

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:	Medical Switching Power Supply
Model:	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")
Rating:	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
Applicant Name and Address:	XP POWER LLC 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 Agreement. Only those products which properly 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.

Any information and documentation involving UL Mark services are provided on behalf of UL LLC (UL) or any authorized licensee of UL.

Issue Date: 2011-12-27 Page 2 of 16 Report Reference # E146893-A29-UL
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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.

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.

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) : None
- 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 + 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

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.
- 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 OBJ2 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.

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"

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	
Supply Frequency	Rated frequency range in hertz
Power Input	Amps, VA, or Watts
Output	Rated output voltage, power, frequency.

Special Instructions to UL Representative

N/A

Production-Line Testing Requirements			
Test Exemptions - The following models are exempt from the indicated test			
Model	Grounding Continuity	Dielectric Voltage Withstand	Patient Circuit Dielectric Voltage Withstand
All Models	Exempt	Test	Exempt
Solid-State Component Test Exemptions - The following solid-state components may be disconnected from the remainder of the circuitry during either Dielectric Voltage Withstand Test:			
Component			
N/A			
Sample and Test Specifics for Follow-Up Tests at UL			
The following tests shall be conducted in accordance with the Generic Inspection Instructions			
Plastic Enclosure or Part	Test	Sample(s)	Test Specifics
N/A			