Test Report issued under the responsibility of:

TEST REPORT
IEC 60601-1
Medical Electrical Equipment
Part 1:General requirements for basic safety and essential performance

Report Reference No ..... :	E146893-A29-CB-1
Date of issue ..... :	2011-12-27
Total number of pages ..... :	21
CB Testing Laboratory ..... :	UL Camas
Address ..... :	2600 N.W. Lake Road, Camas, WA, 98607, USA
Applicant's name ..... :	XP POWER LLC
Address ..... :	SUITE 150 1241 E DYER RD SANTA ANA CA 92705 UNITED STATES
Test specification:	
Standard ..... :	IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
Test procedure ..... :	CB Scheme
Non-standard test method ..... :	N/A
Test Report Form No. ..... :	IEC60601_1G
Test Report Form originator ..... :	UL LLC
Master TRF ..... :	Dated 2010-11

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 ..... :	Medical Switching Power Supply
Trade Mark ..... :	XP
Manufacturer ..... :	XP POWER LLC SUITE 150 1241 E DYER RD SANTA ANA CA 92705 UNITED STATES
Model/Type reference ..... :	ECM40USXX, ECM40US24-XB0194, ECM60USXX, ECM60USXX (3X5) and ECM60US24SF-XE1033 (where XX can be any number between 05 and 48 designating the output voltage, all models may be followed with "- W" or "-SF")
Ratings ..... :	Model ECM40USXX, ECM40US24-XB0194 and ECM60US24SF-XE1033 : Input Rated: 100-240 V~, 50/60 Hz, 1.0A Models ECM60USXX and ECM60USXX (3X5): Input Rated: 100-240 V~, 50/60 Hz, 1.5A All Models (Except ECM40US24 -XB0194, ECM60US24SF-XE1033): Output: See Enclosures 7-02 for details. Model ECM40US24-XB0194: Output: 23 Vdc, 1.74A ECM60US24SF-XE1033: Output: 23Vdc, 1.74A

Testing procedure and testing location:			
[x]	**CB Testing Laboratory**		
	Testing location / address..... :	UL Camas 2600 N.W. Lake Road, Camas, WA, 98607, USA	
[ ]	**Associated CB Test Laboratory**		
	Testing location / address..... :		
	Tested by (name + signature) ..... :	Rahul Baria (Project handler)	Rahul Baria
	Approved by (name + signature) ... :	Elisabeth Gingelmaier (Reviewer)	E Gingelmaier
[ ]	**Testing Procedure: TMP/CTF Stage 1**		
	Tested by (name + signature) ..... :		
	Approved by (+ signature) ..... :		
	Testing location / address..... :		
[ ]	**Testing Procedure: WMT/CTF Stage 2**		
	Tested by (name + signature) ..... :		
	Witnessed by (+ signature)..... :		
	Approved by (+ signature) ..... :		
	Testing location / address..... :		
[ ]	**Testing Procedure: SMT/CTF Stage 3 or 4**		
	Tested by (name + signature) ..... :		
	Approved by (+ signature) ..... :		
	Supervised by (+ signature) ..... :		
	Testing location / address..... :		
[ ]	**Testing Procedure: RMT**		
	Tested by (name + signature) ..... :		
	Approved by (+ signature) ..... :		
	Supervised by (+ signature) ..... :		
	Testing location / address..... :		

List of Attachments

National Differences (2 pages)

Enclosures (26 pages)

Summary of Testing:

No tests were conducted

Summary of Compliance with National Differences:

Countries outside the CB Scheme membership may also accept this report.

List of countries addressed: AT, BE, CA, CH, CZ, DE, DK, FI, FR, GB, HU, IL, IT, NL, PL, SE, SI, SK, TR, UA, US

The product fulfills the requirements of: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10), CAN/CSA-C22.2 No. 60601-1 (2008), IEC 60601-1: 2005, EN 60601-1: 2006 + CORR: 2010

Copy of Marking Plate - Refer to Enclosure titled Marking Plate for copy.

