UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES 60601-1:2005 (Medical electrical equipment – Part 1: General requirements for basic safety and essential performance) CSA C22.2 No. 60601-1:08 (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:	Switching Power Supply
Model:	EMH250PSXXYY-ZZ and EMH350PSXXYY-ZZ, where XX is 12-48, where YY is any number between 0-9, ZZ is "SF" or blank, may also be provided with additional suffixes "-TF", "-VF", "D" and "-S", where "-" considered optional; and EMH350PS12-01 XB0188. **EMH350PS12-XA1007**
Rating:	For Model EMH250PSXXYY-ZZ Series: Input: 100-240Vac, 50/60, Hz, 3.8A, 250W Output: Refer to Model Differences for details. For Model EMH350PSXXYY-ZZ Series and Model EMH350PS12-01 XB0188: Input: 100-240Vac, 50/60, Hz, 4.8A, 350W Output: Refer to Model Differences for details. **For EMH350PS12-XA1007:** **Input: 100-240Vac, 50/60, Hz, 4.8A, 350W** **Output:12Vdc, 29.2 A**
Applicant Name and Address:	XP POWER LLC 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.

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UL LLC

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

Products are component power supplies intended to be used as part of Medical Electrical Equipment. It is an open frame power supply intended for building-in Class I or Class II end-products. Earthing symbol may only be provided for Class I power supplies.

Model Differences

Model EMH250PSXXYY-ZZ Series and Model EMH350PSXXYY-ZZ Series are identical with exception that the EMH250PSXXYY-ZZ Series is designed to be rated for a 250 W output power and the EMH350PSXXYY-ZZ Series designed to be rated for a 350 W output power.

All models within the each series are identical with exception to the output rating, mains transformer windings, and minor secondary components.

Model EMH350PS1201 B0188 is identical to Model EMH350PSXXYY-ZZ except standby output is 12V instead of 5V.

Models EMH250PSXXYY-ZZ and EMH350PSXXYY-ZZ have the following nomenclature:

XX = 12-48, denotes the rated output voltage.
YY= 0-9, denotes non-safety related functions
ZZ = SF or blank, denotes either single pole fusing (SF) or double fusing (blank)

Units provided with additional suffix "-TF" or "-VF" provided with Top Fan and Cover.
Units provided with additional suffix "-S" indicates models provided with input screw terminals.
Units provided with additional suffix "D" provided with integral O-ring diode located in the secondary

See below for the Output Rating for 50°C Ambient provided with 12 CFM Forced Air Cooling. 3 inches Fan distance from Input side with inward air-flow direction.

Model EMH250PS12YY-ZZ: 10.1 Vdc to 13.5 Vdc, 21 A Max. (250 W Max)
Model EMH250PS15YY-ZZ: 13.6 Vdc to 17 Vdc, 16.7 A Max, (250 W Max)
Model EMH250PS18YY-ZZ: 17.1 Vdc to 21 Vdc, 14 A Max, (250 W Max)
Model EMH250PS24YY-ZZ: 21.1 Vdc to 26 Vdc, 10.5 A Max, (250 W Max)
Model EMH250PS28YY-ZZ: 26.1 Vdc to 31 Vdc, 9.0 A Max, (250 W Max)
Model EMH250PS33YY-ZZ: 31.1 Vdc to 33 Vdc, 7.6 A Max, (250 W Max)

Model EMH250PS36YY-ZZ: 33.1 Vdc to 42 Vdc, 6.9 A Max, (250 W Max)
Model EMH250PS48YY-ZZ: 42.1 Vdc to 54 Vdc, 5.2 A Max, (250 W Max)

Model EMH350PS12YY-ZZ: 10.1 Vdc to 13.5 Vdc, 29.2 A Max, (350 W Max)
Model EMH350PS15YY-ZZ: 13.6 Vdc to 17 Vdc, 23.3 A Max, (350 W Max)
Model EMH350PS18YY-ZZ: 17.1 Vdc to 21 Vdc, 19.5 A Max, (350 W Max)
Model EMH350PS24YY-ZZ: 21.1 Vdc to 26 Vdc, 14.6 A Max, (350 W Max)
Model EMH350PS28YY-ZZ: 26.1 Vdc to 31 Vdc, 12.5 A Max (350 W Max)
Model EMH350PS33YY-ZZ: 31.1 Vdc to 33 Vdc, 10.6 A Max, (350 W Max)
Model EMH350PS36YY-ZZ: 33.1 Vdc to 42 Vdc, 9.8 A Max, (350 W Max)
Model EMH350PS48YY-ZZ: 42.1 Vdc to 54 Vdc, 7.3 A Max (350 W Max)

Stand-by Output for all models: 5Vdc, 2 A or 12 Vdc, 0.8 A
Fan Output for all models (V2): 12 Vdc, 0.6 A (Optionally marked on nameplate)

See Enclosure 7-02 for de-rating curve. For Fan or external 12CFM cooling: 50°C at 100% of rated load; 70°C ambient at: 50% of rated load.

Model EMH350PS12-XA1007 is the same as Model EHM350PS12YY-ZZ except Capacitor (C21, C22) are rated 220pF.

