UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1:2005, 3rd ed. (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:	CLC175USXX-M (where XX = 12-48; may also be followed by suffixes SF, A, C or TF)
Rating:	Input: 100-240 Vac, 3.1 A, 50/60 Hz Output: See Enclosure - Miscellaneous Ratings Table 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 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: Longjie Zhang Reviewed by: Andrew Saunders

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 to be used with Medical Electrical Equipment. Units are intended for used with Class I or Class II end-products.

Marking label is representative of all models.

Model Differences

All models in the Model CLC175USXX-M Series are identical with exception to the Mains Transformer, T1, and minor secondary components that allow for different output voltage ratings. See below for 50°C output ratings:

Model CLC175US12-M: Output Rated: 12 Vdc, 13.9 A
Model CLC175US24-M: Output Rated: 24 Vdc, 6.9 A
Model CLC175US48-M: Output Rated: 48 Vdc, 3.5 A
All models provided with Fan Output (12Vdc, 0.5 A) and Standby Output (5.0 Vdc, 0.5A).

See Enclosure 7-01 for Output De-rating Table.

Suffix "SF" indicates single fuse provided in the line side of the primary.
Suffix "TF" indicates units provided with cover and top fan.
Suffix "C" indicates units provided with cover.
Suffix "A" indicates units provided with Transformer, T2.

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) : None
- 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:: 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), 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), EN 60601-1: 2006 + CORR: 2010 (Medical electrical equipment Part 1: General requirements for basic safety and essential performance)

- 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
- 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.
- 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)

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 Two MOPP between Primary and Secondary; One MOPP between primary and Earth; only operational protection between secondary and Earthed trace or chassis for both class I and class II application.
- 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 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 Dielectric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 347 Vpk, 250 Vrms; Primary-SEC: 525 Vpk, 250 Vrms.
- 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 and T1 (Class F, 155°C)
- Printed Wiring Board rated 130°C.
- Cleaning test shall 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.
- When installed in a Class I end product, the power supply shall be mounted in a manner that provides, at a minimum, 2.5 mm Clearance/4 mm Creepage between the primary sides 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.
- 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 mm Clearance/8 mm Creepage between the power supply and any accessible conductive parts.
- 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.
- 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.
- Temperature test conducted with approx 12CFM top fan model forced air cooling, temperature on on Convection cooling condition or other external forced air cooling shall be determined in the end product evaluation.

Additional Information

This report has been previously evaluated by UL to IEC60601-1: 1988+A1: 1991 +A2: 1995, UL 60601-1, 1st Edition, 2006-04-26 (includes National Differences for USA) , EN 60601-1: 1990 + A1:1993 + A2:1995 , CAN/CSA-C22.2 No. 601.1-M90 (R2005) (includes National Differences for Canada) under CBTR Ref. No.E146893-A16-CB-1, CB Test Certificate Ref. No. US/15079/UL. Based on previously conducted testing and the previous review of product construction only limited tests were deemed necessary.

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	
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	All models	No exemptions	All models

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			