CERTIFICATE OF COMPLIANCE

Certificate Number Report Reference Issue Date	20131108-E146893 E146893-A33-UL 2013-NOVEMBER-08
Issued to:	XP POWER L L C SUITE 150 1241 E DYER RD SANTA ANA CA 92705
This is to certify that representative samples of	COMPONENT - POWER SUPPLIES, MEDICAL AND DENTAL ECM140USXX Series (where XX can be any number between 12 to 48 designating the output voltage), all Models may be followed by suffix "-A", may also be followed with additional suffix "S", or "L"), ECM140US12-A-XA1049 ECM140US24 -XD0145, 10012197 Have been investigated by UL in accordance with the Standard(s) indicated on this Certificate
Standard(s) for Safety:	ANSI/AAMI ES60601-1 (2005) & CAN/CSA-C22.2 No. 60601-1, (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
Additional Information:	See the UL Online Certifications Directory at <u>www.ul.com/database</u> for additional information

Only those products bearing the UL Recognized Component Marks for the U.S. and Canada should be considered as being covered by UL's Recognition and Follow-Up Service and meeting the appropriate U.S. and Canadian requirements.

The UL Recognized Component Mark for the U.S. generally consists of the manufacturer's identification and catalog number, model number or other product designation as specified under "Marking" for the particular Recognition as published in the appropriate UL Directory. As a supplementary means of identifying products that have been produced under UL's Component Recognizion Program, UL's Recognized Component Mark: "N, may be used in conjunction with the required Recognized Marks. The Recognized Component Mark is required when specified in the UL Directory preceding the recognitions or under "Markings" for the individual recognitions. The UL Recognized Component Mark for Canada consists of the UL Recognized Mark for Canada: "N and the manufacturer's identification and catalog number, model number or other product designation as specified under "Marking" for the particular Recognition as published in the appropriate UL Directory.

Recognized components are incomplete in certain constructional features or restricted in performance capabilities and are intended for use as components of complete equipment submitted for investigation rather than for direct separate installation in the field. The final acceptance of the component is dependent upon its installation and use in complete equipment submitted to UL LLC.

Look for the UL Recognized Component Mark on the product.

William R. Carney, Director, North American Certification Programs



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UL TEST REPORT AND PROCEDURE

Standard:	ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10)(Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance) CAN/CSA-C22.2 No. 60601-1 (2008) (Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance)
Certification Type:	Component Recognition
CCN:	QQHM2, QQHM8 (Power Supplies, Medical and Dental)
Product:	Power Supply
Model:	ECM140USXX Series (where XX can be any number between 12 to 48 designating the output voltage), all Models may be followed by suffix "-A", may also be followed with additional suffix "S", or "L"), ECM140US12-A-XA1049
	ECM140US24 -XD0145, 10012197
Rating:	Input: 100-240 Vac, 2.5 A, 50/60 Hz Output : 12-48 Vdc, 12 A max.; not to exceed 148W (See Model Differences for details).
	For Model ECM140US24 -XD0145 and 10012197: 24Vdc, 5.8A
Applicant Name and Address:	XP POWER INC SUITE 150 1241 E DYER RD SANTA ANA CA 92705 UNITED STATES

This is to certify that representative samples of the products covered by this Test Report have been investigated in accordance with the above referenced Standards. The products have been found to comply with the requirements covering the category and the products are judged to be eligible for Follow-Up Service under the indicated Test Procedure. The manufacturer is authorized to use the UL Mark on such products which comply with this Test Report and any other applicable requirements of UL LLC ('UL') in accordance with the Follow-Up Service under the indicated Test Property bear the UL Mark are considered as being covered by UL's Follow-Up Service under the indicated Test Procedure.

The applicant is authorized to reproduce the referenced Test Report provided it is reproduced in its entirety.

UL authorizes the applicant to reproduce the latest pages of the referenced Test Report consisting of the first page of the Specific Technical Criteria through to the end of the Conditions of Acceptability.

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Prepared by: Melissa DeGuia

Reviewed by: Glenn Luchen

Supporting Documentation

The following documents located at the beginning of this Procedure supplement the requirements of this Test Report:

- A. Authorization The Authorization page may include additional Factory Identification Code markings.
- B. Generic Inspection Instructions
 - i. Part AC details important information which may be applicable to products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of this Test Report.
 - ii. Part AE details any requirements which may be applicable to all products covered by this Procedure. Products described in this Test Report must comply with any applicable items listed unless otherwise stated in the body of each Test Report.
 - iii. Part AF details the requirements for the UL Certification Mark which is not controlled by the technical standard used to investigate these products. Products are permitted to bear only the Certification Mark(s) corresponding to the countries for which it is certified, as indicated in each Test Report.

