



Underwriters Laboratories (UL LLC) Safety Certification Report

Model: ECP130PSxx, where xx can be any number between 12 and 48, may be followed by -y for alternate input connector and additional suffixes denoting non-safety options.

Device Description: Component power supply for building-in

Applicant: XP Power LLC
15641 Red Hill Ave, Ste. 100
Tustin, CA 92780 USA

Manufacturer: Same as Applicant

Manufacturing Facility(ies): XP POWER (KUNSHAN) LTD
230 BIN JIANG NAN RD
KUNSHAN, JIANGSU 215321 CHINA

ABES TECHNOLOGY CO. LTD.
No 78-1 Zhangma St.
Xiushui Township Changhua County
504 Taiwan TAIWAN

Report No.: E321744-D1006-0/A2/C2-UL

Report (Re)Issue Date: 2015-08-14 (A0/C0);
2016-02-16 (A1/C0); 2017-11-13 (A1/C1); 2017-12-21 (A1/C2);
2020-11-18 (A2/C2)

Base Standard(s): ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14

Additional Standards: N/A

Report Types: This report consists of the following report types:
[Yes] US Certification (UL Recognition)
[Yes] CAN Certification (cUL Recognition)

This report covers the Safety evaluation of the referenced model(s) according to the standard(s) specified above.

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Report Modifications Summary

The following changes were made to this report. If none listed in the below table, this report is the originally issued report.

The following scheme is used throughout this report to reflect the **Report No.:**

(File No.) – (Report Ref. No.) – (x) / A(y) / C(z) – YYY, where:

(x) = Report (Re)Issue No.

(y) = Amendment No.

(z) = Correction No.




YYY = Report Type (UL/CB/IEC)

Date Modified (Year-Month-Day)	Modifications Made (include Report Reference Number)	Modified By
2016-02-16	Amendment 1: The original Report Ref. No. E321744-D1006, dated 2015-08-14 was amended to revise the input current ratings from 1.3 to 1.5A, corrected TR1 insulation system in technical considerations, added alternate primary connector by Degson Electronics Co. Ltd., Type DG350-3.96 series. Based on the review of the information provided, it was determined that no additional testing was considered necessary due to representative testing previously conducted under report E321744-D1002-CB.	Haydee T. Gonzalez
2017-11-13	SR4404682.1067322 - Correction: revise Mfr's address of Abes Technology Co Ltd (Account 582300 / Party Site 34023) for UL report (E321744-D1006/A1/C1)	Melissa Lai
2017-12-11	SR#4449488 - Correction Mfr's address of Abes Technology Co Ltd(Account#582300, org#67659) New address: No 78-1 Zhangma St Xiushui Township Changhua County 504 TAIWAN for UL report (E321744-D1006/A0/C2)	Echo Ho
2020-11-18	<p>Technical Amendment 2 to E321744-D1006-0/A1/C2-UL (E321744-D1006-0/A2/C2-UL)</p> <p>No testing was required to make the following changes to the report:</p> <ol style="list-style-type: none"> 1) Updated TRF Version from J to P. 2) CI 8.9.4 was re-evaluated based on the product series change from Pollution Degree 2 to Pollution Degree 3. Cut-outs on printed wiring board were verified to measure a minimum spacing of X= 1.5mm. The Isolating transformer (TR1) was inspected and verified that it does not rely on groove transverses to meet spacing requirements. <p>Based on the review of documentation and verification of spacings, it was determined that no additional testing was required based on the results of previous investigations.</p>	Jose Ordaz

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-D1006-0/A2/C2-UL
Date of issue	2015-08-14 (A0/C0); 2016-02-16 (A1/C0); 2017-11-13 (A1/C1); 2017-12-21 (A1/C2); 2020-11-18 (A2/C2)
Total number of pages	183
Testing Laboratory	UL Brea
Address	1075 West Lambert Road. Unit B. Brea, CA 92821 USA
Applicant's name	XP Power LLC
Address	15641 Red Hill Ave, Ste. 100 Tustin, CA 92780 USA
Test specification:	
Standard	IEC 60601-1:2005, COR1:2006, COR2:2007, AMD1:2012 (or IEC 60601-1:2012 reprint)
Test procedure	UL Certification
Non-standard test method.....	N/A
Test Report Form No.	IEC60601_1P
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 UL testing laboratory. The authenticity of this Test Report and its contents can be verified by contacting UL.	

