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. ..... :	E146893-D1016-1/A0/C0-ULCB
Date of issue ..... :	2017-10-18
Total number of pages ..... :	145
CB Testing Laboratory ..... :	UL Fremont
Address ..... :	47173 Benicia St., Fremont, CA 94538-7366, USA
Applicant's name ..... :	XP POWER L L C
Address ..... :	15641 RED HILL AVE, SUITE 100 Tustin, CA 92780 US
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

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.

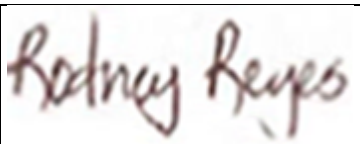
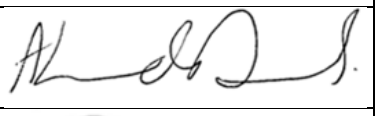
General disclaimer:

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 Power Supply
Trade Mark:	Trademark image(s): 
Manufacturer:	Same as Applicant
Model/Type reference:	ECF40USXX Series, where XX can be 12,15,18,24,28,36, or 48
Ratings:	Input: 100-240 Vac, 50/60- HZ, 1.2A Max Output: See Model Differences for details.

Testing procedure and testing location:		
[] CB Testing Laboratory:		
Testing location/ address:		
[ ] Associated CB Testing Laboratory:		
Testing location/ address:		
Tested by (name, function, signature):		
Approved by (name, function, signature):		
[ ] 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:	XP Power LLC 15641 Red Hill Ave, Suite 100, Tustin, CA 92780 USA	
[ ] Testing procedure: CTF Stage 4:		
Testing location/ address:		

Tested by (name, function, signature):	Rodney Reyes, Tester	
Witnessed by (name, function, signature):		
Approved by (name, function, signature):	Ahmad Daoudi / Project Reviewer	
Supervised by (name, function, signature):	Janice Pham/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:	Building - in
Device type (component/sub-assembly/ equipment/ system):	Component
Intended use (Including type of patient, application location):	Building - in
Mode of Operation:	Continuous
Supply Connection:	Building - in
Accessories and detachable parts included:	NA
Other Options Include:	NA
Testing	
Date of receipt of test item(s) .....:	2017-02-10
Dates tests performed .....:	2017-02-14 to 2017-02-28, 2017-03-24, 2017-04-06
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: Before starting to use the TRF please read carefully the 4 instructions pages at the end of the report on how to complete the new version “K” of TRF for IEC for 60601-1 3rd edition with Amendment 1. "(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) .....:	XP Power Inc 990 Benecia Ave Sunnyvale, CA 94085 US XP POWER (KUNSHAN) LTD 230 BIN JIANG NAN RD JIANGSU 215321 CHINA China XP POWER (VIETNAM) CO., LTD. LOT D-4Q-CN MY PHUOC 3 INDUSTRIAL PARK, BEN CAT DISTRICT BINH DUONG VIET NAM XP Power Horseshoe Park Pangbourne RG8 7JW UNITED KINGDOM

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

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.

Model Differences

All models in the ECF40USXX series are identical with exception to model designation, Transformer (T1) and secondary components/circuitry that allow for different output voltage ratings.

Model output ratings as follows.

Model ECF40US12: Output Rated: 10.1 Vdc - 13.5 Vdc, 3.34 A Max., 40 W Max.

Model ECF40US15: Output Rated: 13.6 Vdc - 17 Vdc, 2.67 A Max., 40 W Max.

Model ECF40US18: Output Rated: 17.1 Vdc - 21 Vdc, 2.23 A Max, 40 W Max.

Model ECF40US24: Output Rated: 21.1 Vdc - 26 Vdc, 1.67 A Max., 40 W Max.

Model ECF40US28: Output Rated: 26.1 Vdc - 31 Vdc, 1.43 A Max., 40 W Max.

Model ECF40US36: Output Rated: 33.1 Vdc - 42 Vdc, 1.11 A Max, 40 W Max.

Model ECF40US48: Output Rated: 42.1 Vdc - 54 Vdc, 0.83 A Max., 40 W Max.

Additional Information

Licenses older than 3 years to be provided by the manufacturer upon request. A marking plate for Model ECF40US28 is not provided/required, since the input rating are identical for all models. Marking plates provided in the enclosures are representative of all models.

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,

CAN/CSA C22.2 No. 60601-1:14, IEC 60601-1 :2005 +A1 :2012

From Country Differences:

- Austria: EN 60601-1:2006/A1:2013
- Korea, Republic of: KS C IEC 60601-1
- USA: ANSI/AAMI ES60601-1: 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:

None

- The following additional investigations were conducted: None
- 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:

The power supply was evaluated for use at the maximum ambient temperature permitted by the manufacturer's specification of : 50 deg. C at full rated load and 70 deg. at 50% rated load.

Consideration shall be given to measuring the temperature on power electronic components and transformer windings when the power supply is installed in the end-use equipment. The end use product shall ensure that the power supply is used within its ratings.

Repeat of leakage current testing and consideration of non-frequency weighted leakage test shall be considered in the end product application.

This power supply was evaluated with Two MOPP between Primary and Secondary for 354Vpk/240Vrms; One MOPP primary and Earth for 350Vpk/240Vrms; One MOPP between Secondary to Ground for working voltage of 48Vdc.

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 maximum investigated branch circuit rating is: 20 A

The end-product Electric Strength Test to be conducted shall be based upon a maximum working voltage

of: Primary-Earthed Dead Metal: 240 Vrms, 354 Vpk; Primary-SEC: 240 Vrms, 354 Vpk; Secondary to

Ground: 240Vrms, 354Vpk.

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): TR1 (Class F, 155°C)

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

Printed Wiring Board rated 130°C.

The need for Marking Durability and Marking Legibility Testing shall be considered as part of the end product installation.

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 accessible conductive parts.

When installed in a Class I end product, proper bonding to the Class I end-product main protective earthing

termination is required (via mounting holes on the PCB).
Protective earthing testing shall be conducted in the end product application.
The need for a fire enclosure shall be determined in the end product

Report Modifications

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