Additional Information:

Models covered under this Report have been additionally evaluated to AAMI ES60601-1:2005 (R2012), CSA CAN/CSA-C22.2 No. 60601-1:14 and IEC 60601-1 Edition 3.1 (2012).

Technical Considerations

- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1:2005/C1:2009**+A1(2012)** (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:08+**A1 (2014)** (includes National Differences for Canada), EN 60601-1:2006**+A1 (2013) + IEC 60601-1, Edition 3.1 (2012)**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
- The product is Classified only to the following hazards: Casualty, Fire, Shock
- The degree of protection against harmful ingress of water is: Ordinary
- The mode of operation is: Continuous
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No

- The product is suitable for use in the presence of a flammable anaesthetics mixture with air or oxygen or with nitrous oxide: No
- Manufacturer's Recommended Ambient: 50°C at 100% rated output and 70°C at 50% rated output ((See Enclosure 7-02 for De-rating Curve details)
- Classification of installation and use: Building-in
- Supply connection: Building-in
- Accessories and detachable parts included in the evaluation: None
- Options included: None
- Units provided with either a Cover or Chassis should be used only in a Class I application with earthing symbol applied. The cover and chassis shall be reliably earthed in the end-use application.
- Unit also complied with spacing requirements of UL60601-1 (1st), CSA C22.2 No. 60601-1 (2nd), and IEC 60601-1 (2nd) for Basic for 250 Vac from Primary to Ground, Double/Reinforced for 250 Vac from Primary to Secondary, and Basic for 250Vrms from Secondary to Earth/Chassis.

Risk Controls/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:

- Considerations to the Applied Parts requirements shall be considered as part of the end-product evaluation.
- The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
- 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.
- The output circuits have not been evaluated for direct patient connection (Type B, BF or CF).
- The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
- The input/output connectors are not acceptable for field connections, they are only intended for connection to mating connectors of internal wiring inside the end-use equipment.
- Primary Heatsink was considered floating live and should not be connected to earth in the end-product.
- The "floating" mounting hole shall be mounted on insulating post or properly earthed for Class I end-product.
- Units may be provided with one fuse in the Line side for models with SF suffix or one fuse in both the Line and Neutral sides. The need for additional fusing shall be determined as part of the end-product evaluation.
- Units provided with either a Cover or Chassis should be used only in a Class I application with earthing symbol applied. The cover and chassis shall be reliably earthed in the end-use application.
- When installed in a Class I end product, and if the Chassis and Cover are not provided, the power supply shall be mounted in a manner that provides, at a min. 2.8 mm Clearance between the primary side of the power supply and protectively earthed accessible conductive parts. In addition, when installed in a Class I end product, the protective bonding terminal of the power supply shall be reliably connected to the main protective earthing terminal of the end product.
- When installed in a Class II end product, the power supply shall be mounted, on insulating posts, in a manner that provides, at a min. 5.5 mm Clearance between the primary side of the power supply and any accessible conductive parts.
- Power supply provides the following MOPP (means of patient protection): two MOPP based upon a working voltage 250 Vrms, 680 Vpk between Primary to Secondary, one MOPP based upon a working voltage 250 Vrms, 354 Vpk between Primary and Earth/Enclosure. Power supply additionally provides one MOPP based for 250Vrms between secondary and earthing trace or chassis consistent with BF output consideration.
- Temperature, Leakage Current including when measured with a non-frqeuency-weighted device (Clause 8.7.3e), Protective Bonding, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- The product was submitted and evaluated for use at the maximum ambient temperature (Tmra) permitted by the manufacturer's specification of: 50°C at 100% rated output and 70°C at 50% rated output with external 12CFM forced air ((See De-rating Curve Enclosure 7-02 for details)
- Temperature test was conducted with 12CFM force air cooling as part of this evaluation. Suitability of convection cooling shall be fully determined as part of the end product evaluation and Temperature Test.
- Magnetic devices T1, T2 L12, L13, and PFC employ a Class F (155°C) insulation system.
- The PWB is rated 130°C.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- The need for Marking Durability and Legibility of Marking testing to be considered as part of the end product application.

- The power supplies have been evaluated as continuous operation and have not been evaluated for use in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide.
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- A single maximum current rating of 3.8A or 4.8A were provided for the entire 100-240Vac voltage range. The end product evaluation shall consider the acceptability of this component power supply rating as it relates to the requirements of Clause 7.2.7.

Additional Information

The clearance distances have additionally been assessed for suitability up to 3000 m elevation.
The need for the additional testing and evaluation shall be determined in the end product investigation.

The power supply series covered by this report employ Double/Reinforced Insulation between Primary and Secondary circuits.

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
Alternating current	
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Direct current	
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.
Serial Number or lot or batch identifier	**Eight alpha numeric characters (A BB CC DDD where A = factory code; BB = year; CC=week; DDD = serial number)**
Date of Manufacturer	**Provided as part of the serial number**

Special Instructions to UL Representative

N/A

Production-Line Testing Requirements

Test Exemptions - The following models are exempt from the indicated test

Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
All Models	Test	Test	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:

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

Model	Samples	Test	Test Details
N/A			