Issue Date: 2011-06-30 Page 1 of 17 Report Reference # E146893-V1-S11

# **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:** Model MHP650PSXXYY (XX = Output Voltage 12-48 and YY = EF,

TF or blank)

**Rating:** Input Rated: 100-240 Vac, 50/60 Hz, 9 A

Output Rated: See refer to Model Differences for details.

**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 Underwriters Laboratories Inc. ('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.

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

Prepared by: Longjie Zhang

Underwriters Laboratories Inc.

Reviewed by: Michael J. Howell

Underwriters Laboratories Inc.

Issue Date: 2011-06-30 Page 2 of 17 Report Reference # E146893-V1-S11

## **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 -
  - 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**

Component Medical Power Supply intended for use in Medical Electrical Equipment. The need for the additional testing and evaluation shall be determined in the end product evaluation.

Magnetic device, T301 and T303 employ a Class B (130°C) or higher insulation system. Magnetic devices L1, L2, L50, L301, T201, T302 employ a Class F (155°C) or higher insulation system.

The open frame Class I power supply, is for building-in.

# **Model Differences**

The power supplies in this series are differentiated by the output voltage and current ratings, number of turns of primary/secondary windings in the Power Transformers (T302), type of Chassis Fan Cover and minor differences in the secondary circuit components and PWB layout.

See below for Model Ratings Table, Maximum output rating listed below are based upon 50C ambient:

Model MHP650PS12YY: Output Rated: 12 Vdc, 50 A (607 W) Model MHP650PS15YY: Output Rated: 15 Vdc, 40 A (607W) Model MHP650PS24YY: Output Rated: 24 Vdc, 27 A (657 W) Model MHP650PS28YY: Output Rated: 28 Vdc, 23 A (651 W) Model MHP650PS36YY: Output Rated: 36 Vdc, 18 A (657 W) Model MHP650PS48YY: Output Rated: 48 Vdc, 13.5 A (657 W)

All models are provided with Fan Supply Connection (12Vdc, 0.5 A) and Standby Connection (5 Vdc, 0.2A).

See also Enclosure-Miscellaneous for additional details.

Models provided with the following YY values differ as follows:

Model MHP650PSXXEF provided with top cover with fan located at the end of the power supply chassis. Model MHP650PSXXTF provided with top cover with fan located at the top of the power supply chassis. Model MHP650PSXX not provided with top cover and no fan, only provide with U-shaped chassis

## **Technical Considerations**

The product was investigated to the following additional standards: ANSI/AAMI ES60601-

Issue Date: 2011-06-30 Page 3 of 17 Report Reference # E146893-V1-S11

1:2005/C1:2009 (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:08 (includes National Differences for Canada), EN 60601-1:2006

 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 Full Load and 70°C at Half Load.

#### Risk Controls/Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. 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.
- Units not provided with a fan were evaluated with 5m/s airflow across the unit. The need for airflow across units not provided with a fan shall be determined as part of the end-product evaluation.
- The end product should ensure that the requirements related to accompanying documents clause 7.9 are met.
- Attention to the output temperature limit of 120°C shall be considered in the end-use application when determining the appropriate level of airflow across the unit.
- 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

Issue Date: 2011-06-30 Page 4 of 17 Report Reference # E146893-V1-S11

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 input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.
- The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
- Power supply provides the following MOPP (means of patient protection): two MOPP based upon a
  working voltage 246 Vrms, 348 Vpk between Primary to Secondary, one MOPP based upon a working
  voltage 250Vrms, 354 Vpk between Primary and Earth/Enclosure
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
- Proper bonding to the end-product main protective earthing termination is required. Protective Earthing test should be conducted in the end-use product.
- The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C at Full Load and 70°C at Half Load.
- Magnetic devices T301 and T303 employ a Class B (130°C) or higher insulation system. Magnetic devices L1, L2, L50, L301, T201, T302 employ a Class F (155°C) or higher 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 available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
- The need for marking durability 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.
- A single maximum current rating of 9 A was provided for the entire100-240Vac 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 creepage and clearance measurement in Table: To insulation diagram are derived from 2<sup>nd</sup> edition evaluation.

No tests were considered necessary to make Y-Capacitors (C2, C3, C5, C6, C10, C11) optional, due to testing with the Y-Capacitors provided being considered worst case.

Marking Plate is representative of all models.

### 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

Issue Date: 2011-06-30 Page 5 of 17 Report Reference # E146893-V1-S11

Alternating current	$\sim$		
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.		
Funtional Earth Terminal	<u></u>		
Special Instructions to UL Representative			
N/A			

Production-Line Testing Requirements						
Test Exemptions - The	following models are exempt fr	om the indicated test				
Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand			
All Models	Test	Test	Exempt			
from the remainder of the circuitry during either Dielectric Voltage Withstand Test:  N/A						
	N/.	A				
Sample and Test Specifics for Follow-Up Tests at UL						
Sample and Test Spec	ifics for Follow-Up Tests at U	<u>L</u>				
	ifics for Follow-Up Tests at U be conducted in accordance w	_	Instructions			
	•	_	Instructions Test Details			

Issue Date: 2011-12-16 Page 1 of 16 Report Reference # E146893-V1-S23

# **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: Model MHP1000PSXX (where xx can be any number between 12 and

48 designating the output voltage)

**Rating:** Input Rated: 100-240 V~, 50/60 Hz, 13 A

Output Rated: Refer to Model Differences for details

**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 Underwriters Laboratories Inc. ('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.

