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. ..... :	E321744-D1022-1/A0/C0-ULCB
Date of issue ..... :	2019-04-19
Total number of pages ..... :	165
CB Testing Laboratory ..... :	UL Brea
Address ..... :	2929 E. Imperial Hwy, Suite 100, Brea, CA, 92821, USA
Applicant's name ..... :	XP POWER L L C
Address ..... :	15641 Red Hill Avenue, Suite 100 Tustin, CA 92780 USA
Test specification:	
Standard ..... :	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure ..... :	CB Scheme
Non-standard test method…….:	N/A
Test Report Form No..... :	IEC60601_1K
Test Report Form Originator ..... :	UL(US)
Master TRF ..... :	2015-11

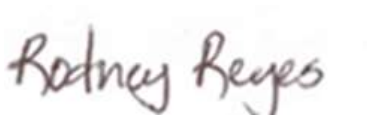
General disclaimer:

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:	Power supply for Building-In
Trade Mark:	Trademark image(s): 
Manufacturer:	Same as Applicant
Model/Type reference:	ECP180PSXX, where XX can be any number between 12 and 48 designating the output voltage, may also be provided with suffix "SF" for removal of F2
Ratings:	Input: 100-240 Vac, 2.5 A, 50/60 Hz Output: See Enclosure Miscellaneous - (001), Ratings Table for details.

Testing procedure and testing location:		
[X] CB Testing Laboratory:		
Testing location/ address:	UL Brea 2929 E. Imperial Hwy, Suite 100, Brea, CA, 92821, USA	
[ ] Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name, function, signature):	Rahul Baria, Project Handler	
Approved by (name, function, signature):	Ahmad Daoudi, Project Reviewer	
[ ] Testing procedure: CTF Stage 1:		
Testing location/ address:		
Tested by (name, function, signature):		
Approved by (name, function, signature):		
[ ] Testing procedure: CTF Stage 2:		
Testing location/ address:		

Tested by (name, function, signature):		
Witnessed by (name, function, signature):		
Approved by (name, function, signature):		
[X] Testing procedure: CTF Stage 3:		
[ ] Testing procedure: CTF Stage 4:		
Testing location/ address:	XP Power LLC, 15641 Red Hill Ave, Suite 100, Tustin CA 92780 USA	
Tested by (name, function, signature):	Rodney Reyes, Tester	
Witnessed by (name, function, signature):	N/A	
Approved by (name, function, signature):	Ahmad Daoudi, Project Reviewer	
Supervised by (name, function, signature):	Rahul Baria, Project Handler	

List of Attachments (including a total number of pages in each attachment): Refer to Appendix A of this report. All attachments are included within this report.
Summary of testing
Tests performed (name of test and test clause): Testing location: *Refer to the Test List in Appendix D of this report if testing was performed as part of this evaluation.*
Summary of compliance with National Differences List of countries addressed: Austria, Korea, Republic of, USA, Canada, United Kingdom, Sweden [X] The product fulfils the requirements of IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint) .

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.

Refer to the enclosure(s) titled Marking Label in the Enclosures section in Appendix A of this report for a copy.

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, Power Supply
Intended use (Including type of patient, application location):	To supply regulated power
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) .....:	2013-10-17; 2019-04-01
Dates tests performed .....:	2013-10-17 to 2013-12-05; 2019-04-02
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
- test object does not meet the requirement.....:	Fail (F)
Abbreviations used in the report:	
- normal condition: N.C.	- single fault condition: S.F.C.
- means of Operator protection: MOOP	- 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 point is used as the decimal separator.	
Manufacturer's Declaration per sub-clause 4.2.5 of IECEE 02:2012	
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
When differences exist; they shall be identified in the General product information section.	

Name and address of factory (ies) .....:	Abes Technology Co Ltd No 78-1 Zhangma St Xiushui Township, Changhua County 504 TAIWAN XP POWER (KUNSHAN) LTD 230 BIN JIANG NAN RD ZHANGPU TOWN KUNSHAN JIANGSU 215300 CHINA

GENERAL PRODUCT INFORMATION:

Report Summary

All applicable tests according to the referenced standard(s) have been carried out.

Refer to the Report Modifications for any modifications made to this report.

Product Description

The model covered in this report is a component power supply intended for use in Medical Equipment. It is an open frame power supply intended for building-in Class I or Class II end-products. Double insulated symbol is optionally provided. Earthing symbol may only be provided for Class I power supplies.

Model Differences

All models in the Model ECP180PSXX series are identical with exception to the Mains Transformer, TR1, and minor secondary components that allow for different output voltage ratings.

See below for Model Ratings Table for 50°C ambient with 10 cfm fan applied 5 cm from input connector CN1 blowing inward:

Model ECP180PS12: Output Rated: 12 Vdc, 15A
Model ECP180PS15: Output Rated: 15 Vdc, 12A
Model ECP180PS18: Output Rated: 18 Vdc, 10A
Model ECP180PS24: Output Rated: 24 Vdc, 7.5 A
Model ECP180PS28: Output Rated: 28 Vdc, 6.43 A
Model ECP180PS36: Output Rated: 36 Vdc, 5A
Model ECP180PS48: Output Rated: 48 Vdc, 3.75A

See Enclosure "Miscellaneous - (001) 7-01 Ratings Table" for additional ratings information.

Additional Information

This report is a re-issue of CBTR Ref. No. 4786640925-20141121A , CB Test Certificate Ref. No.US-24350-UL and E321744-A18 merged into a combined report. Based on previously conducted testing and a review of the product construction, it was determined that partial testing was necessary in order to comply with the standard(s) referenced in this report.

