100-240VAC 50/60Hz 1.9A. Output: See Model Differences for details
Applicant Name and Address:	XP POWER LLC 15641 RED HILL AVE., STE 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.

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

Prepared by: Haydee Gonzalez Reviewed by: Ahmad Daoudi

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 model covered in this report is a component power supply intended for use in Medical Equipment. It is an open frame power supply 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.
Refer to the Report Modifications page for any modifications made to this report.

Model Differences

Model AVPQ150M165170Z, where Z is optional and may be represented by any letter A-Z corresponding to non-safety related options.

Model AVPQ150M165170Z consist of Model GCS350PS15 mounted on a chassis, connected to an Inlet and Rocker Switch. Output of model GCS350PS15 connects to a secondary board.

Model AVPQ150M165170Z: Output 1: 16.3 Vdc, 6A, 149W MAX; Output 2: 5.1Vdc, 10A

All models in the Model GCS350PSXX series are identical with exception to the Mains Transformer, T1 and secondary components/circuitry that allow for different output voltage ratings.

See below for Model Ratings:

Model GCS350PS12: Output Rated: 10.1 Vdc - 13.5 Vdc, 29.2 A Max., 350 W Max.
Model GCS350PS15: Output Rated: 13.6 Vdc - 17 Vdc, 23.3 A Max., 350 W Max.
Model GCS350PS18: Output Rated: 17.1 Vdc - 21 Vdc, 19.4 A Max, 350 W Max.
Model GCS350PS24: Output Rated: 21.1 Vdc - 26 Vdc, 14.6 A Max., 350 W Max.
Model GCS350PS28: Output Rated: 26.1 Vdc - 31 Vdc, 12.5 A Max., 350 W Max.
Model GCS350PS33: Output Rated: 31.1 Vdc - 33 Vdc, 10.6 A Max., 350 W Max.
Model GCS350PS36: Output Rated: 33.1 Vdc - 42 Vdc, 9.72 A Max, 350 W Max.
Model GCS350PS48: Output Rated: 42.1 Vdc - 54 Vdc, 7.29 A Max., 350 W Max.
Model GCS350PS56: Output Rated: 54.1 Vdc - 60 Vdc, 6.25 A Max., 350 W Max.

See Enclosure - Miscellaneous for max Power Outputs based on model, ambient, and forced air cooling.

Units provided with suffix "C" is provided with cover.
Units provided with suffix "TF" is provided with top fan.
Units provided with suffix "EF" is provided with end fan
Units provided without suffix "C", "TF" or "EF" are open frame (without cover).
Units provided with additional suffix "SF" to indicate single pole fusing.
Units provided with additional suffix "S" to indicate screw terminal block.
Units provided with suffix “J” employs dual row output connector (J2)

Additional Information

Marking label is representative of all models.

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

The required clearance values have been assessed for suitability up to 5000 m elevation for Patient Protection (MOPP) (1.29 correction factor as per Table 8).

The models covered under this Report have been additionally evaluated to EN 60601-1:2006+A1 (2013)/A11:2011/A12:2014. Additional evaluation into EN 60601-1/A11:2011/A12:2014 was considered and deemed not applicable for the devices covered under this Report as they are component power supplies.

This Report is a reissue of CBTR Ref. No. E146893-D1003-2-ULCB, CB Test Certificate Ref. No. US-25067-A1-UL. Based on previously conducted testing and the review of product construction. In addition a new Model AVPQ150M165170Z is being added. Client provided a representative sample for evaluation. Limited testing was conducted.

Technical Considerations

- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1:2005/C1:2009 +AM1(R2012) (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:14 (includes National Differences for Canada), EN 60601-1:2006+A1 (2013)/A11:2011/A12:2014, IEC 60601-1: 2012, 3rd Edition with Am. 1
- The following additional investigations were conducted: N/A
- 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 following accessories were investigated for use with the product: N/A
- 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;
- 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 power supply Model GCS350PS Series was evaluated for use in ambients ranging from 30 deg. C to 70 deg. C depending upon the configuration. See the Output Ratings Table in the Enclosures - Miscellaneous section for details.
- The power Supply Model AVPQ150M165170Z was evaluated at ambient temperature range: 55 to 70°C.

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 power supply was evaluated for use in ambients ranging from 30 deg. C to 70 deg. C depending upon the configuration. See the Output Ratings Table in the Enclosures - Miscellaneous section for details.
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- • Consideration shall 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.
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- • Repeat of leakage current testing and consideration of non-frequency weighted leakage test shall

be considered in the end product application.

- • This power supply was evaluated with Two MOPP between Primary and Secondary for 304Vpk/240Vrms; One MOPP primary and Earth for 340Vpk/240Vrms; Two MOPP between Secondary to Ground for working voltage of 60Vdc and 1 MOPP for working voltage of 240Vrms between Secondary and Earth of BF output considerations .
- • 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 output connectors are suitable for factory wiring only.
- • The maximum investigated branch circuit rating is: 20 A
- • The end-product Electric Strength Test to be conducted shall be based upon a maximum working voltage of: Primary-Earthed Dead Metal: 240 Vrms, 340 Vpk; Primary-SEC: 240 Vrms, 304 Vpk; Secondary to Ground: 240Vrms, 354Vpk.
- • 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): L1, L4, T1 (Class F, 155°C)
- +
- • The following end-product enclosures are required: Mechanical, Fire, Electrical
- • For an open frame (forced air) configuration without the Top or End Fan, the maximum continuous power supply output (Watts) relied on forced air cooling from: 15 cfm fan applied 1 inch from input side, blowing inward.
- • Printed Wiring Board rated 130°C.
- • 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.
- • Protective earthing testing shall be conducted in the end product application.

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- • Model AVPQ150M165170 secondary output of power supply GCS350PS15 is connected to ground.
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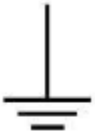
Markings and instructions	
Clause Title	Marking or Instruction Details
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Model	Model number
Serial number or lot or batch identifier	Serial number or lot or batch identifier
Date of manufacture or use by date	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.
Functional Earth Terminal	

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:	All models 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:	All models exempt
Solid-State Components	The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:	All models exempt

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
None	NA	NA	NA