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) .....:	None			
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) .....:	N/A			
Dates tests performed .....:	N/A			
Possible test case verdicts:				
- test case does not apply to the test object .....:	N / A			
- test object does meet the requirement .....:	P(Pass)			
- test object was not evaluated for the requirement :	N / E			
- test object does not meet the requirement .....:	F(Fail)			
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. 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:				Yes
The application for obtaining a CB Test Certificate includes more than one factory 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 ..... 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 215321 CHINA

GENERAL PRODUCT INFORMATION:

Report Summary

The original report was modified on 2016-08-08 to include the following changes/additions:
Addition of Model ECM60US24SF-XE1033
Addition of Model with suffix "-SF" for single fused types.
Tests conducted on models with suffix "- W" were considered representative of models with suffix “-SF”

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

Model ECM40USXX Series and Model ECM60USXX Series are identical with exception to input and output ratings, all models may be followed by suffix "-W".

All models in Model ECM40USXX and Model ECM60USXX series are identical with exception to the Mains Transformer, T1, and minor secondary components that allow for different output voltage ratings.

Models followed by "-W" are optionally provided with two Y1 bridging capacitors (C22 and C23) and provide 2 MOPP between primary and secondary and Models without the "-W" are provided with one Y1 bridging capacitors (C17) and provide 1 MOPP between primary and secondary.

Additional Suffix "-SF" denotes units with only a single line side fuse.

See Enclosures 7-02 for Model Output Ratings for up to 50°C ambient.

See Enclosures 7-01 for de-rating curve for ambient temperatures up to 70°C.

Model ECM60USXX Series is identical to Model ECM60USXX (3X5) with exception to Model ECM60USXX (3X5) being provided on a 3 by 5 in. printed wiring board.

Model ECM40US24-XB0194 is identical to Model ECM40US24-W with exception to the board layout, provided earthed heatsink construction, and modification to the output voltage and current rating.
Model ECM60US24SF-XE1033 is identical to ECM60US24-W except the mains supply fuse is in the phase only.

Additional Information

This report is a reissue of CBTR Ref. No.E146893-A1-CB-2, CB Test Certificate Ref. No. US/12319/UL. Based on previously conducted testing and the previous review of product construction it was determined that the product continues to comply with the standard.

Nameplate marking provided is considered representative of the series.

Tests conducted on models with suffix "- W" were considered representative of models without suffix "-W". Additional Suffix "SF" denotes units with only a single line side fuse.

For licenses older than 3 years, manufacturer to provide updated licenses upon NCB's request.

Models covered under this Report have been additionally evaluated to AAMI ES60601-1:2005 (R2012), CSA CAN/CSA-C22.2 No. 60601-1:14 and IEC 60601-1 Edition 3.1 (2012).

Ammendment 3: Insertion of suffix "-SF2 for single fused devices.
Tests conducted on models with suffix "- W" were considered representative of models with suffix “-SF”

Technical Considerations

- The product was investigated to the following additional standards: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10 + 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 + CORR: 2010 + 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
- Unit also complied with spacing requirements of UL60601-1 (1st), CSA C22.2 No. 60601-1 (2nd), and IEC 60601-1 (2nd) for Basic for 250 Vac from Primary to Ground, Double/Reinforced for 250 Vac from Primary to Secondary. --
- The power supply was 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) --

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. --
- Repeat of leakage current testing and consideration of non-frequency weighted leakage to be considered as part of the end product. --
- Power supply Models with the suffix "- W" are provided with two Y1 bridging capacitor (C22 and C23) and evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth. Models without the suffix "- W" are provided with one Y1 bridging capacitor (C17) 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 following secondary output circuits are at hazardous energy levels: Main Power Output --
- The 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 (except Model ECM40US24 -XB0194) was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 347 Vpk, 244 Vrms; Primary-SEC: 356 Vpk, 240 Vrms. --
- For Class I application: Protective bonding testing shall be considered in the end product application. --
- 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): L1 and T1 (Class F, 155°C) --
- Printed Wiring Board rated 130°C. --
- 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. --
- Fire/ Mechanical/ Electrical Enclosure to be provided as part of the end product. --
- 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. --
- Models without the suffix "- W" are evaluated for 1 MOPP between primary and secondary. The end-product evaluation shall consider the need for additional protection. --
- The Dielectric Strength Test conducted on this power supply, Model ECM40US24 -XB0194, was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 353 Vpk, 243 Vrms; Primary-SEC: 491 Vpk, 249 Vrms. --
- For Model ECM40US24 -XB0194: Heat Sink (HS1) to be protectively earthed as part as end product evaluation. --