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Prepared by: Linus Park

Underwriters Laboratories Inc.

Reviewed by: Paul Hilgeman

Underwriters Laboratories Inc.

Issue Date: 2011-12-16 Page 2 of 16 Report Reference # E146893-V1-S23

# **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 -
  - 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 covered are open frame power supplies intended for building-in to be used with Medical Electrical Equipment. Units are intended for used with Class I end-products.

#### **Model Differences**

The power supplies in this series are differentiated by the output voltage and current ratings, number of turns of primary/secondary windings in the Power Transformers (T302), type of Chassis Fan Cover and minor differences in the secondary circuit components and PWB layout. See below for Model Ratings for up to 50°C ambient:

Model MHP1000PS12: Output Rated: 12 Vdc, 83 A (1001 W) Model MHP1000PS15: Output Rated: 15 Vdc, 67 A (1010 W)

Model MHP1000PS24: Output Rated: 24 Vdc, 42 A (1013 W)

Model MHP1000PS24 (For 180-240 Vac Input): Output Rated: 24 Vdc, 50 A (1200 W)

Model MHP1000PS24: Output Rated: 28 Vdc, 36 A (1013 W)

Model MHP1000PS28 (For 180-240 Vac Input): Output Rated: 28 Vdc, 40 A (1204 W)

Model MHP1000PS36: Output Rated: 36 Vdc, 28 A (1013 W)

Model MHP1000PS36 (For 180-240 Vac Input): Output Rated: 36 Vdc, 33 A (1188 W)

Model MHP1000PS48: Output Rated: 48 Vdc, 21 A (1013 W)

Model MHP1000PS48 (For 180-240 Vac Input): Output Rated: 48 Vdc, 25 A (1200 W)

All models are provided with Fan Supply Connection (12Vdc, 0.5 A) and Standby Connection (5 Vdc, 0.2A).

See also Enclosure-Miscellaneous for additional details.

### **Technical Considerations**

§ Classification of installation and use : For building-in

§ Supply connection : For building-in

§ Accessories and detachable parts included in the evaluation: None

Issue Date: 2011-12-16 Page 3 of 16 Report Reference # E146893-V1-S23

- § Options included: None
- § The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1:2005/C1:2009 (includes National Differences for USA); CAN/CSA-C22.2 No. 60601-1:08 (includes National Differences for Canada), EN 60601-1:2006
- Scope of Power Supply evaluation defers the following clauses to the be determined as part of the end product evaluation: Clause 7.5 (Safety Signs), Clause 7.9 (Accompanying Documents), Clause 9 (ME Hazard), Clause 10 (Radiation), Clause 14 (PEMS), Clause 16 (ME Systems)
- § Supply connection: Overvoltage Category II
- § 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 anesthetics mixture with air or oxygen or with nitrous oxide: No
- Unit also complied with spacing requirements of UL60601-1 (1<sup>st</sup>), CSA C22.2 No. 60601-1 (2<sup>nd</sup>), and IEC 60601-1 (2<sup>nd</sup>) for Basic for 250 Vac from Primary to Ground, Double/Reinforced for 250 Vac from Primary to Secondary.
- The product was submitted and evaluated for use at the maximum ambient temperature (Tmra) permitted by the manufacturer's specification of: 50°C with output loaded to 100% rated and 70°C with output loaded to 50% rated (See De-rating Curve, Enclosure 7-01 (III. 14) for details).

### Risk Controls/Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by Underwriters Laboratories Inc. When installed in an end-product, consideration must be given to the following:

- § The component shall be installed in compliance with the Marking (clause 7) and Separation (clause 8) requirements of the end use application.
- Repeating leakage current testing and consideration of non-frequency weighted leakage to be considered as part of the end product.

Issue Date: 2011-12-16 Page 4 of 16 Report Reference # E146893-V1-S23

- This power supply was evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth.
- § 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 should ensure that the requirements related to accompanying documents, clause 7.9, are met.
- § The available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions
- § The following secondary output circuits are at hazardous energy levels: Main Power Output
- § The output connectors are not acceptable for field connections; they are only intended for connection to mating connectors of the end-use equipment.
- § The maximum investigated branch circuit rating is: 20 A
- § The Dielectric Withstand Voltage Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 359 Vpk, 244 Vrms; Primary-SEC: 578 Vpk, 240 Vrms.
- § Protective bonding testing shall be considered in the end product application.
- § For Class I application: Protective bonding testing shall be considered in the end product application.
- § 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-L3, T201, T301-T303, and L301 (min. Class B, min. 130°C) and L50 (min. Class F, min. 155°C)
- § Printed Wiring Board rated 130°C.
- § Cleaning test to 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.
- § Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.

### **Additional Information**

§ Marking label is representative of all models. The nameplate labels included in this report depict the draft artwork for the marking plate pending approval by National Certification Bodies and it will not be affixed to products prior to such approval.

### Markings and instructions

Issue Date: 2011-12-16 Page 5 of 16 Report Reference # E146893-V1-S23

Clause Title	Marking or Instruction Details		
Company identification	Classified or Recognized company's name, Trade name, Trademark or File		
Model	Model number		
Alternating current	$\sim$		
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.		
Functional Earth Terminal	<u></u>		
Special Instructions to UL Representative			
N/A			

Production-Line Testing Requirements  Test Exemptions - The following models are exempt from the indicated test						
All Models	Test	Test	Exempt			
<u>Solid-State Component Test Exemptions</u> - 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			