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Product Description

The products covered in this report are medical switching power supplies to be used factory installed in an end-use equipment.

Model Differences

All models covered under the series are similar with exception to the output voltage and current ratings, transformer (T1), minor differences in the secondary circuit component, and PWB layouts. Models with the -A suffix include transformer T2 for 5V standby. Models with additional suffix "S" indicate screw terminal block provided for the input and output connections or suffix "L" indicate leads are provided for the input and output connection.

Models ECM140USXX where XX can be any number between 12 to 48 designating the output voltage range. The configured output voltage should fall within one of the voltage ranges below:

ECM140US12 - 10.1 to 13.5Vdc, 11.7A max., 148W max. ECM140US15 - 13.6 to 17Vdc, 9.3A max., 148W max. ECM140US18 - 17.1 to 21Vdc, 7.7A max., 148W max. ECM140US24 - 21.1 to 26Vdc, 5.8A max., 148W max. ECM140US28 - 26.1 to 31Vdc, 5.0A max., 148W max. ECM140US48 - 42.1 to 54Vdc, 2.9A max., 148W max.

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

Model ECM140US24 -XD0145 is identical to Model ECM140US24, except for changes to Inductor (L1), Secondary to Ground/Floating Mounting Hole Capacitors, and other minor non-safety related component changes.

Model ECM140US24-XD0145 is identical to Model 10012197, with exception to the model designation.

Model ECM140US12-A-XA1049 is identical to Model ECM140US12-A except for model designation for marketing purposes.

Technical Considerations

- § 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
- § Mode of operation : Continuous
- **§** Supply connection : For building-in
- § Accessories and detachable parts included : None
- § Other options include : None
- § The product was investigated to the following additional standards:: ANSI/AAMI ES60601-1 (2005 + C1:09 + A2:10) (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) (Medical Electrical Equipment Part 1: General Requirements for Basic Safety and Essential Performance) (includes National Differences for Canada), EN 60601-1: 2006 + CORR: 2010 (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 power supply was evaluated for use in 50°C ambient at Full Rated Output and 50% of the Rated Output in 70°C ambient for convection cooling. (See De-rating Curve, Enclosure 7-01 for details)
- § The power supply was evaluated for use in 60°C ambient at Full Rated Output and 75% of the Rated Output in 70°C ambient for 10CFM forced air cooling. (See De-rating Curve, Enclosure 7-01 for details)

Engineering Conditions of Acceptability

For use only in or with complete equipment where the acceptability of the combination is determined by UL LLC. 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.
- § This power supply was evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth (Class I); and One MOPP between Secondary and Ground/Floating Mounting Holes when mounted with a plastic standoff that meets the creepage and clearance requirements for 1 MOPP at the mounting hole adjacent to the connector J2
- § 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 was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 339 Vpk, 240 Vrms; Primary-SEC: 488 Vpk, 274 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 in a manner that provides sufficient clearance and creepage distance between the hazardous parts and accessible conductive parts.
- § The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary.
- § Temperature, Leakage Current, Protective Earthing, Dielectric Voltage Withstand, and Interruption of the Power Supply tests should be considered as part of the end product evaluation.

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.

Manufacturer to provide up to date IEC Licensed for component licenses greater than 3 years upon request.

In addition to testing covered under IEC 60601-1, 3rd Edition, some tests were conducted as part of the previous UL60601-1, 1st Edition/ IEC 60601-1, 2nd Edition evaluations and the results and methods, as applicable, were considered representative as part of the testing conducted.

Some of the results is this Report are based on a previous CB Scheme Investigation by CSA International, Report Reference No. CB 155548-2004167, CB Certificate No. CA/9544/CSA issued in 2008-03-17.

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

All models covered under this Report was evaluated for a maximum operating altitude of 5000m. The required Clearance distances were updated with the appropriate Correction Factor from Table 8 in accordance with IEC 60664-1:1992.

Additional Standards

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

Markings and instructions		
Clause Title	Marking or Instruction Details	
Model	Model number	
Company identification	Classified or Recognized company's name, Trade name, Trademark or File	
Supply Connection	Voltage range, ac/dc, phases if more than single phase	
Alternating current	\sim	
Power Input	Amps, VA, or Watts	
Output	Rated output voltage, power, frequency.	
Special Instructions to UL Representative		
N/A		