



Test Report issued under the responsibility of:



IEC 60601-1	
Medical electrical equipment	
Part 1: General requirements for basic safety and essential performance	
Report Reference No.....:	4786488108-12
Date of issue	2014-08-20 (Amendment 2: 2016-09-27)
Total number of pages.....:	194
CB Testing Laboratory.....:	UL Fremont
Address	47173 Benicia St, Fremont, CA 94538 USA
Applicant's name.....:	XP Power LLC
Address	15641 Red Hill Ave, Suite 100 Tustin, CA 92780 USA
Test specification:	
Standard	IEC 60601-1: 2005 + CORR. 1:2006 + CORR. 2:2007 + AM1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure.....:	CB Scheme
Non-standard test method.....:	N/A
Test Report Form No.....:	IEC60601_1I
Test Report Form Originator	UL (US)
Master TRF	2014-03
Copyright © 2014 Worldwide System for Conformity Testing and Certification of Electrotechnical Equipment and Components (IECEE), Geneva, Switzerland. All rights reserved.	
This publication may be reproduced in whole or in part for non-commercial purposes as long as the IECEE is acknowledged as copyright owner and source of the material. IECEE takes no responsibility for and will not assume liability for damages resulting from the reader's interpretation of the reproduced material due to its placement and context.	
If this Test Report Form is used by non-IECEE members, the IECEE/IEC logo and the reference to the CB Scheme procedure shall be removed.	
This report is not valid as a CB Test Report unless signed by an approved CB Testing Laboratory and appended to a CB Test Certificate issued by an NCB in accordance with IECEE 02.	
General disclaimer:	
The test results presented in this report relate only to the object tested. This report shall not be reproduced, except in full, without the written approval of the Issuing CB testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting the NCB, responsible for this Test Report.	

Test item description	Component Switching Power Supply	
Trade Mark		
Manufacturer	XP Power LLC 15641 Red Hill Ave, Suite 100, Tustin, CA 92780 USA	
Model/Type reference.....	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)	
Ratings.....	Input: 100-240 V~, 50/60 Hz, 2.7 A See Model Differences for output configurations.	
Testing procedure and testing location:		
<input checked="" type="checkbox"/>	CB Testing Laboratory:	
	Testing location/ address	UL Fremont 47173 Benicia St, Fremont, CA 94538 USA
<input type="checkbox"/>	Associated CB Testing Laboratory:	
	Testing location/ address	
	Tested by (name + signature).....	Janice Pham/Project Handler 
	Approved by (name + signature)	Haydee Gonzalez/Project Reviewer 
<input type="checkbox"/>	Testing procedure: TMP/CTF Stage 1:	
	Testing location/ address	
	Tested by (name + signature).....	
	Approved by (name + signature)	
<input type="checkbox"/>	Testing procedure: WMT/CTF Stage 2:	
	Testing location/ address	
	Tested by (name + signature).....	
	Witnessed by (name + signature)	

Amendment 2: 2016-09-27

Approved by (name + signature)			
<input type="checkbox"/>	Testing procedure: SMT/CTF Stage 3 or 4:		
Testing location/ address			
Tested by (name + signature).....			
Witnessed by (name + signature)			
Approved by (name + signature)			
Supervised by (name + signature).....			

List of Attachments (including a total number of pages in each attachment):

National Differences (9 pages)

Enclosures (65 pages)

Summary of testing: Unless otherwise indicated, all tests were conducted at XP POWER LLC, 15641 Red Hill Ave., Suite 100, Tustin, CA 92780 USA.

All testing conducted under the Applicant's IEC 60601-1, 3rd Ed investigation issued under CBTR No. E146893-A37-CB-1, CBTC No. US-18340-UL was consider to cover the requirements of IEC 60601-1: 2005, Third Edition with Am .1

Tests performed (name of test and test clause):

Testing location:

Input Test (4.11)
Temperature (11)
Transformer Overload and Short-Circuit Tests (15.5.1)

Summary of compliance with National Differences

List of countries addressed: Austria, Canada, Republic of Korea, Sweden, UK, USA

The product fulfils the requirements of IEC 60601-1: 2005, Third Edition with Am. 1

Copy of marking plate

The artwork below may be only a draft. The use of certification marks on a product must be authorized by the respective NCBs that own these marks.

The following label is representative of all models covered under this Report.



