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:	Component Switching Power Supply
Model:	RCL175PXY series (where X can be S, D, T or Q indicating single, dual, triple, or quad output configurations, Y can be 00 to 99, or AA-ZZ), may be provided with additional suffixes U, C, F, or blank and/or W. See Model Differences for nomenclature. Model 101372-xx (where x can be any alphanumeric character or blank)
Rating:	Input: 100-240 V~, 50/60 Hz, 2.7 A See Model Differences for output configurations.
Applicant Name and Address:	XP POWER LLC 15641 RED HILL AVE, SUITE 100 TUSTIN CA 92780 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: Haydee Gonzalez Reviewed by: Ahmad Daoudi

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

The products covered in this report are component power supplies intended for use in Medical Electrical Equipment.

Model Differences

Model numbers are as follows: RCL175PXY, where X can be S, D, T, or Q, indicating single, double, triple or quad (4) output configurations respectively, where Y can be 0 to 99 or AA thru ZZ. The 0 to 99 representing output voltages from 3.3 to 60 Vdc for Models where X is S, and AA to ZZ represents the no. of output and configurations. Individual Outputs V1-V4 have the following limitations; V1: 3.3-60 Vdc, 204 W max; V2: 3.3-60 Vdc, 120 W max; V3: 3.3-60 Vdc, 120 W max; V4: 3.3-60 Vdc, 30 W max. Total maximum combined input power is 204 Watts when provided with fan cover. TMRA is 50 degrees Celsius. See models and ratings and Enclosure Diagram 4-01 for specific ratings.

The power supply chassis can be provided in 4 configurations - No suffix = open frame with heatsinks; Suffix -U provided with U channel chassis; Suffix -C provided with Cover; Suffix -F provided with fan cover kit. See enclosure Enclosures Diagram 4-02 for further details.

Models followed with the suffix W are for Class II applications employing two Y1 bridging capacitors (C41 and C41A) providing two MOPP between primary and secondary and Class II Models without the suffix W employ one Y1 bridging capacitor (C41) providing one MOPP between primary and secondary. Additionally, when configured for Class II construction, with the suffix W, Capacitors C6A, C7A and C10A are also provided. See Enclosure Schematics 5-04 for details.

Models for Class I applications employing two Y1 bridging capacitors (C41 and C41A) provide two MOPP between primary and secondary. Class I applications employing one Y1 bridging capacitor (C41) provide one MOPP between primary and secondary. See Enclosure Schematics 5-04 for details.

Model 101372-xx (where x can be any alphanumeric character or blank) is identical to Model RCL175PSAA provided with optional open frame fan assembly with exception to the model designation. "xx" suffix is a revision indicator.

Technical Considerations

- Classification of installation and use : Building-in
- Device type (component/sub-assembly/ equipment/ system) : Component
- Intended use (Including type of patient, application location) : To supply regulated power
- Mode of operation : Continuous
- Supply connection : To be determined in the end product
- Accessories and detachable parts included : Fan Cover, U Channel Chassis
- Other options include : None
- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005 + C1:09 + AM1 (2012)) (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) + AM1 (2014)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), EN 60601-1: 2006 + AM1 (2013) (Medical electrical equipment Part 1: General requirements for basic safety and essential performance), IEC 60601-1, Edition 3.1 (2012)
- The product was not investigated to the following standards or clauses:: Electromagnetic

Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1)

- The degree of protection against harmful ingress of water is:: Ordinary
- The following accessories were investigated for use with the product:: Fan Cover, U Channel Chassis
- 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
- 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
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No

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.
- Temperature, leakage and Dielectric Tests should be considered in the end product.
- Touch current test to be conducted as part of the end product.
- Class II Power supply Models with the suffix W employ two Y1 bridging capacitor (C41and C41A) and evaluated as Two MOPP between Primary and Secondary; One MOPP primary and Earth. Class II Models without the suffix W employ one Y1 bridging capacitor (C41) and evaluated for 1 MOPP between primary and secondary and 1 MOPP between 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 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 input/output connectors are suitable for factory wiring only.
- The maximum investigated branch circuit rating is: 20 A. If used on a branch circuit greater than this, additional testing may be necessary.
- The Electric Strength Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 240Vrms, 466 Vpk; Primary-SEC: 466 Vpk, 240Vrms.
- 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. Capacitors C6A, C7A and C10A shall be provided when two MOPP is required.
- An investigation of the protective bonding terminal has: Not been conducted.
- For Class I application: Protective bonding testing shall be considered in the end product application.
- Proper bonding to the Class I end-product main protective earthing termination is required (via mounting holes on the PCB), unless for Class II applications. For Class II applications the primary side mounting pads are isolated from accessible conductive chassis by Reinforced Insulation
- The equipment has been evaluated for use in a Pollution Degree 2 environment.
- Residual Voltage in Attachment Plug should be conducted in the end product with the final configuration/values of Y and bridging capacitors.
- Consideration should be given to the measuring the temperature on the ferromagnetic components when installed in the end product. Primary components T1, T2, T3, L1, L2, L3 and L4 are provided with Class F insulation systems. Secondary components L5, L6 and L9 are provided with Class F insulation systems.
- The PWB is 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.
- Models RCL175PXY is rated for use in an ambient of 50°C.
- The total maximum combined output power shall not exceed 175 Watts.
- For Class II applications, the power supply must be configured as an open frame and must not be used with the U-channel chassis or fan cover options. Capacitor connected between primary and earth terminal is type Y1.
- For Class I operation, consideration for conducting the grounding impedance test, from heatsink 1 and heatsink 2 to the protective earth terminal in the end product, should be given.
- The need to measure the leakage current with a non-frequency weighted device per Clause 8.7.3 (e) shall be considered in the end-product.
- Class I Power supply employing two Y1 bridging capacitors (C41 and C41A) between Primary and Secondary evaluated as Two MOPP between Primary and Secondary; One MOPP primary and Earth. Class I Models employing one Y1 bridging capacitor (C41) evaluated for 1 MOPP between primary and secondary and 1 MOPP between primary and earth.

Additional Information

When submitting this Test Report to other Certification Body, the manufacturer is responsible for providing any additional information that the Body may need in order to issue its Mark, including testing for compliance with the applicable collateral standards.

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

Only one marking plate is provided which is representative of the other models in the series except for the output ratings.

The Heating Test data and peak working voltage measurements were derived from CB Report issue to IEC 60950-1:2005 covered in Test Report Reference E139109-A11-CB-1 issued 2010-12-14 with CB Test Certificate US/16253/UL issued 2010-12-14.

The models covered under this Report have been additionally evaluated to ES 60601-1, AM1 (2012), CSA C22.2 No. 60601-1, AM1 (2014), and IEC/EN 60601-1, Edition 3.1 (2012).

Additional Standards

The product fulfills the requirements of: ANSI/AAMI ES60601-1 (2005 + C1:09 + AM1 (2012)) (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) + AM1 (2014) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), EN 60601-1: 2006 + A1(2013)(Medical electrical equipment Part 1: General requirements for basic safety and essential performance)

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
Supply Frequency	Rated frequency range in hertz
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.
Cl. 7.2.2 from A1	Serial or lot or bathc number and Date of Manufacturer (provided as part of 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	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			