The following test(s) were conducted as a result of the noted changes to the report:
Cl 8.8.3 – Dielectric Voltage Withstand Test
Cl 13 – Component Abnormal test w/ Earth leakage (Cl 8.7.4.5) after the test.

The following changes were made to the report:
1) Addition of 2b., Alternate Secondary Connector (CN2,CN3), to the critical component list.
2) Updated Critical Component 13-1, Transformer (TR1), model 225-15, to include “for model ECP180PS18.”
3) Added new Model ECP180PS18, Rated Output: 18 Vdc, 10A to report.
4) Model differences are added in the GPI; the addition being “Model ECP180PS18: Output Rated: 18Vdc,

10 A."
5) Updated Ratings Table enclosure Miscellaneous (001) "01 Ratings Table" to include Model ECP180PS18.
6) Corrected Test Table 8.2.4 (Working Voltage /Power Measurement) to "8.5.4."
7) Removed label RT-05 from CC table, not tested per clause 7.3 or 7.4
8) Removed Essential Performance at the request of report applicant.
9) Updated critical components list to include applicable standards and applicable IEC licenses.
10) Added alternate Fuse (F1,F2), Littelfuse 215 Series, Rated 3.15 A, 250 V, 1500A Interrupting rating. IEC license (VDE, 40013521).
11) Corrected required creepages & clearance distances and Working voltages in the Insulation Table.
12) Corrected Insulation Area B from 2 MOPP to 1 MOPP in insulation table. Additionally revised Clause 8.5.1.2.
13) Revised Clause 8.5.1.3 to "Pass"
14) Added load conditions to Test Table 11.1.1 and corrected typo for ECP180PS12 (Convection Cooling): 60 Hz, Ambient = 50C, Duration= 2 hours, Test Voltage from "164V" to "264V".

Additional Information:
The clearance distances have additionally been assessed for suitability up to 5000 m elevation (1.29 correction factor from Table 8 of IEC 60601-1, 3.1 Ed.).
The need for the additional testing and evaluation shall be determined in the end product investigation.
The nameplate markings provided are considered representative of the entire series.
The power supply series covered by this report employ 2 Means of Patient Protection (MOPP) between Primary and Secondary circuits.

Technical Considerations

- The product was investigated to the following standards:

  Main Standard(s):

  ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14, IEC 60601-1 Edition 3.1 (2012)

  From Country Differences:

  - Austria: EN 60601-1:2006/A1:2013
  - Korea, Republic of: KS C IEC 60601-1
  - USA: AAMI/IEC 60601-1:2005 + AMD 1:2012
  - Canada: CSA CAN/CSA-C22.2 NO. 60601-1:14
  - United Kingdom: BS EN 60601:2006 A1
  - Sweden: SS-EN 60601-1:2006+A11:2011+A1:2013+AC1:2014+A12:2014

  Additional Standards:

  EN 60601-1:2006 +A1:2013+A12:2014

- The following additional investigations were conducted:
- The product was not investigated to the following standards or clauses: Biocompatibility (ISO 10993-1)

  Clause 14, Programmable Electronic Systems
- The following accessories were investigated for use with the product: None
- 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

Engineering Conditions of Acceptability

When installed in an end-product, consideration must be given to the following:

For use only in (or with) complete equipment where the acceptability of the combination is determined by UL LLC.

Considerations to the applied parts requirement, to be conducted as end-product.
The input/output connectors are not acceptable for field connections, they are only intended for factory wiring inside the end-use product.
The component shall be installed in compliance with the enclosure, mounting, marking, spacing, and separation requirements of the end use application.
Power supply provides the following MOPP (means of patient protection): 2 MOPP based upon a working voltage 250 Vrms, 388 Vpk between Primary to Secondary, 1 MOPP based upon a working voltage 241 Vrms, 343 Vpk between Primary and Earth, two MOPP based upon a working voltage 48Vdc between secondary to floated earth trace on PWB for BF output consideration, one MOPP based upon a working voltage 250 Vrms between secondary and earthing trace or chassis for BF output consideration.
Temperature, Leakage Current (including the use of non-frequency weighted device of 8.7.3e), Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.
The product was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C at Full Load and 70°C at Half Load.
Magnetic devices TR1 employ a Class B (130°C) or higher insulation system.
The PWB is rated 130°C.
The end-product evaluation shall ensure that the requirements related to Accompanying Documents, Clause 7.9 are met.
The following input terminals/connectors must be connected to the end-product supply neutral: AC-N CN1
The maximum continuous power supply output (Watts) relied on forced air cooling from: 10 cfm fan applied 5 cm from input connector CN1 blowing inward
For models marked "SF", additional fusing may be required in the end product to meet the requirement of Cl. 8.11.5, Mains fuses and Over Current Release. These products are only provided with a single fuse.
Unit is rated 100-240 Vac with an output of 120W, however when conducting heating test at -10% tolerance (90 Vac) using convection cooling, the unit was loaded to 110W. Consideration for additional testing to be considered in the end product.
When installed in a Class I end product, the power supply shall be mounted in a manner that provides sufficient clearance and creepage distance between the primary side of the 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 in a manner that provides sufficient clearance and creepage distance between the hazardous parts and any accessible conductive parts.
Overcurrent releases of adequate breaking capacity must be employed in the end product.

Report Modifications

Date Modified *(Year-Month-Day)*	Modifications Made (include Report Reference Number)	Modified By