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:	FCM400PSXX (where XX is any number between 12-48 designating output voltage), may also be provided with suffix "SF"
Rating:	Input Rated: 100-240 Vac, 50/60 Hz, 5 A Output Rated: See 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.

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 Underwriters Laboratories Inc. (UL) or any authorized licensee of UL.

Prepared by: Linus Park
Underwriters Laboratories Inc.

Reviewed by: Underwriters Laboratories Inc.

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 covered in this report are component power supplies intended for use in Medical Electrical Equipment. They are open frame power supply intended for building-in. Units are intended for used with Class I end-products.

Model Differences

All models in the Model FCM400PSXX series are identical with exception to the Mains Transformer, T3, and minor secondary components that allow for different output voltage ratings. See table below) for Model Ratings for up to 50°C ambient:

Model FCM400PS12: Output Rated: 12 Vdc, 33.3 A; Standby: 5 Vdc, 0.5 A
Model FCM400PS15: Output Rated: 15 Vdc, 26.6 A; Standby: 5 Vdc, 0.5 A
Model FCM400PS24: Output Rated: 24 Vdc, 16.6 A; Standby: 5 Vdc, 0.5 A
Model FCM400PS28: Output Rated: 28 Vdc, 14.2 A; Standby: 5 Vdc, 0.5 A
Model FCM400PS36: Output Rated: 36 Vdc, 11.1 A; Standby: 5 Vdc, 0.5 A
Model FCM400PS48: Output Rated: 48 Vdc, 8.3 A; Standby: 5 Vdc, 0.5 A

See Enclosure 7-01 (Ill. 17) and Enclosure 7-02 (Ill. 18) for de-rating curve and table, respectively, for ambient temperatures up to 70°C.

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

Technical Considerations

§ Classification of installation and use : Building-in

§ Supply connection: Building-in

§ Accessories and detachable parts included in the evaluation: None

§ 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 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

§ 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 (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 250Vac from Primary to Secondary.

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.

§ The power supply was evaluated for use in 50°C ambient at Full Rated Output and 50% of the Rated Output in 70°C ambient. (See De-rating Curve, Enclosure 7-01 for details)

§ 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.

§ Repeat of leakage current testing, including applicability of Clause 8.7.3e, shall be considered in the end product application.

- § This power supply was evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth.
- § This power supply has been evaluated for continuous operation, as 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 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 machine.
- § The Electric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 353 Vpk, 244 Vrms; Primary-SEC: 441 Vpk, 240 Vrms.
- § The maximum investigated branch circuit rating is: 20 A
- § The power supply shall be mounted in a manner that provides, at a minimum, 2.5 mm Clearance/4 mm Creepage between the primary side of 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.
- § An investigation of the protective bonding terminal has: Not been conducted.
- § 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 min. Class F (155°C): L1, L5, L6 and T1-T4.
- § Printed Wiring Board rated 130°C.
- § The need for marking durability testing shall be considered as part of the end-use product.
- § Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- § Units provided with suffix "SF" are provided with only one line side fuse. The need for additional fusing shall be considered 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

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.
Earthing	
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	Exempt	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			