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:	Power Supply
Model:	ECP60US05, ECP60UD01, ECP60UD02, ECP60UD03, ECP60UT01, ECP60UT02, ECP60UT03, and ECP60UT04
Rating:	Input: 100-240 V, 1.2 A, 50/60 Hz Model ECP60US05: Output 1: 5 V dc, 11 A Model ECP60UD01: Output 1: 5 V dc, 7 A Output 2: 12 V dc, 3 A Model ECP60UD02: Output 1: 5 V dc, 7 A Output 2: 15 V dc, 2 A Model ECP60UD03: Output 1: 5 V dc, 7 A Output 2: 24 V dc, 1.5 A Model ECP60UT01: Output 1: 5 V dc, 7 A Output 2: 12 V dc, 3 A Output 3: -12 V dc, 0.3 A Model ECP60UT02: Output 1: 5 V dc, 7 A Output 2: 15 V dc, 2 A Output 3: -15 V dc, 0.3 A Model ECP60UT03: Output 1: 5 V dc, 7 A Output 2: 24 V dc, 1.5 A Output 3: +12 V dc, 0.3 A Model ECP6UT04: Output 1: 5 V dc, 7 A Output 2: 24 V dc, 1.5 A Output 3: -12 V dc, 0.3 A

Applicant Name and Address:	XP POWER INC 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: Linus Park Reviewed by: Ned Devine

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 are open frame power supplies intended for building-in in Medical Electrical Equipment.

Model Differences

Models ECP60US05, ECP60UD01, ECP60UD02, ECP60UD03, ECP60UT01, ECP60UT02, ECP60UT03, and ECP60UT04 are identical except for number of outputs, output ratings, transformer secondary windings, secondary components, and model designation.

See Output Rating for 50°C indicated below:

Model ECP60US05:
Output 1: 5 V dc, 11 A

Model ECP60UD01:
Output 1: 5 V dc, 7 A
Output 2: 12 V dc, 3 A

Model ECP60UD02:
Output 1: 5 V dc, 7 A
Output 2: 15 V dc, 2 A

Model ECP60UD03:
Output 1: 5 V dc, 7 A
Output 2: 24 V dc, 1.5 A

Model ECP60UT01:
Output 1: 5 V dc, 7 A
Output 2: 12 V dc, 3 A
Output 3: -12 V dc, 0.3 A

Model ECP60UT02:
Output 1: 5 V dc, 7 A
Output 2: 15 V dc, 2 A
Output 3: -15 V dc, 0.3 A

Model ECP60UT03:
Output 1: 5 V dc, 7 A
Output 2: 24 V dc, 1.5 A
Output 3: +12 V dc, 0.3 A

Model ECP6UT04:
Output 1: 5 V dc, 7 A
Output 2: 24 V dc, 1.5 A
Output 3: -12 V dc, 0.3 A

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) : Provide regulated power
- 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), 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), 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)
- The product was not investigated to the following standards or clauses:: Biocompatibility (ISO 10993-1), Clause 14, Programmable Electronic Systems, Electromagnetic Compatibility (IEC 60601-1-2)
- 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 power supply was evaluated for use in 50°C ambient at Full Rated Output and 50% of the Rated Output in 70°C ambient.
- 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

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 component shall be considered for compliance with the Marking (clause 7) and Separation (clause 8) requirements as part of the end use application evaluation.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage to be considered as part of the end product.
- This power supply was evaluated with One MOPP/ Two MOOP between Primary and Secondary; One MOPP/ One MOOP between primary and Earth. Additional MOPP between Primary and Secondary shall be considered in the end product
- 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 available voltage for the secondary outputs does not exceed 25 Vac or 60 Vdc, under normal and single fault conditions.
- The Dielectric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal: 356 Vpk, 245 Vrms; Primary-SEC: 603 Vpk, 250 Vrms.
- 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): TR1 (Class B, 130°C)
- 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.
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- 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.

- Unit to be properly earthed as part of the end product.
- Q1 Heatsink considered live and should not be earthed.
- End product shall provide necessary creepage and clearance for 250Vrms from input connector pins to mounting means.
- Power supply fuse was provided with limited breaking capacity and was evaluated for installation where the maximum fault current was limited. End product shall ensure the power supply is used in applications where the limited breaking capacity does not result in unacceptable risk.

Additional Information

Manufacturer to provide up to date IEC Licensed for component licenses greater than 3 years upon request.

Additional Standards

The product fulfills the requirements of: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10), CAN/CSA-C22.2 No. 60601-1 (2008), IEC 60601-1: 2005, EN 60601-1: 2006 + CORR: 2010

Markings and instructions

Clause Title	Marking or Instruction Details
Model	Model number
Company identification	Classified or Recognized company's name, Trade name, Trademark or File
Supply Connection	Voltage range, ac/dc, phases if more than single phase
Alternating current	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.

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:			
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			