Description

UL TEST REPORT AND PROCEDURE

Standard:	AAMI ES60601-1:2005,ES60601-1:2005/AMD1 1:2012 , ES60601-1:2005/AMD2:2021, CAN/CSA-C22.2 No. 60601-1:08, CAN/CSA-C22.2 No. 60601-1:14 (including amendment 1) and Amendment 2:2022 (MOD) to CAN/CSA-C22.2 No. 60601-1:14
Certification Type:	Component Recognition
CCN:	QQHM2 / QQHM8
Complementary CCNs:	QQHM8
Product:	Component Switching Power Supply
Model:	ECM60UDxx, ECM60UTxx, ECM40UDxx, ECM40UTxx, ECC60UDxx, ECC60UTxx, ECC40UDxx, ECC40UTxx, ECM60UDxx (3X5), ECM60UTxx (3X5), where xx can be 21-22, 31-37, all models may be followed by W. ECM60UT31>2449, ECM60UT31 -XD0166, 10013486, ECM60UT31 -XE0410, 10013489
Rating:	Input Rated: 100-240 V ac, 50/60 Hz, 1.5 A Output rated: 3.3, 5, 12, 15, 24, -12 or -15 V dc, Max 40 or 60 W, Dual or Triple outputs. For Models ECM60UT31 -XD0166 and 10013486: Output Rated: Output 1: 5.6Vdc, 8A Output 2: 12.5Vdc, 3A Output 3: -12Vdc, 0.5A For Models ECM60UT31 -XE0410 and 10013489: Output Rated: Output 1: 5Vdc, 2.5 A Output 2: 12.5Vdc, 3A Output 3: -12Vdc, 1A For Model ECM60UT31>2449; Output Rated: Output 1: 5Vdc, 2.5 A Output 2: 12Vdc, 3.0A Output 3: -12Vdc, 1A
Applicant Name and Address:	XP POWER LLC 340 Commerce, Suite 100 Irvine, CA 92602, 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 as applicable.

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

Prepared by:	Longjie Zhang, Project Handler	Reviewed by:	Grzegorz Kowalski, Reviewer

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

The products covered in this report are component power supplies intended for use in Medical Electrical Equipment.

Refer to the Report Modifications page for any modifications made to this report.

Model Differences

All models are identical except output electrical ratings, designation and may be provided with either dual or triple outputs. Models with designation UD represent dual outputs and UT represents triple outputs. Models rated 40 W are identical in construction to Models rated 60 W and differ for marketing purposes only. ECM models are identical to ECC models and differ in designation only. See Enclosure Misc. 04 for differences in output rating and manufacturers recommended ambient Tma relative to output loading and cooling.

Model ECM60UT31>2449 is identical to Model ECM60UTXX series with exception to changes to components: Optical Isolator, U3, and Capacitors, C2, C3, C22, C29.

Models ECM60UDxx (3X5) and ECM60UTxx (3X5) are identical to Models ECM60UDxx and ECM60UTxx respectively except the PWB size is larger (3X5 inches) and changes to the trace layout and secondary circuitry.

Models followed by W are provided with two Y1 bridging capacitors(C22 and C22A) and provide 2 MOPP between primary and secondary and Models without the W are provided with one Y1 bridging capacitors(C22) and provide 1 MOPP between primary and secondary.

Model ECM60UT31 -XD0166 is identical to Model ECM60UT31 -W, with exception to the capacitor configuration.

Model ECM60UT31 -XD0166 is identical to Model 10013486, with exception to the model designation.

Model ECM60UT31 -XE0410 is identical to Model ECM60UT31>2449, except it is provided with two bridging capacitors (C22, C22A) instead of one.

Model ECM60UT31 -XE0410 is identical to Model 10013489, with exception to the model designation.

Additional Information

These models have not been evaluated for use with a cover.

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.

Only one marking plate is provided which is representative of the other models in the series except for the output ratings.