GENERAL INFORMATION	
Test item particulars (see also Clause 6):	
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 to medical devices
Mode of operation	Continuous
Supply connection	For building-in
Accessories and detachable parts included.....	None
Other options include	None
Testing	
Date of receipt of test item(s)	2006-09-21, 2006-11-28, 2011-10-20, 2011-11-17, 2012-03-05, 2016-03-21
Dates tests performed	2006-10-18, 2006-10-19, 2006-10-23, 2006-11-03, 2006-11-15, 2006-12-12, 2011-10-24, 2011-10-25, 2011-10-26, 2011-10-27, 2011-10-28, 2011-12-15, 2011-12-16, 2012-03-07, 2016-03-31 to 2016-03-30
Possible test case verdicts:	
- test case does not apply to the test object	N/A
- test object does meet the requirement.....	Pass (P)
- test object was not evaluated for the requirement	N/E (collateral standards only)
- test object does not meet the requirement.....	Fail (F)
Abbreviations used in the report:	
- normal condition	N.C.
- means of Operator protection	MOOP
- single fault condition.....	S.F.C.
- means of Patient protection	MOPP
General remarks:	
"(See Attachment #)" refers to additional information appended to the report. "(See appended table)" refers to a table appended to the report. The tests results presented in this report relate only to the object tested. This report shall not be reproduced except in full without the written approval of the testing laboratory. List of test equipment must be kept on file and available for review. Additional test data and/or information provided in the attachments to this report.	
Throughout this report a <input type="checkbox"/> comma / <input checked="" type="checkbox"/> point is used as the decimal separator.	

Amendment 2: 2016-09-27

Manufacturer's Declaration per sub-clause 4.2.5 of IEC60060:2012

The application for obtaining a CB Test Certificate includes more than one factory location and a declaration from the Manufacturer stating that the sample(s) submitted for evaluation is (are) representative of the products from each factory has been provided..... : Yes Not applicable

When differences exist; they shall be identified in the General product information section.

Name and address of factory (ies)..... : XP POWER LLC
990 BENECIA AVE
SUNNYVALE CA 94085
UNITED STATES

XP POWER (KUNSHAN) LTD
230 BIN JIANG NAN RD
ZHANGPU TOWN
KUNSHAN
JIANGSU 215300 CHINA

XP POWER (VIETNAM) CO LTD
LOT D - 4Q - CN, MY PHUOC 3 INDUSTRIAL
PARK, BEN CAT DISTRICT
BINH DUONG VIETNAM

XP POWER
HORSESHOE PARK
PANGBOURNE RG8 7JW UNITED KINGDOM

Test Report Summary:

Amendment 1 Report: The Test Report Ref. No. 4786488108-12, was modified on 2016 April 20 to include the following changes and/or additions:

- 1.) Add two additional factory locations.
- 2.) Add alternate "Y2" capacitor in the CC Table.
- 3.) Add alternate T2 transformer construction, limited testing was conducted.

Amendment 2 Report: The Test Report Ref. No. 4786488108-12, was modified on 2016 September 27 to include the following changes and/or additions:

- 1.) Update the Insulation Table to include the requirements for altitude of 5000 Meters.
- 2.) Add insulation sheet to the Critical Components Table. No additional testing was required as it was previously evaluated for Dielectric compliance.

General product information:

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.

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.

Amendment 2: 2016-09-27

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.

No additional testing was deemed necessary to evaluate the models covered under this Report to IEC 60601-1, Edition 3 with Am.1 based on previously conducted testing and the review of product technical documentation including photos, schematics, wiring diagrams, etc. conducted under separate CB Scheme investigation to IEC 60601-1, 3rd ed issued under CBTR No. E146893-A37-CB-1, CBTC No. US-18340-UL.

Technical Considerations:

- The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)+AM1 (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: AM1 (2013) (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
- The equipment has been 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)
- 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: Shock, Fire, Casualty
- The following accessories were investigated for use with the product: Fan Cover, U Channel Chassis
- Power Supply was considered Overvoltage Category II (OVCI)
- Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No

Engineering Conditions of Acceptability

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.
- This power supply has been evaluated as a continuous operation, ordinary equipment and has not

Amendment 2: 2016-09-27

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 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 340 Vpk, 232 Vrms for Primary-Earthed Dead Metal; 320Vpk, 180Vrms from Primary-secondary.
- Power supply provides the following MOPP (means of patient protection): two MOPP based upon a working voltage 240 Vrms, 466 Vpk between Primary to Secondary, one MOPP based upon a working voltage 240Vrms, 466 Vpk between Primary and Earth/Enclosure.
- 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.
- 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 PWB is rated 130°C.
- 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
- Device has been evaluated for a 5000 m altitude.
- 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.
- Repeat of leakage current testing and consideration of non-frequency weighted leakage current (clause 8.7.3e) to be considered as part of the end product.
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product.
- Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of

Amendment 2: 2016-09-27

the Power Supply tests should be considered as part of the end product evaluation.

- 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.
- 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.
- Class II Power supply Models with the suffix W employ two Y1 bridging capacitor (C41 and 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.