Test item description:	Component power supply for building-in	
Trade Mark:	Trademark image(s): 	
Manufacturer:	Same as Applicant	
Model/Type reference:	ECP130PSxx, where xx can be any number between 12 and 48, may be followed by -y for alternate input connector and additional suffixes denoting non-safety options.	
Ratings:	Input: 100-240 Vac, 50/60 Hz, 1.5A Output: See report enclosure Miscellaneous -(002) for max Power Output ratings	
Testing procedure and testing location:		
<input checked="" type="checkbox"/> UL/DAP Testing Laboratory:		
Testing location/ address:	UL Brea 1075 West Lambert Road. Unit B. Brea, CA 92821 USA	
Tested by (name, function, signature):	Jose Ordaz, Project Handler	
Approved by (name, function, signature):	Ahmad Daoudi, Reviewer	
[] Testing procedure: WMT:		
Testing location/ address:		
Tested by (name, function, signature):		
Approved by (name, function, signature):		

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.

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 owners of 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
Intended use (Including type of patient, application location):	Component power supply for use in medical equipment
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).....:	2015-06-01, 2015-07-17
Dates tests performed.....:	2015-06-02 to 2015-06-19, 2015-08-07
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:	
<p>"(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.</p>	
Throughout this report a point is used as the decimal separator.	
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 Electrical Equipment.	

Model Differences

All models in the Model ECP130PSXX series are identical with exception of the Mains Transformer, TR1, and secondary components/circuitry that allow for different output voltage ratings. See Enclosure - Miscellaneous for max Power Output ratings based on model, forced air and ambient.

Additional Information

The clearance distances have additionally been assessed for suitability up to 5000 m elevation (1.48 correction factor as per IEC 60664-1, Table A2).

The need for the additional testing and evaluation shall be determined in the end product investigation. The power supply series covered by this report employ 2 Method of Protection of Insulation between Primary and Secondary circuits.

Licenses older than 3 years to be provided by the manufacturer upon request. The acceptability of CB certificates and/or licenses which are greater than 3 years old will be left to the discretion of the governing NCB.

Marking label is representative of all models.

SR#4449488:

MFR. Abes Technology Co Ltd(Account#582300, org#67659) New address: No 78-1 Zhangma St Xiushui Township Changhua County 504 TAIWAN. (Original address: No 78-1 Zhangma St Xiushui "Shiang" Changhua County 504 TAIWAN)

Technical Considerations

- The product was investigated to the following standards:

Main Standard(s):

ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14

From Country Differences:

- Austria: EN 60601-1:2006/A1:2013
- Republic of Korea: KS C IEC 60601-1
- USA: ANSI/AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)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:

N/A

- The following additional investigations were conducted: N/A
- The product was not investigated to the following standards or clauses: Biocompatibility, PESS, EMC, Annex Z of EN standards for compliance with the MDD
- The following accessories were investigated for use with the product: None
- None

Engineering Conditions of Acceptability

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

Power supplies covered by this report were evaluated for both Class I and Class II (double insulated). Double insulated symbol is optionally provided. See Conditions of Acceptability for insulation required for Class II. Earthing symbol may only be provided for Class I power supplies.

The product was submitted and evaluated for use at the maximum ambient temperature (T_{ma}) permitted by the manufacturer's specification of: Forced Air Cooling - 50°C at 100% of Output Rating, 70°C at 50% of Output Rating; Convective Cooling: 50°C at 100W Output Rating, 70°C at 50W Output Rating, 80°C at 30W Output Rating. See Miscellaneous enclosure Power Output Table for additional information regarding power output and the various configurations.

Printed Wiring Board rated 130°C.

Clearance spacing evaluated for 5000 m altitude. Additional consideration maybe necessary in the end-use product

Heating test should be repeated in the end-use product

The end-product Electric Strength Test is to be based upon a maximum working voltage of: Primary-Earthed Dead Metal: 240 Vrms, 340 Vpk and Primary-SELV: 240 Vrms, 340 Vpk

The power supply terminals and/or connectors are: Suitable for factory wiring only

The maximum investigated branch circuit rating is: 20 A

Proper bonding to the end-product main protective earthing termination is: required when the power supply is used in a Class I end product. The power supply will be considered Class II only when protection against electric shock does not rely on 1 Method of Protection of Insulation

An investigation of the protective bonding terminals has: Not been conducted

The following input terminals/connectors must be connected to the end-product supply neutral: CN1

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): L2, L3, L4 and TR1 (Class B, 130°C)

The following end-product enclosures are required: Mechanical, Fire, Electrical

The equipment is suitable for direct connection to: AC mains supply. Means of connection will need to be evaluated in the end product.

Repeat of leakage current testing and consideration of non-frequency weighted leakage test shall be considered in the end product 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 need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation.

The suitability of the breaking capacity of the fuse per Clause 8.11.5 shall be verified in the end product.

Models provided with suffix SF only provided with one line side fuse. Consideration should be made in the end-use product to determine the need of double pole fusing

Insulation Diagram - (001) ECP130 Insulation diagram

Insulation Diagram - (001) ECP130 Insulation diagram