Technical Considerations

- The product was investigated to the following additional standards: EN 60601-1:2006/2006+A12:2014+A1:2013+A2:2021, National standard JIS T 0601-1:2023
- The following additional investigations were conducted: none
- The product was not investigated to the following standards or clauses: Electromagnetic Compatibility (IEC 60601-1-2), Clause 14, Programmable Electronic Systems, Biocompatibility (ISO 10993-1), Usability
- The following accessories were investigated for use with the product: none
- 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
  Scope of Power Supply evaluation excludes the following: Patient applied parts clauses: 4.6, 7.2.10, 8.3, 8.5.2, 8.5.5, 8.7.4.7-8.7.4.9, 8.9.1.15; Battery related clauses: 7.3.3, 15.4.3; Hand Control related clauses: 8.10.4; Oxygen related clauses: 11.2.2; Fluids related clauses: 11.6.2 – 11.6.4; Sterilization clause: 11.6.7; Biocompatibility Clause: 11.7 (ISO 10993); Motor related clauses: 13.2.13.3, 13.4; Heating Elements related clause: 13.2; Flammable Anaesthetic Mixtures Protection: Annex G, Usability
  Supply connection: Overvoltage Category II
  Software is relied upon for meeting safety requirements related to mechanical, fire and shock: No

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:

- • When installed in an end-product, consideration must be given to the following:
  • Power supply Models with the suffix W are provided with two Y1 bridging capacitor (C22 and C22A) and evaluated with Two MOPP between Primary and Secondary; One MOPP primary and Earth and Models without the suffix W are provided with one Y1 bridging capacitor (C22) 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 input/output connectors are not acceptable for field connections, they are only intended for connection to mating connectors of internal wiring inside the end-use equipment.
  • The maximum investigated branch circuit rating is: 20 A. If used on a branch circuit greater than this, additional testing may be necessary.
  • The Dielectric Voltage Withstand Test conducted on this power supply was based upon a maximum working voltage of: Primary-Earthed Dead Metal (Class I units): 340 Vpk, 240 Vrms; Primary-SEC: 406 Vpk, 261 Vrms.
  • 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. 7 mm Clearance/8.3 mm Creepage between the power supply and any accessible conductive parts.
  • An investigation of the protective bonding terminal has: Not been conducted.
  • For Class I application: Protective bonding testing shall be considered in the end product

application.
• Suitable fire enclosure shall be provided in the end use application
• Proper bonding to the Class I end-product main protective earthing termination is required (via mounting holes on the PCB), unless for Class II applications. For Class II applications the primary side mounting pads are isolated from accessible conductive chassis by Reinforced Insulation
• Model ECM60xx series, convection cooled was submitted and tested for use at the manufacturer's recommended ambient temperature (Tmra) of 50°C, at 100% of its rated output. The output is then de-rated linearly to 50% in an ambient 70°C. Models ECM60xx provided with 5CFM of forced air cooling are rated for 100% output in an ambient of 60°C decreasing linearly to 50% of output in an ambient of 80°C. Models
• ECM40xx series, convection cooled, in an ambient of 60°C is rated for 100% output, decreasing linearly to 75% in an ambient of 70°C. For 5CFM of forced air cooling, in an ambient of 70°C, the output is 100%, decreasing linearly to 75% in an ambient of 80°C.
• The products were tested on a 20 A branch circuit. If used on a branch circuit greater than this, additional testing may be necessary
• The equipment has been evaluated for use in a Pollution Degree 2 environment
• Residual Voltage in Attachment Plug should be conducted in the end product with the final configuration/values of Y and bridging capacitors.
• 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 are min. Class F (155°C).
• The PWB is rated 130°C.
• Cleaning test to 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
• The need to measure the leakage current with a non-frequency weighted device per Clause 8.7.3 (e) shall be considered in the end product.
• A 5cfm fan should be provided based on the end product rated ambient temperature and load.
• 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.
• Temperature, leakage and Dielectric Tests should be considered in the end product
• Touch current test to be conducted as part of the end product.